Government of Montenegro

Ministry of Economy

Questionnaire

Information requested by the European Commission to the Government of Montenegro for the preparation of the Opinion on the application of Montenegro for membership of the European Union

28 Consumer and health protection

Minister: Branko Vujovic

Podgorica, December 2009

TABLE OF CONTENTS

CHAPTERS OF THE ACQUIS – ABILITY TO ASSUME THE OBLIGATIONS OF MEMBERSHIP

Chapter 28: Consumer and health protection

I. CONSUMER PROTECTION A. Horizontal aspects

A. Horizontal aspects

1. Please describe the scope of your consumer protection policy. Is consumer protection recognised as a specific policy in your country? Are there specific rules on consumer protection in other policy areas?

Consumer protection is recognized as a separate policy in Montenegro:

- Based upon the fundamental legal act of the State - Constitution, which prescribes that the State must protect consumer, and that any action violating consumer's health, safety and privacy is forbidden;
- Regulated by the Law on Consumer Protection (Official Gazette of the Republic of Montenegro 26/07), containing provisions on: protection of consumer's safety of life and health, protection of economic interests of consumers, educating consumers and keeping them informed, property rights protection; institutional protection and market surveillance;
- National Consumer Protection Programme - which in a more detailed manner lays down objectives and tasks for the establishment of consumer protection policy, manner and dynamics of the achievement of goals, entities authorized for the implementation of those objectives, as well as necessary financial resources important for the establishment of consumer protection - has been enacted based on the Law on Consumer Protection. The integral part of the Programme is the Action Plan which contains individual courses of action, protagonists and implementation deadlines, and a special Inter-sectoral Committee monitoring the Programme implementation has been constituted as well.

There are also special rules on consumer protection in other sectors (safety of products placed on the market, transport and telecommunications, health care, tourism and other services). Therefore, apart from the Law on Consumer Protection, which is being fundamental for this area, there is a series of other laws and regulations containing provisions relating to consumer protection in other sectors.

2. Please describe the institutional set-up for consumer affairs in your country.

Institutional system for consumer protection has been regulated by the Law on Consumer Protection and other regulations. The Ministry of Economy is the protagonist of consumer protection policy in Montenegro. It is on this Ministry’s proposal that the Government is enacting the National Consumer Protection Programme for the two-year period and is establishing criteria for carrying out activities defined in the National Programme - which are to be entrusted based upon public call for tenders - as well as detailed criteria for provision of financial support to the NGO for consumer protection (consumer organization). It is on the proposal of the Ministry of Economy that special funds from the budget are allocated for consumer protection. The Ministry monitors the programme implementation, and on an annual basis reports to the Government on its progress. The Ministry cooperates with the consumer organizations and exercises other actions aimed at the enhancement of the level of consumer protection, and the Ministry especially: keeps record on registered consumer organizations; establishes criteria and invites tenders for carrying out works laid down in the National Programme, as well as for provision of financial support to consumer organizations; establishes further criteria for the selection of members of the Arbitration Committee for Extrajudicial Protection, the manner of instituting proceedings and the proceedings before the board Panel; examines annual report on the Arbitration Committee work.

Within the Ministry there is a special Department for consumer protection, and a Commission to follow the implementation of activities laid down in the National Programme has been formed with the Ministry. The Commission is comprised of representatives of competent administration authority, consumer organizations and the industry.

Inspection control over the implementation of the Law on Consumer Protection is exercised by the Ministry through its market inspectors, other ministries and administration bodies through inspectors competent in respective areas, including the local administration bodies through local inspectors, in accordance with the Law. Apart from the supervision over the implementation of this Law, inspection bodies supervise the implementation of other regulations aimed at the protection of consumers.

Competent inspectorates deal with consumers' appeals relating to the issues in exercising due rights while purchasing goods and using services.

Based on the Law and pursuant to secondary legislation an Arbitration Committee for Extrajudicial Settlement of Consumer Disputes has been established with the Montenegrin Chamber of Commerce. Protection of consumers' interests in trial proceedings has also been provided.

Consumer organizations have an active part in protection of consumers. Their participation in relevant phases of the preparation of Law and other regulations has been defined, as well as in the creation of the National Consumer Protection Programme and other consumer protection measures, in expressing opinion on adoption of standards etc. It is the obligation of consumer organizations to act in accordance with the law, to perform their work in a manner that would exclusively be in favour of consumers and to work on exercising of consumers' rights and interests. It is also their obligation to provide public access to the data and information in their possession.

Following the need of consumer organizations to be as efficient in their acting as possible and to be inter-connected so as to strengthen their influence over those endangering consumers' rights, these organizations were in 2008, the first year of National Programme validity, allocated funds from the State Budget, totaling €40,000, as a financial support to their strengthening and implementation of certain activities set out in the National Consumer Protection Programme.

Two consumer organizations have been registered in Montenegro so far, these are: "CEZAP" and "ECOM", both based in Podgorica.

3. It should be specified whether there are bodies within the public administration which are competent for:

The Ministry of Economy, pursuant to the Law on Consumer Protection, has general competence over the consumer protection policy and is responsible for the initiation and coordination of activities in the area of consumer protection. An important role in the coordination of activities with other public administration sectors engaged in this area belongs to the Inter-Sectoral Committee for the supervision of the National Programme implementation coordinated by the Ministry. (More details on this in the Response to question No. 2.)

a) General co-ordination of consumer affairs: is general competence on consumer policy allocated to one designated authority, which is responsible for taking initiatives and for coordinating actions in the consumer area?

The Ministry of Economy, pursuant to the Law on Consumer Protection, has general competence over the consumer protection policy and is responsible for the initiation and coordination of activities in the area of consumer protection. An important role in the coordination of activities with other public administration sectors engaged in this area, belongs to the Inter-Sectoral Committee for the supervision of National Programme implementation coordinated by the Ministry (more details on this in the Response to question no. 2)

b) Market surveillance/general product safety: are there independent administrative structures and enforcement powers monitoring the market for consumer goods, in order to detect breaches of product safety rules and to ensure they are corrected? This would include dealing with consumer complaints and infringement of rules. [Specific questions on product safety and market surveillance are to be found in section B. below.]

Inspection control over market (general product safety and protection of economic interests of consumers) is executed by competent ministries and other state administration bodies/inspection bodies/, through inspectors authorized for the supervision of application of regulations in certain areas, in accordance with the competences laid down in particular laws.

Inspection bodies do the supervision and take measures and actions according to the inspection control procedure rules, authorizations and duties of inspectors prescribed by the Law on Inspection Control (Official Gazette of the Republic of Montenegro 39/2003). Provisions of this Law are accordingly applied by the local administration when carrying out inspection control, pursuant to the Law and other regulations. Inspection control is also regulated by special acts on individual inspectorates (market, health and sanitary inspectorate...), as well as by provisions on supervision contained in substantive regulations.

Apart from the aforementioned regulations, administration measures and actions regarding product safety on the market and protection of economic interests of consumers are also regulated by substantive provisions relating to product safety and protection of economic interests of consumers such as: Consumer Protection Law, General Product Safety Law, Law on Technical Requirements regarding Products and Product Conformity Assessment, on the basis of which inspectors do the supervision in accordance with previously adopted technical regulations (unless in contradiction with this law) by the time of adoption of new technical regulations by which the EU directives will be transmitted into national legislation, The Law on Standardization, Law on Accreditation, Law on Metrology, Law on Hygienic Correctness of Foodstuffs and General Purpose Products, regulations relating to medical and other requirements regarding general purpose products, as well as administrative measures and activities to be taken in case of failure to meet all requirements (provisions relating to foodstuffs ceased to have effect from the date of entry into force of The Law on Food Safety), Law on Medicines, Law on Medical Devices, Law on Chemicals, Law on Plant Health Products, Law on Plant Feeding Products, Law on Seeds of Agricultural Species, Law on Seedlings, Law on Tobacco Products Usage Restriction, Law on Tourism, Law on Electronic Communications, Law on Carriage in Road Transport, Law on Air Transport, Law on State Railways, Law on Safety in Railway Transport, Law on Postal Services, Law on Energy, Law on Environmental Protection, Law on Genetically Modified Organisms, Law on Carriage of Hazardous Materials, Law on Ionizing Radiation Protection, Law on Air Quality, Law on Waste Management, Law on Ratification of Amendment to The Montreal Protocol on Substances that Deplete the Ozone Layer, Law on Foreign Trade, Law on Domestic Trade laying down conditions and forms of doing domestic trade, basic rules of trading in products and trade services on the domestic market, protection against unfair competition etc.

Inspection bodies responsible for the market control are:

The Ministry of Economy/Market inspectorate: safety of consumer durables (technical, machines, furniture, products made of textile and glass, footwear, and other consumer goods which have not been placed under authority of other inspections) on the market and the protection of economic interests of consumers while purchasing products and using services (handicraft services, trade services and certain public services), in accordance with the Law and other regulations on consumer protection, general product safety, technical requirements for products, standardization, metrology, tobacco, medicines, energy, trade etc. This inspectorate is a section within the Department for the Internal Market and Competition at the Ministry of Economy, and it has 56 inspectors carrying out control all over Montenegro. It is organized on territorial basis - in three regional units: RU I Central area (Podgorica, Cetinje, Danilovgrad, Kolašin, Nikšić, Plužine, Šavnik) based in Podgorica; RU II - Southern area (Budva, Ulcinj, Bar, Tivat, Kotor, Herceg Novi), based in Budva, RU III Northern area (Bijelo Polje, Mojkovac, Berane, Rožaje, Plav, Andrijevica, Pljevlja, Žabljak), based in Bijelo Polje. Funds for the operation of this inspectorate are provided from the state budget, which, after the budget revision due to the global financial crisis, amounts

to € 916,183.00, of which € 250,533.00 is destined for material expenses and equipping.

The Ministry of Health/ Health and Sanitary Inspectorate: safety and sanitary correctness of cosmetic products, toys, detergents, tobacco products, materials coming into contact with food and packaging, poisons, medicines and medical devices on the market and protection of economic interests of consumers while purchasing these products, pursuant to the Law and other regulations on sanitary correctness of general purpose products, on production and trade of poisonous materials, on carriage of dangerous goods, on medicines and medical devices. This inspectorate is a section within the Ministry of Health, it has 37 inspectors - 33 of which are sanitary inspectors, the rest are health inspectors. Sanitary inspectors carry out control all over Montenegro, assigned to 8 regional units, while 3 health inspectors are organizationally positioned in the Podgorica-based head office of the Department. Funds for the operation of this inspectorate are provided from the state budget within the funds destined for the activities of the Ministry of Health.

Ministry of Spatial Planning and Environmental Protection - Environmental Protection Agency/ Environmental Inspectorate: in the field of protection of people's health and environmental condition as one of the basic consumer's rights, control of radioactivity for certain goods, control of permits for import, export and transit of dangerous ionizing radiation resources, substances depleting ozone layer, products containing those substances, of harmless waste, as well as permits for export and transit of dangerous waste, influence of noise in the environment, registering and release of new and existing chemicals, classification, packaging, marking, import and export of chemicals, environmental s usage in accordance with other regulations in the environmental protection field. Environmental inspectorate exists within the Environmental Protection Agency and has 9 environmental inspectors, carrying out control all over Montenegro. Funds for the activities of this inspectorate are provided from the state budget within the funds destined for the activities of the Environmental Protection Agency.

Ministry of Agriculture, Forestry and Water Management - Phytosanitary Administration/ Phytosanitary Inspectorate: safety of funds for plant nutrition and funds for protection of plants, seeds and seedlings on the market, as well as protection of economic interests of consumers while purchasing these, according to the Law and other regulations relating to these kinds of products. This inspectorate is a department in the Phytosanitary Administration, employing 16 inspectors who carry out control all over Montenegro. Funds for the operation of this inspectorate are provided from the state budget within the funds destined for the activities of the Phytosanitary Administration.

Ministry of Economy - Metrology Office/ Metrology Inspectorate: trade, installation, usage, maintenance and repair of measuring devices, as well as control of the correctness of amounts marked and contained in previously packaged products, pursuant to the law and other acts regulating the field of metrology. Apart from metrology inspectors, control over the use of legal measuring units and devices, as well as marks on previously packaged foodstuffs is carried out by other inspectorates within their competence. Pursuant to the act on internal organization and job descriptions in the Office, two metrology inspectors are planned for employment, and the process of selection and appointment of the chief metrology inspector is being in progress. Metrology inspectors will be carrying out control all over Montenegro from the head office based in Podgorica. Funds for the operation of this inspectorate will be provided from the state budget within the funds destined for the activities of the Metrology Office.

Ministry of Tourism/Tourism Inspectorate: protection of economic interests of consumers when using tourism and catering services, pursuant to the laws and other regulations on tourism (including special conventional customs applied in the tourism industry), on ski resorts etc. This inspectorate is a section within the Department of Legal and Inspection Activities, with 17 inspectors and 6 civil servants authorized by the minister for carrying out duties of a tourism inspector on a fixed-term basis due to the increased scope of work. The inspectors are assigned to 11 regional units and carry out control all over Montenegro. Funds for the operation of this inspectorate are provided from the state budget within the funds destined for the activities of the Ministry of Tourism.

Ministry of Transport, Maritime Affairs and Telecommunications/ Electronic Communications Inspectorate and Postal-Service Inspectorate: protection of economic interests of consumers while using electronic communication services and postal services. Currently there is one inspector in charge of both electronic communication and postal services. The inspector carries out control all over Montenegro. Funds for the operation of this inspectorate are provided from the state budget within the funds destined for the activities of the Ministry of Transport, Maritime Affairs and Telecommunications.

Railway Transport Inspectorate: protection of economic interests of consumers while using transportation services in the railway transport. There is one inspector employed with the inspectorate, who carries out control all over Montenegro. Funds for the operation of this inspectorate are provided from the state budget within the funds destined for the activities of the Ministry of Transport, Maritime Affairs and Telecommunications.

Road Transport Inspector: protection of economic interests of consumers while using transportation services in the road transport. This inspectorate is comprised of 6 inspectors in charge, amongst others, of the roads. The inspectors carry out control all over Montenegro. Funds for the operation of this inspectorate are provided from the state budget within the funds destined for the activities of the Ministry of Transport, Maritime Affairs and Telecommunications.

Maritime Affairs Inspectorate: protection of economic interests of consumers while using transportation services in maritime transport. This inspectorate is comprised of 4 inspectors. The inspectors carry out control all over Montenegro. Funds for the operation of this inspectorate are provided from the state budget within the funds destined for the activities of the Ministry of Transport, Maritime Affairs and Telecommunications.

Inspectors are officers with special competences and responsibilities and are independent in carrying out inspection control, within the rights and duties regulated by law and other rules. Minister, i.e. head of the body, appoints an officer as inspector on a four year period. Inspectorates are managed by chief inspectors appointed on a four year period by ministers, i.e. heads of the bodies, with the consent by the government. Administrative measures and actions inspectors take during the control procedure aiming to bring the existing situation in line with the regulations, are governed by the Law on Inspection Control (Article 16). Other stated laws set forth special measures and actions to be taken in order to protect safety of products on the market as well as economic interests of consumers, and those are:

- warrant for correction of established irregularities,
- sample taking and their delivery for testing and conformity assessment;
- prohibition or restriction of placing into market of products which are not in conformity with the prescribed requirements,
- order to recall a dangerous product from the market,
- order to destroy the product for which it is in a final procedure established to be dangerous,
- order to traders to deal with consumer's complaint in prescribed situations etc.

Pursuant to Article 63 of the Law on Inspection Control, inspection bodies are in performing their duties obligated to cooperate mutually as well as with other bodies and organizations. Upon inspectors request state bodies, local government bodies and organizations are obligated to submit required data and information necessary for the realization of inspection control. The Law prescribes for the proceedings upon inspectors' requests and complaints to be urgent. It is the duty of an authorized body to immediately examine all inspector's requests and complaints, and no later than 8 days upon the day of submission of complaint. Cooperation of all bodies has been regulated by the Decree on Joint Inspection Control (Official Gazette of the Republic of Montenegro, No. 48/03), prescribing that inspection control can simultaneously be carried out by several inspection bodies, where appropriate.

National Consumer Protection Programme (2008-2010) also prescribes that it is obligatory for market control bodies to cooperate, while more detailed manner and forms of cooperation of inspectorates and other bodies involved in market surveillance is the subject of the Market

Surveillance Strategy, adopted by the Government of Montenegro on 5 November 2009. On the same date the Government adopted the conclusion on establishment of Market Surveillance Coordination Body. Special coordination relating to the exchange of information on dangerous products is the subject of the Law on General Product Safety, and it will be closely regulated by secondary legislation to be enacted for the implementation of this law. /more on this in the response to question No. 10. /

Dealing with consumers' complaints/ It is inspector's obligation to examine the consumer's initiative, i.e. appeal, and to advise them on the decision with regard to it. The inspector is authorized to order the trader to act upon consumer's appeal, i.e. to correct the established irregularity and meet the consumer's request in case a product or service has a failure that is not caused by consumer's fault. If the inspector did not order correction of the established irregularities and fulfillment of consumer's requests, he/she will then in written inform the consumer that the fulfillment of their requests can be asked for in an extra-judicial and judicial proceedings (Article 126 of the Law on Consumer Protection). The manner of lodging of complaint and trader's obligations upon consumer's appeal in case of any failure on the product (of goods and services), as well as in case of improperly calculated price, and the manner of execution of rights from the guarantee are contained in the Chapter III Protection of Consumers' Interests (Article 19-27) of the Law.

Acting upon appeals in the field of certain services (tourism, transport services, telecommunication, bank services etc.) is in a more detailed manner regulated by special laws and is contained in the responses relating to these types of services.

Apart from administrative measures and actions, inspectors in accordance with the abovementioned laws institute misdemeanor and other adequate proceedings before competent legal authorities, against persons breaking rules relating to rights of consumers, their execution and protection.

c) Market surveillance/protection of economic interests of consumers: are there independent administrative structures and enforcement powers monitoring the market for consumer goods and services, in order to detect breaches of rules protecting the economic interests of consumers and to ensure they are corrected? This would include dealing with consumer complaints (individual complaints and cases harming the collective interests of consumers) and infringement of rules. [See also section C. below.]

The response is under item b) of this question.

d) Are there regular statistical processes which monitor the levels and evaluation of prices for consumer's goods and services? Are there surveys intended to determine the level of satisfactions with consumer goods or the percentage of consumers who have switched their service provider?

Consumer prices in Montenegro are monitored in four cities: Podgorica, Niksic, Kotor and Pljevlja. The list contains around 500 items. Consumer price index is pondered on the basis of the poll on proceeds and expenses of households. The index is made on a monthly basis and as a lump sum on an annual basis. /See Chapter 18 Topic 2.06. Prices/. Statistical Office of Montenegro does not carry out polls to determine the level of satisfactions with consumer goods, or the percentage of consumers who have switched their service provider.

As a part of the financial support to the NGO for consumer protection, the Ministry of Economy, being competent for consumer protection, allocated funds out of the budget for 2008 to finance the "Monitoring and Analysis of Prices of Foodstuffs" programme, realized in 2009 through monitoring prices in some major supermarkets in Podgorica. Consumers and general public were informed about the results of the analysis through press releases and press conferences organized by the NGO.

The Ministry of Tourism and Tourism Inspectorate, as well as the National Tourism Organization, have the possibility to monitor the level of prices, especially through the level of prices published in

a six-month period for accommodation of guests, as well as during the alteration of prices of services published in the price-list certified by the Ministry.

Regular surveys intended to determine the level of satisfactions with consumer goods, are conducted at the level of the National Tourism Organization, local tourism organizations and certain hoteliers.

4. Have consultation structures or procedures been established in order to allow consumer interests to be represented in discussions on consumer policy, when drafting and implementing legislation?

The Law on Consumer Protection (Article 121) prescribes that consumer organizations can participate in public discussions during the phase of preparation of laws and other rules regulating consumer's rights, in the creation of the national consumer protection programme, that these can express opinion during the standardization process. Consumer organizations can also institute proceedings and provide support in executing economic interests of consumers before competent state authorities. Consumer organizations representatives are members of the Committee for Monitoring of National Programme Implementation, and half of the total number of members of Arbitration Committee for Resolution of Consumer Disputes are representatives of consumers. The amendment of the Law on Consumer Protection is planned for 2010, when it will be amended by the provisions on the Consumer Protection National Council, which will prescribe Council's competences, the manner of its establishment and composition, which will certainly include NGO for consumer protection representatives.

5. Access to justice: which measures are in place, if any, to facilitate consumers' access to justice through the courts to seek individual redress? Are there measures to simplify and speed up small claims litigation? Do out-of-court bodies exist which provide alternative dispute resolution systems (e.g. mediation or conciliation systems)?

The Law on Consumer Protection, Article 112, prescribes that the consumer whose right or interest has been violated can in accordance with general rules file a request for compensation of damages before the competent court. Consumer organizations also have the right to it. Article 27, paragraph 3 of this law prescribes the instructions to consumer with regard to judicial review in cases when the trader fails to act upon their request in due time, or rejects the complaint. In that sense, apart from the initiative for the protection of rights the consumer can file at the competent inspection body, the consumer is advised to ask for the execution of their rights before the Arbitration Committee or the competent court. Also, pursuant to Article 127, paragraph 2, if the inspector, acting upon the consumer's complaint, fails to order the trader to meet the consumer's requests, he/she will in written notify the consumer that the protection of consumer's rights can be sought in judicial proceedings.

The Law on Consumer Protection (Article 97-111) also prescribes extrajudicial protection that can be exercised through the Arbitration Committee, established within the Montenegrin Chamber of Commerce at the end of 2008, as an independent body, for the sake of mutually consented settlement of disputes between a trader and consumer (consumer case). The proceedings before the court can be initiated in case that there was an attempt for the case to be corrected with the trader. The complaint can be lodged by the consumer or the consumer organization, and the dispute is settled by a three-member Council or, if agreed by parties, by a Committee member having the role of the Council. The Committee's decision is binding if the trader at the beginning of the process, i.e. lodging of complaint or after the publication of the decision, declared willing to accept the decision as binding. The Committee's decision is a recommendation if the trader after the beginning of the proceedings declares that they do not accept the decision of the Committee as binding. The proceedings before the Council of the Arbitration Committee are in a more detailed manner described in the Rulebook on Arbitration Committee for Resolution of Consumer Disputes (Official Gazette of the Republic of Montenegro 28/08), and the issue of allowances for the engagement in the Arbitration Committee is regulated by the Decree on criteria for setting allowances for the Arbitration Committee members (Official Gazette of the Republic of Montenegro 46/08).

The Law on Mediation (Official Gazette of the Republic of Montenegro 30.05) prescribes the rules for the process of mediation in civil-legal disputes of legal and physical entities, which is initiated on the basis of the accord of parties, and in case judicial proceedings have been started, on the basis of the recommendation by the court.

The Law on Civil Proceedings (Official Gazette of the Republic of Montenegro 22/04...76/06) governs the small claims litigation, which is simplified and lasts less. Small-claim litigation within the meaning of this law is litigation where the claim does not exceed the amount of €500. In proceedings in such disputes a special claim is allowed only against the decisions that close the proceedings, the judgment is pronounced immediately upon closing of the main hearing, and the deadline to appeal the decision is 8 days from the day of pronunciation of judgment/decision, i.e. from the day of its delivery to the party. The article 329 of this law prescribes that if the court assesses that the dispute could successfully be resolved by mediation, the court will cease the proceedings and will refer the parties to the mediation procedure, which is carried out in accordance with the Law on Mediation. Should the parties fail to resolve the dispute within 90 days, the court will set down a hearing.

6. Is there in the consumer area a court or an administrative procedure which enable entities such as consumer organisations/public authorities to seek an injunction to stop an illegal practice of a trader and to describe the system?

The Law on Consumer Protection prescribes cases in which consumer organizations and other interested entities can from a competent

Court seek injunction bringing an illegal practice of a trader to a close, and these are:

- action for prohibition of production and trading in unsafe goods: to the producer, distributor and trader (Article 113). Final and enforceable decision upon this claim which imposes prohibition of production and trading in unsafe product is published in the "Official Gazette of the Republic of Montenegro" and in no less than one daily newspaper distributed all over Montenegro, and the decision becomes binding for all participants in the trading process as of the day of its publication in the Official Gazette of the Republic of Montenegro.
- claim against an individual trader, more traders doing business in the same economic sector, or against the association of traders, for the sake of cancellation of unfair contractual provisions (Article 144). A consumer contract provision formulated in advance can be contested before the court in terms of the legal effect in the subject case, as well as in terms of similar provisions of future agreements. If the Court assesses that there is another provision formulated in advance that is unfair, the Court shall annul it ex officio. Finally binding court decision issued in these proceedings is delivered to consumer organizations so as for those to inform the consumers on it.
- complaint for the prohibition of an advertisement which is not permitted within the meaning of the Article 84-89, i.e. for proceedings for the prohibition of publishing of such an advertisement, should the advertisement has not yet been published (Article 115). Burden of proof of veracity of messages contained in the advertisement is born by the advertiser against whom the proceedings have been instituted, and a court decision can order fulfilment of certain conditions such as removal of the disputed contents from the advertisement, making of certain corrections in the advertisement etc. Finally-binding court decision ordering the ban of the advertisement or the fulfilment of certain conditions is published in the "Official Gazette of the Republic of Montenegro" and in no less than one daily newspapers distributed all over Montenegro, and the decision becomes binding for all participants in the trading process and persons having access to the mass media as of the day of its publication in the Official Gazette of the Republic of Montenegro.

In all three cases the Court can, by the time decision is rendered, define a proper interim banning measure, i.e. the prohibition of production and trade of the product which the plaintiff makes plausible not to be safe, i.e. the prohibition of using contractual provisions which are plausible to be unfair within the meaning of Article 63 and 64 of the Law, i.e. the prohibition of the

advertisement plausible to have elements of a prohibited advertisement within the meaning of this Law.

Apart from the aforementioned court prohibitions, proper administrative measures to stop illegal practice of traders are prescribed, taken by competent inspection bodies in prescribed cases. Namely, during the inspection control process, when it is assessed that a certain law or regulation has been broken, or that prescribed standards and normative acts are not observed, the inspector is obligated to take prescribed measures and actions, as well as to institute administrative proceedings as well as all other necessary proceedings before the competent authority. Apart from administrative measures established by law and regulating inspection control, provisions of the Article 126 of the Law on Consumer Protection prescribe that the competent inspector can order trader to act upon consumer's complaint, if the complaint is admissible, to provisionally ban trading in certain goods in prescribed cases as well as to take other relevant measures to stop an illegal practice of the trader (Article 127). Administrative measure to ban production and trading of a product has been prescribed by the Law on General Product Safety and the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements. Consumer and consumer organizations can also submit requests to competent inspection authorities to take administrative measures and actions within their competence. /More on competences of inspection authorities in the response to the question No. 3 (b) and (c)/.

7. Has the government drawn up any education, information and awareness-raising programme on consumer issues, which would help consumers be aware of their rights and able to exercise them?

The Government of Montenegro have not drawn up any education, information and awareness-raising programme on consumer issues, but this field is the subject matter of the National Consumer Protection Programme and Action Plan for their implementation (III Consumer Education and Informing).

III CONSUMER EDUCATION AND INFORMING		
1. Education		
1.1 Analysis of curricula on possible introduction of consumer protection issues in the education process	The Ministry of Education and Science, Education Office, State Textbook Publishing House, Vocational Education Centre and the NGO for Consumer Protection	Continuously
1.2. Creation of manuals for teachers and other consumer-related materials aimed at children of pre-school and school age.	The Ministry of Education and Science, State Textbook Publishing House, and the NGO for Consumer Protection	
1.3 Raising consumers' educational level aiming at the enhancement of their status on the market	The Ministry of Education and Science, Education Office, State Textbook Publishing House, Vocational Education Centre, the NGO for Consumer Protection and other NGO's	Continuously
2. Informing		
2.1. Broadcasting of special TV and Radio shows and organizing of debates, within the programme scheme of the public service, aimed at the consumers' education	Public service in cooperation with line ministries - competent inspectorates and NGO for consumer protection	Continuously
2.2. Organizing of seminars, publishing of magazines, brochures and other printed media aimed at consumers and informing the public on consumer protection-related activities	Line ministries - competent inspectorates and NGO for consumer protection	Continuously

Coordinated by the Committee Monitoring National Programme Implementation, the Ministry of Education and Science have in cooperation with educational establishments, institutions for vocational education and State Textbooks Publishing House, as well as the NGO for consumer protection, initiated activities aiming at the introduction of this field in curricula. In that sense meetings were held to discuss the ways to approach the innovation of curricula with certain contents aimed at consumer protection, and to provide manuals and brochures for that purpose.

As a result of these activities CEZAP did the "Analysis of possibilities to introduce consumer protection elements in the curricula - education of teachers to educate children as consumers" project, and was provided support by the FOSI Foundation: East-East Programme, to organize and implement two forums and a seminar with the title: "Introduction of consumer protection in primary and secondary school education - research and recommendations". First forum was held at the beginning of September, in Skopje, in partnership with the Consumer Organization of the F.Y.R. of Macedonia, where the Macedonian Consumer Organization and Ministry of Education - Education Development Bureau of Macedonia - presented their experience in the field of introducing consumer protection in primary and secondary schools to Montenegrin representatives. Upon the completion of the project CEZAP and the Ministry of Education and Science - Education Office presented their work in this field to the Committee for Monitoring of the Consumer Protection National Programme Implementation and to the Ministry of Economy as an authority competent for consumer protection.

The ministry competent for consumer protection, NGO and other institutions carrying out consumer protection activities share information on consumer protection activities through interviews in printed and electronic media, contact shows and other types of communication. In this manner consumers are informed on their rights and duties while purchasing goods and using services, on establishing and operations of institutions protecting consumers, as well as on activities of authorized inspectorates carrying out market Surveillance.

Since the education of consumers is planned as a continuous activity in the National Programme Implementation Action Plan, the bearers of these activities will strengthen the cooperation with the public service so as for this field to become a part of their programme scheme.

8. Do non-governmental organisations representing consumer interests exist in your country? If so, please describe their situation: how many are there? When were they created? How is their membership composed? Are they representative of consumer interests at national level? Is the government promoting and assisting their development? What are their objectives? Which kind of activities do they carry out? What are their main sources of financing? How many staff do they employ?

There are two non-governmental organizations for consumer protection (CEZAP and ECOM), both based in Podgorica, which are, pursuant to the Law on Consumer Protection and the Rulebook on the contents of keeping record on consumer organizations (Official Gazette of the Republic of Montenegro, No. 17/2007) listed in the Consumer Organization Register with the Ministry of Economy.

CEZAP is founded in September 1999, when recorded in the Register of Non-governmental Organizations with the Ministry of Justice, while it was recorded in the Register of the Ministry of Economy on 29th January 2008, i.e. immediately upon the setting up of this register, in accordance with the Rulebook. This organization employs four on a permanent basis, and has a membership of over 50.

ECOM is founded in June 2005 when recorded in the Register of Non-governmental Organizations with the Ministry of Justice, while it was recorded in the Register of the Ministry of Economy on 20th February 2008, i.e. immediately upon the setting up of this register, in accordance with the Rulebook. This organization employs two on a permanent basis, and has a membership of over 50.

With their activities these organizations influence the raising of consumers' awareness of their rights, provide direct support upon consumers' request, or refer them to the authorized administration and court bodies. With their public acting they also help in shaping public opinion in

concrete cases of unfair acting on the market. Apart from that, consumer organizations with their pressure and opinions strive to improve the work of administration authorities and responsible institutions, as well as to influence the enactment of regulations to the benefit of citizens and consumers. Consumer organizations are through their representatives present in the Committee for Consumer Protection National Programme Implementation, as well as in the Arbitration Committee for Resolution of Consumer Disputes. Every citizen of Montenegro interested in this type of acting can become a member of the organization.

These organizations represent citizens' interests at the national level.

The Government promotes and supports the development of NGO's representing consumers' interests. So in 2008 these organizations were, in accordance with the Law, allocated financial support from the state budget, aimed at the realization of the projects: "Monitoring and Analysis of Foodstuff Prices" and "Enhancement of consumer protection in the field of utility services - waste disposal. The public call for tenders for carry out certain works prescribed by the Consumer Protection National Programme was responded by consumer organizations, so the competent ministry allocated those funds for the implementation of the following projects: "Informing consumers on their rights deriving from the Law on Energy and Rights on Supply with Electric Power", "Informing passengers on alternative and renewable energy sources, energy saving and energy efficiency", "The Analysis of the Level of Consumer Protection in the Public Service Sector" and "The Analysis of the Existing Legislation and Its Application in Advertising". /more on this in the response to question No. 3 (d), 27 (delusive and comparative advertising/.

Consumer organizations manage with minimal, i.e. insufficient funds for operation. The basic financial sources for these organizations are set out in the Law on Consumer Protection (membership fees, registration fee for organizing of seminars, conferences and other meetings aimed at consumer education, reimbursements for provision of legal assistance, financial support of the State in case the organization has the membership of no less than 50; donations and other sources in accordance with the Law).

9. Have you developed any relations with other countries on consumer protection issues (e.g. cross-border co-operation activities, exchange of information and best practices, etc.)?

Cooperation of state bodies of Montenegro with certain countries is carried out mostly on the level of exchange of information about national regulations on consumer protection issues and the implementation of these, but the cooperation also involves some concrete practical activities. Thus the Ministry of Economy of Montenegro/ Market Inspectorate, aiming at the improvement of good practice, especially in the part of market surveillance which is in the function of consumer protection, established cooperation with the Market Inspectorate of Slovenia, through which Montenegrin Market Inspectorate get acquainted with the operation and cooperation with other relevant institutions (Customs Administration, Quality and Laboratories Institute, Consumer Protection Office). Market Inspectorate also established communication with the State Market Inspectorate of F.Y.R. of Macedonia for the sake of further cooperation and exchange of best practices.

Cross-border cooperation is carried out with Serbia, in the exchange of information on improvement of consumer protection institutions, implementation of the consumer legislation and cooperation of state bodies and NGO's for consumer protection as well as through the ad hoc exchange of information important for the safety of products on the market. The Market Inspectorate of Montenegro has also established cooperation with the State Inspectorate of the Serb Republic with reference to the exchange of information on establishing an information system, so, with that aim to that end, the Inspectorate have this year attended the presentation of the system in Banja Luka.

Exchange of best practices in the field of consumer protection and market surveillance is done in the annual expert counselling of market inspectorates of the neighbouring and some countries from the region, where representatives of these bodies present their accomplishments in these areas. Thus, during the counselling of the Montenegrin Market Inspectorate held in October 2008, apart from the support to the initiative to establish an association of South-Eastern market inspectorates,

instituted during the counselling of the Serbian Market Inspectorates in mid-October 2008 (aiming at the exchange of experience and best practices of market inspectorates from the region, acquisition of new knowledge, exchange of inspectors, works on international projects, mutual education etc.), the conclusion was to also start the initiatives for:

- establishment of the system for exchange of information on dangerous products on the market, between the signatories to CEFTA agreement, and in that sense it is necessary to recommend a project of joint training for market Surveillance authorities, all with the aim of raising the level of protection from dangerous products on the market and preparation of competent authorities of these countries for joining the EU RAPEX system in the future.
- establishment and strengthening of cooperation between market Surveillance authorities of the Western Balkan countries (exchange of information on legislation and competence, organizing, working methods etc.) with the aim of establishment of better market control, as a logic continuation of projects that have already been taken under the GTZ-ORF auspices.

One such a project gathered the countries from the region (Montenegro, Serbia, Croatia, Bosnia and Herzegovina, F.Y.R. Macedonia, and Albania) on several regional conferences on consumer protection issues during 2007 and 2008. There European experts presented European legislation and practices related to this field, while the representatives of Governments and Consumer Protection NGO's from the countries in the region presented their consumer-related legislation, institutional framework and capacities of bodies competent for consumer protection, as well as the cooperation of the governmental and non-governmental sectors in this field, and revealed their plans for further development in this area. Such an acquainting with the EU standards and the consumer-protection situation in some Western Balkan region countries was very useful for positioning and further planning of enhancement our own consumer protection system in accordance with the best practices from the surrounding countries and EU member states.

Montenegro will, upon adoption of secondary legislation for application of Laws on general product safety and establishment of the national-level system for exchange of information on dangerous products, re-initiate establishment of information exchange with the countries from the region, which has already been presented as a necessity for the (regional) IPA support project in the field of quality infrastructure, relating to market Surveillance.

Environmental Inspectorate has also established good cooperation with all environmental inspectorates in the region, with which the Inspectorate do the control in cross-border cases. This inspectorate is, together with other environmental inspectorates in the region, involved in the training organized by ECENE and REC, aimed at environmental inspectors from the surrounding countries.

B. Product safety-related measures:

Legislation

10. In the framework of your consumer protection policy, indicate whether the following sectors are covered and to what extent they are in line with the relevant EC acquis:

- general product safety (Directive *2001/95/EC)*

Directive *2001/95/EC* on general product safety was transposed to the Law on General Product Safety (Official Gazette of the Republic of Montenegro, no 48/2008). The Law provides definitions of the terms "product", "safe product", "delusive product", "producer", "distributor", "interested party", "serious risk", "ban on sale and distribution", "recall and withdrawal of products", RAPEX. The Law governs the requirements to be met by products already placed on the market (if their safety is been regulated, or is not fully regulated by special regulations), responsibilities and duties of producers and distributors, the manner of informing and exchanging information on product risks, competences and measures of inspection bodies, i.e. Surveillance, including the safeguard clause, duties of the custom authorities, as well as penalty measures /more on this in response to question No. 19 (a) and (b)/.

For the implementation of the Law, secondary legislation will be adopted, which is now being in the process of drafting and these are:

- Decree on the manner of exchanging information on dangerous products (article 12, paragraph 3 of the Law), which encompasses the manner of working and co-operation of competent state bodies in the processes of national and international exchange of information on dangerous products, and
- Rulebook on the content of notification on dangerous product (Article 10, paragraph 4 of the Law), relating to the acting of producers and distributors towards authorized inspectorates.

During the application of the Decree the competent bodies shall use the Guidelines for managing the RAPEX system (more on this in the response to the next secondary question, and for the easier creation of the Rulebook, guidelines for producers and distributors are being created, setting out the rules on how to inform competent bodies on dangerous products.

This Directive has partially been implemented in the Law on Consumer Protection, within the part describing ban of production and placing of unsafe products on the market, to which provision of the Article 2, paragraph 1, items 25 and 26 have been dedicated, giving the definitions of a dangerous product, as well as the measure for prohibiting the production, i.e. placing a product on the market, aimed at prevention of display, offer and distribution of a product dangerous to the consumer, and the measure for withdrawal of a product already delivered or made available to the consumer. The way in which these measures are to be taken is provided in the Article 127 of the Law. This Law also contains provisions prescribing obligation to display warning on risks posed by usage of a product (Article 78), as well as the obligations of competent bodies to warn consumers through the mass media about the risks of products already placed on the market, for which it was in a due procedure established not to be safe (Article 79).

Apart from the Directive 2001/95/EC, Directive 87/357/EEC is also implemented in the Law on General Safety Product /more on this in the response to the secondary question relating to this directive/, as well as the Regulation EC No. 399/93 /More on this in the response to question no 19 (d) /.

- Guidelines for the RAPEX system and application in accordance with the Article 11 of the Directive 2001/95/EC (Decision *2004/418/EC*)

Pursuant to the Law on General Product Safety, the preparation of the Decree on the Manners of Exchanging Information on Dangerous Products is being in progress, during the application of which the competent bodies of Montenegro will use Guidelines (Decision 2004/418/EC) for managing the RAPEX system and for informing in accordance with the Law as well as the Decree (Article 1, paragraph 2 of the Decree). The guidelines have been translated form English into Montenegrin.

- Limitations regarding placing on the market of new lighters and securing that only those with children-safety mechanisms are placed on the market (Decision 2006/502/EZ amended by Decisions 007/231/EC, 2008/322/EC, 2009/298/EC)

Decision 2006/502/EC, 2007/231/EC, 2008/322/EC, 2009/298/EC has not been transposed into the national legislation. /More on plans for transposing in the response to question No. 18)/

- Ban on placing on the market of products containing biocide (DMF) dimethylfumarate (Decision 2009/251/EC)

Decision 2009/251/EC was made during this year and the Decision has not been transmitted into the national legislation.

/On plans for the transmission in the response to question no 18/

- dangerous copies (Directive 87/357/EEC)

Directive 87/357/EEZ) has been transposed into the General Product Safety Law (Article 4, paragraph 4), by which it is not permitted to produce, import, export or place on the market delusive products. Inspection control in this area is carried out by an inspector of the body competent for health issues, regardless of the type of the product (Article 13, paragraph 2). For the

violation of the provision of Article 4, paragraph 4, a fine for the offender has been prescribed (article 17, paragraph 1, item 2).

- liability for defective products (Directive 85/374/EEC)

Directive 85/374/EEC has been transposed to the Law on Obligations (Official Gazette of Montenegro 47/2008) and the Law on Consumer Protection (Official Gazette of Montenegro 26/2007).

More on this in response to the next question/

11. Do you have legislation concerning liability for defective products?

Liability of producers of defective products is regulated by Law on Obligations, which prescribes cases of liability of producers of defective products, types of liability, definition of products and producers, cases of relieving of liability, expired debts, as well as the definition of what is deemed to be defective product (so-called negative definition). The Article 175 of the Law on Obligations lays down that anyone placing on the market an object they produced, and which object due to the deficiencies the producer did not know of poses risk for persons and things, will be held liable for the damage which could have occurred due to the deficiency, regardless of their guilt. The product can be dangerous when it has usual properties, but it lacks instructions for use, warning to dangerous properties or safe packaging. A product is not safe if, having taken into account all circumstances of the case, and especially the manner in which the product has been presented, the purposes for which, according to reasonable expectations, the product can be used and the date and time when the product was placed on the market, do not provide safety which is justifiably expected of such a product. The product safety is assessed by the time of its placing on the market, thus no improvements of the subject matter the producer makes at a later stage are of any importance. However, a product is not deemed defective only because a better product was placed on the market afterwards. The injured party is obligated to prove the deficiency of the product, damage and a causal relationship between the deficiency of the product and the damage. / More on this in the response to the next question. /

Liability for deficient products is regulated by the Law on Consumer Protection, Chapter "Compensation for damage caused by the use of a deficient product". The Article 96 lays down that the consumer that has suffered damage due to the use of a product with deficiency is entitled to the compensation of damage caused by: death, injury or harm to health, damage or destruction of the product aimed for the personal use. Paragraph 2 of the same Article provides that the consumer also has the right to compensation in the cases when the damage is caused simultaneously by the product with deficiency and acting or non-acting of a third party.

Apart from the abovementioned liability of producers of products with deficiency, the legislation of Montenegro prescribes criminal responsibility aiming at the consumer protection. The Article 285 of the Criminal Code of Montenegro (Official Gazette of the Republic of Montenegro 73/03, 13/04, 47/06 and Official Gazette of the Republic of Montenegro 40/08) defines criminal offense - delusion of consumers, the incrimination of which covers all types of deluding consumers. Criminal offense delusion of consumers is made by a person who, desirous of deluding consumers places on the market products with the label containing information which does not correspond to the content, type, origin and quality of the product, or places on market products which in their quantity and quality do not correspond to what is regularly assumed at such products, or places on the market products with no label whatsoever containing information on content, type, origin or quality of the product when such a label is prescribed, or such a person obviously uses false advertisement while placing such products on the market. The law carries a penalty for this criminal offense of up to three years in prison or a fine. Aiming at the protection of life and health of citizens, the Criminal Code in its Article 297 also defines criminal offense production and placing on the market of harmful products.

12. Are there legal provisions in force establishing the principle of objective liability or liability without fault of the producer in cases of damage caused by a defective product? If such provisions are in force, is there a rule of joint liability in cases where more than one person is liable for the same damage?

In accordance with the Law on Obligations, the producer's liability for the damage caused by defective products is non-contractual objective liability. The producer is liable regardless of fault, and the ground of liability is in production and marketing of defective products.

According to the rules of objective liability, a producer is also liable for dangerous properties of an object after failing to take all necessary measures to prevent the damage that he was able to foresee by means of an appropriate alert, safer packaging or some other appropriate measure.

Apart from liability of a direct producer, liability is also extended to quasi producers, i.e. persons who present themselves as producers by affixing their name, trademark or other distinguishing feature on the product.

While a producer of defective products is made liable according to the rules of objective liability, liability of a seller of defective products is of subjective nature, i.e. a seller of defective products is liable only if he is at fault. The seller is able to free himself from liability if he furnishes proof that he was not able to discover the existence of a defect in the product or other features that make it dangerous, and as such was not able to prevent the damage.

In the case when more producers are liable for the same damage caused by the defectiveness of a product, they are liable jointly. Joint liability also exists in the case when the damage was caused by a third person. Producers cannot be exempted or restricted from liability for the damage caused by defective products in advance by. Liability of producer for the damage caused cannot not be excluded or restricted in advance by the contract with the injured person.

13. If legal provisions on product liability are in force, what products do they cover? Are some products excluded from the scope of these rules? What is the definition of "damage"?

In accordance with the provision of Article 175 of the Law on obligations, liability for the damage caused by a defective product is not limited to certain types of products; instead it covers all the products put in circulation by a producer. According to the Law on Obligations, product is any movable thing, as well as any independent component integrated into another movable or into an immovable. In addition, electric power and other forms of energy are deemed to be products.

Product within the meaning of the Law on Consumer Protection denotes goods or services that may be distributed including also public services, while goods denote tangible things that may be placed on the market, including also the facilities that may be used in accordance with this Law.

According to the provision of Article 149 of the Law on Obligations, damage is defined as diminution of someone's property (simple loss) and preventing its increase (profit lost), as well as inflicting on another physical or psychological pain or causing fear, as well as violation of personal rights and infringement of reputation of a legal person (non - material damage)

The Law on Consumer Protection also provides for liability for the damage caused to a product submitted for repair (Article 95), and makes a person who destroyed, lost or damaged the product liable for the damage. This person is obliged to act upon the consumer request for compensation; otherwise he is liable for the offence in accordance with Article 129 paragraph 1 item 26.

14. If legal provisions on product liability are in force, how is the producer defined, what are the rules applicable to burden of proof?

The term producer is defined in Article 178 of the Law on Obligations. The term producer denotes a person who is the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part or a part integrated in the finished product and any person who, by putting his name, trademark or other distinguishing feature on the product presents himself as its producer.

In the case of an imported product, any person who imports a product for sale, renting or any other form of putting of the product into circulation in the course of his business is deemed to be a producer.

In the case where the producer cannot be identified, each supplier of the product is treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the person who supplied him with the product. These rules are also applicable to the case when the importer cannot be identified, even if the name, factory or title of the producer is indicated on the product.

In order to exercise the right to compensation for the damage deriving from defective products, the injured person is required to prove the defect in the product, the damage and the casual relationship between defect and damage (it needs to be proved that the producer put a defective product into circulation and that the damage to the injured person was caused due to the defect of the product).

According to the Law on Consumer Protection (Article 2 paragraph 1 item 10), a producer is a person who, in the course of his business activity, manufactures or produces the goods or provides services or a person who is designated as a producer by attaching his name, trademark or other distinguishing feature to a person whose activities may impact the safety of goods when they are placed on the market. The importer of goods is also deemed to be the producer when the registered office of the producer is outside the territory of Montenegro.

15. If legal provisions on product liability are in force, are there any rules exempting the producer from liability (e.g. producer did not put the product into circulation, the defect causing the damage came into being after the product was put into circulation by the producer, the product was not manufactured for profit making sale, the product was neither manufactured nor distributed in the course of producer's business, the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered, the defect is due to compliance of the product with mandatory regulations issued by the public authorities)?

Article 180 of the Law on Obligations regulates certain cases concerning the exemption of producers of defective products from liability. Namely, the producer is exempted from liability if he proves that he did not put the product into circulation; that, having regard to the circumstances, it ensues that neither the defect causing the damage nor the cause of the damage existed at the time when he put the product into circulation; that the product was neither manufactured for profit making sale or leasing or any other economic purpose, nor manufactured or distributed by him in the course of his business activity; that the defect is due to compliance of the product with mandatory regulations in effect at the time when he put the product into circulation; that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the defect to be discovered and that the damage was caused exclusively by the act of injured person or person for whom he is held liable, or the act of the third person which the manufacturer could not have predicted and the consequences of which he could not have avoided or eliminated.

16. If legal provisions on product liability are in force, is the producer's liability altered when the damage is caused both by a defect in the product and by an act or omission of a third party?

In accordance with the Law on Consumer Protection, the consumer is entitled to compensation when the damage was caused by the defect in the product and by the concurrent act or failure to act by a third party. (Article 96 paragraph 2).

The Law on Obligations: in the case when the damage was caused by the defect in the product, a manufacturer of a component of a product is to be exempted from liability if he proves that the defect is attributable to the design of the principal product or by instructions given by the manufacturer of the principal product. The manufacturer is partly exempted from liability if the injured party or person for whom he is held liable partly contributed to the occurrence of the

damage. If the third person partly contributed to the occurrence of damage, such person is liable jointly with the manufacturer.

17. If legal provisions on product liability are in force, are there any rules on expiration of liability?

Article 182 of the Law on Obligations provides for the rules on deadlines for exercising the right to compensation for damage caused by a defective product. Namely, claim for compensation of damage caused by the defective product expires within three years from the date when the injured person learned or should have learned of the damage, defect and manufacturer (special expiration deadline). The right to compensation for the damage caused by a defective product expires within ten years from the date of the product being put into circulation, unless within such period an action commenced against manufacturer before the court or other competent authority for determination or enforcement of the claim for compensation for the damage.

At the same time, the Law on Consumer Protection refers to the general rules on expiration of liability of producers of a defective product (article 96, paragraph 3).

18. Do you have any plans to modify the existing legislation? Please give details and timetables.

The existing legislation, which is not fully harmonized with the EU legislation, will be amended or the new ones will be adopted in order to provide for transposition of all the European legislation that has been adopted until now into the national one. Concurrently, the adoption of the new European legislation will be monitored in order to be transposed in the national legislation.

With regards to legislation from the previous group of questions (no. 10-17), our plans are as follows:

Directive 2001/95/EC, on general product safety, is fully transposed into the Law on General Product Safety, and the RAPEX notifications translated for the use purpose.

Directive 85/374/EEC (concerning liability of defective products) is fully transposed into the Law on Obligations* and the Law on Consumer Protection.

Directive (87/357/EEC) concerning products which, appearing to be other than they are, endanger the health or safety of consumers, is fully transposed in the Law on General Product Safety.

Decision 2006/502/EC, 2007/231/EC, 2008/322/EC, 2009/298/EC ensuring that only lighters which are child-resistant are placed on the market and to prohibit the placing on the market of novelty lighters, will be transposed in the national legislation.

Decision 2009/251/EC, ensuring that products containing the biocide dimethyl fumarate are not placed or made available on the market, will be transposed in the national legislation.

* The Law on Obligations was adopted in August 2008. During the work on the proposal for the Law, adequate decisions from the Principles of European Contract Law have also been taken into consideration as a result of work of the Commission on European Contract Law (so called Lando-Commission, 1998), Principles of International Commercial Contracts (UNDROIT), numerous conventions of the United Nations and its organs in charge of obligations, and in particular the United Nation Convention on Contracts for the International Sale of Goods (so-called Vienna Convention), EU Directives in this field: Directive 1999/44/EC on certain aspects of the sale of consumer goods and associated guarantees, Directive 85/374/EC concerning liability for damage caused by a defective product , Directive 99/314/EEC on package travel, Directive 86/653/EC relating to self-employed commercial agents, Directive 2000/35/EC on combating late payment in commercial transactions, Directive 1999/93/EC on a community framework for electronic signatures, and Directive 2000/31/EC on electronic commerce.

The Draft Law on Obligations was a subject to expertise by the Council of Europe experts, who assessed it as an overall codification of obligation relations based on classical institutions in this field, which also fully corresponds to contemporary requests of the market economy, trade in goods, intellectual goods and performance of different services.

Implementation and enforcement

19. Please comment on the important aspects of the infrastructure for general product safety as described below by referring to your national system for market surveillance:

a) market surveillance/enforcement authorities with defined responsibilities and sufficient powers and resources to monitor the compliance of products with the directive and to react to complaints;

General product safety market surveillance (the Law on General Product Safety) is performed by the inspectorate authorities within their competences through the inspectors competent for a relevant area, or authorized persons, in accordance with the Law (Article 13 paragraph 1).

/See more detailed information on individual responsibilities of inspectorates in the response to the question no. 3 (b) and (c)/

Inspectorial supervision of implementation of provisions of this Law related to misleading products is performed by an inspector of the authority competent for health sanitary affairs (Health Sanitary Inspectorate) regardless of the type of product in question (Article 13 paragraph 2)

Competences of authorized inspectors and measures they are empowered to take in order to ensure product safety on the market are regulated by Articles, 7, 11-14 and 16 of the Law, while responsibilities of customs authority are prescribed by Article 15. Punitive provisions of this Law set forth in Article 17 contain offences and fines prescribed for offenders in case of violation of the Law.

/See more details on reaction of inspectorates to complaints in the response to the question no. 3 (b) and (c) and the question no. 20 (a), while you may read more on competences, responsibilities, measures and sanctions in the response to the following question.

b) rapid and well functioning legal system for taking measures in cases of breaches of the legislation and for appropriate means of redress in respect of measures taken;

Apart from competences and measures deriving from the law that regulates inspectorial supervision, the Law on General Product Safety prescribes special measures aimed at ensuring product safety on the market. According to the provision of Article 7, a competent inspection authority may take appropriate prescribed measures if, on the basis of obtained evidence, it establishes that a product is not safe, although the product is in conformity with the safety requirements or criteria (protective clause). The provision of Article 11 refers to obligations of competent authorities to supply concerned parties with the information of the product risks to the health and safety of consumers and other users, and of Article 12 to the exchange of information about risks at national level and with Community authorities (RAPEX).

According to Article 14, the competent inspectors are entitled to take the following measures:

- for any product: to perform and organize appropriate checks on the product safety properties, on an adequate scale, up to the final stage of use; to require all the necessary information from producers or distributors; to take samples of products and subject them to safety checks.
- for any product that could pose risks in certain conditions: to require that such a product is marked with easily comprehensible warnings of the risks it may present in the official languages of Montenegro; to make its placement on the market subject to prior requirements so as to make it safe;
- for any product that could pose risks for certain persons, to order that they be given warning of the risks in good time and in an appropriate form, including also the publication of special warnings through the mass media;
- for any product that could be dangerous, to temporarily ban its offer, display, supply and putting into service, until the safety assessment procedure is terminated;

- for any dangerous product, to ban its placement on the market and impose the accompanying measures necessary for enforcement of the ban measure;
- for any dangerous product already on the market: to order or organize immediate prevention of distribution and sale of the product and alert consumers and other users to the risks such product presents; to order or organize together with producers and distributors its recall; to order, for a product determined in the final procedure as dangerous, its destruction in suitable conditions;

.Competent inspectorial authorities may take measures, in accordance with this Law, not only against producers and distributors, but also against traders and other persons, when necessary to do so in the course of supervision.

An appeal against the decision on taken measures is to be submitted within eight days from the day of the submission of the decision whereas the appeal does not postpone the enforcement of the decision.

According to Article 17, pecuniary fines are prescribed for business organizations and entrepreneurs, as well as for responsible persons in a legal person and physical persons if they place on the market a product that is not safe or violate any other provision of the Law. Inspectors are entitled to initiate misdemeanour or other procedures for violation of the Law.

/See more details on obligations of customs authorities in the response to this question-sub question (d)/

c) systematic approaches (surveillance programs, follow up of scientific and technical knowledge, review and revision of the functioning of the activities) to ensure the effectiveness of market surveillance;

Systematic approach to ensure effective market surveillance implies planning surveillance programmes aimed to ensure a continuous control of product compliance on the market, including a product risk assessment, checks of the market through inspection of documentation, visual controls and testing of products, as well as information campaigns directed to producers, traders and consumers, and national and international cooperation in the field of monitoring scientific and technical achievements. Inspection authorities adopt annual work plans and regularly monitor the realization of planned tasks. Planning activities usually begin with the existing legislation and expected amendments to the legislation, the existing and expected situation on the market, irregularities that were more often present on the market in the past period, initiatives/claims of citizens and other subjects or proposals of other market surveillance authorities. Annual work plan is just a framework plan of inspection's performance and it has been continuously adjusted to the situation on the market via monthly and other specific operational plans and instructions issued to inspectors in order to ensure effective market surveillance and follow the basic strategic goal that is a regulated market. Therefore, on the basis of the analysis of work and irregularities determined in the previous year, the surveillance programmes are planned to be implemented in the coming period along with inspectors' field activities.

In order to ensure effective market surveillance, inspectors have been educated by means of diverse forms of instructive trainings, participation in various scientific conferences and meetings, seminars, study trips and others, with a special focus on the role of the EU assistance programmes.

d) system for co-operation between market/surveillance bodies with responsibilities in relation to enforcement of different types of consumer products as well as with customs (Regulation (EC) No 339/93, Regulation (EC) No 765/2008 replacing as of 1 January 2010 the Regulation (EC) No 339/93);

In accordance with the Law on State Administration, ministries and other state administration authorities are obliged to establish mutual cooperation and inform each other on their work (Article 65). Joint inspectorial supervision is regulated by the Law on Inspectorial Supervision and Decree on Joint Inspectorial Supervision.

The Law on General Product Safety provides for cooperation between market surveillance authorities in the area of general product safety. The exchange of information among competent market surveillance authorities at the national level, as well as with the European Community authorities (RAPEX) is regulated by Article 12, which further says that the information includes notifications on the following: application of the protective clause and measures taken by the competent authorities and activities implemented by producers and distributors regarding the products posing a serious risk. On the basis of paragraph 3 of this Article, the secondary legislation (Decree on the manner of exchange of information on products posing a serious risk) providing for more detailed procedure and contents of information, as well as authorities competent for the exchange of information is prepared. Cooperation with the Customs Administration and the role of customs authorities is subject to Article 15, which prescribes that this body is entitled to postpone for three days the release of the product or the lot/batch of products, and immediately inform thereof a competent inspection authority, providing that:

- specific products or the lot/batch of products show certain characteristics that cause a reasonable doubt that they could pose a serious risk to health and safety of consumers, or
- specific products or the lot/ batch of products are not accompanied with the prescribed documents or that they are not marked in a prescribed manner.

If a competent inspection authority does not take the prescribed measures within three business days, or does not inform a customs authority of taking measures within that deadline, the customs authority will release the product or the lot/batch of products whose release has been delayed, provided that other prescribed requirements are met.

The issue of coordination of inspectorates involved in the market surveillance and customs authorities, in accordance with requirements taken upon the adoption of the Law on General Product Safety and Decree to be adopted, is also the subject of the Market Surveillance Strategy adopted by the Government. The Strategy was prepared by a working group consisting of heads of inspectorates in charge of market surveillance, as well as represesntatives of the Customs Authorities and Section for Quality Infrastructure (Ministry of Economy).The EU funded project TRIM MNE provided for the expert assistance in the process of drafting the Strategy.

e) defined methodology for risk-assessment and access to technical expertise and competent and independent testing facilities for checking conformity of products;

Assuming that a risk-assessment is the basic instrument for product safety control and that it is in function of efficient market surveillance, inspectors assess the risk by using all available data from the market, which they collect individually or via other inspectors/inspectorates, including cooperation with the authorities of other countries, as well as the information from the available data bases, and complaints of citizens and other parties. However, apart from harmonization of legislation, for the purpose of having a risk assessment of higher quality, it is necessary to further advance conditions, which would enable market surveillance authorities to access all the appropriate national and international data bases, and the system providing for the exchange of information at national and international level, both among market surveillance authorities and with other relevant authorities. In addition, the education of inspectors in the field of risk assessment methodology is of a great importance, and certain inspection authorities have already been working on improving their knowledge in this field under the EU funded project assistance. According to the Law on Inspectorial Supervision (Article 30), the inspector, during his inspectorial supervision procedure, may ask for the opinion and cooperation of professional institutions, or appropriate experts, if necessary for an accurate assessment of factual situation. This Law also provides for the methodology of sampling, sampling proceedings, informing the owners of goods and other interested parties, costs of testing and others.

There are special regulations for certain groups of products which provide for methods of average sampling and testing methods and parameters related to conformity of a product with requirements and declaration properties.

The inspectors are given opportunity to check the conformity of a product in the authorized laboratory checks.

f) access to information on product dangers to the public respecting professional secrecy and restrictions required for monitoring and investigation activities;

A competent state administration authority is obliged to, through means of mass communication, warn the consumers against the risks of using the products that are placed on the market and determined in the prescribed procedure to be unsafe (Article 80, the Law on Consumer Protection).

The information available to competent authorities relating to risks to health and safety of consumers and other users that may be caused by products are deemed to be the information of public interest. The competent authorities are entitled to submit the information about the risks at the request of the parties concerned. The information about the risks is available to the public, even if they are determined as professional secret by another law. (Article 11 of the Law on General Product Safety). /See more details in the response to the question no. 20 (g)/.

g) system for co-operation and information with producers and distributors and consumer associations with regard to providing and receiving information and exchange of experiences;

Mandatory cooperation of producers and distributors with inspectorates with regard to enforcement of measures aimed at risk assessment and risk prevention and mandatory information about products at risk is laid down in provisions of Articles 8 and 9 of the Law on General Product Safety and it will be subject to a special secondary legislation to be adopted on the bases of this Law (Draft Rulebook)

The system for cooperation with producers and distributors and consumer associations is also established through their joint participation in certain bodies in charge of protection of consumer rights, as for example in the Commission for Enforcement of National Programme for Consumer Protection, in the Arbitration Committee and others.

h) system for providing rapid information to consumers and businesses through the media;

Competent state administration authorities in charge of market surveillance, according to the Law on Consumer Protection (Article 80) are obliged to, through means of mass communications, warn the consumers against the risks of using the products that are placed on the market and that are determined in the prescribed procedure to be unsafe (Article 80, the Law on Consumer Protection). /See more details in the response to the question no. 20 (g)/.

i) system for ensuring administrative co-operation with other countries;

We have not yet developed a separate system for ensuring administrative cooperation with other countries, which would encompass a separate field of consumer protection and market surveillance. You can find more details on the issue concerning the current level of cooperation in the response to the question no 9. Currently, the administrative cooperation with other countries has been conducted through the Ministry of Foreign Affairs and competent ministries.

j) co-operation with the national standardisation body with regard to the use of standards under the directive and to ensure co-operation of all parties concerned (including consumers) in the development of standards related to consumer products;

Good communication that we have had with the Institute for Standardization of Montenegro during the process of drafting the Law on General Product Safety resulted in the adoption of Montenegrin standards that are identical to harmonized standards contained in the Directive 2001/95/EC on general product safety. These standards are available to all the parties concerned (including market inspectorate and consumers) and may be obtained in the Institute for Standardization of Montenegro.

In order to broaden knowledge with regard to standardization and standards, the Market Inspectorate in cooperation with the Institute for Standardization of Montenegro and other institutions of quality infrastructure, in the past period, organized certain number of trainings and seminars for market inspectors, which, among others, tackled the issues of standardization and standards. This type of education intended for market inspectors is expected to be intensified in the coming period.

Within the Institute for Standardization of Montenegro there are ongoing preparations for establishing technical committees and other professional bodies of the Institute. The membership in these bodies in charge of adoption and development of standards, in accordance with general and internal acts governing the work of the Institute, is voluntary and open to all interested parties, including market inspectorate and consumers.

k) systems for collection of product related injury data (such as the EU EHLASS programme);

The system for collection of product related injury data does not exist.

/See more details on this questions in the response to the question no. 20 (j)/

l) number of controls carried out and the results, the reasons for the controls (own initiative/complaints), type of products controlled, the geographical coverage of the controls, the way the controls have been carried out (ocular examination/testing).

Data on the number of controls carried out and their results, i.e. measures taken in the course of 2008, are given in the response to the answer no. 20 (b).

As a rule, inspectors are entitled to carry out control *ex officio*, but they are also entitled to act in accordance with initiatives/complaints of citizens and other persons. It is priority to act in accordance with initiatives/complaints and persons who submitted initiatives/complaints are informed on the control results.

All types of products on the market are under the surveillance of competent inspectorates.

Inspectorates competent for control in the area of general product safety carry out control throughout the entire territory of Montenegro through inspectors in their organizational or branch units.

In order to establish the conformity of a product with the prescribed requirements, inspectorates use prescribed procedures and methods, including administrative, visual and sample test controls. During the enforcement of control proceedings, firstly, the administrative control is carried out, i.e. control of documents establishing the origin of the product (proof of purchase) and control of supporting documents attached to the marketed product (certificate, warranty, technical specifications and others), i.e. whether a product has required documents and whether they are in accordance with legislation, as well as whether the marketed product was declared properly. In addition, inspectors use also methods of visual control, and they also can take product samples and submit them for testing to a professional institution in charge of testing. Further actions and type of taken measures depend on the results of control.

20. Please give some indication of the level of activities in the field of market surveillance by providing statistics, as available, referring to some of the following examples:

a) number of complaints received, from whom and actions undertaken;

In order to ensure efficient market surveillance, Market Inspectorate has undertaken special activities with regards to informing consumers and other persons of the role of the Inspectorate in the field of market surveillance, and in particular of the role of consumer protection when purchasing goods and services. Telephone numbers of the Inspectorate are announced in two printed media, which are distributed all over Montenegro in order to provide for much easier contact between the parties concerned and the Inspectorate. Receipt of complaints of citizens and others during working hours is organized through the duty inspector, and after the end of working hours, complaints can be submitted via an automated telephone device. Complainants contact Market Inspectorate by telephone, by submission of complaints in writing, and directly, i.e. by direct visit to the closest office of market inspectorate. Apart from the receipt of complaints, the duty inspector gives advice to consumers at their request, and when on duty, he is obliged to keep records of received complaints and given information and advice to complainants, and to submit the report thereof to the chief inspector, every morning for the previous day. Received complaints are given to inspectors to act accordingly on the same day, and the inspector in charge, after carrying out control, submits the report to the submitter of complaint and, through a coordinator of branch unit, refers it to the chief inspector. For the purpose of monitoring consumer complaints, and within the EU funded project TRIM MNE, a special programme is prepared for Market Inspectorate. Testing and further improvement of the programme is underway.

In 2008, the Market Inspectorate received 436 complaints in total, out of which 324 referred to protection of consumer rights. Within the total number of complaints, there were 161 complaints for purchased products. The rest of the registered irregularities referred to irregular accentuation of prices (40%), irregular issuance of bills (35%), irregular declaration of marketed goods (13%), failing to deliver goods within agreed time frame and other things.

In 95% of cases, complaints referred to product quality (technical goods, furniture, clothes and shoes, construction material and others), while 5% of cases referred to wrongly calculated price. Out of total number of received complaints 88 or 54% was decided in favour of consumers, in 6 cases consumers were referred to contact the seller, in 6 cases submitters withdrew complaints, and in some cases they were referred to exercise their rights before other authorities.

Acting upon complaints, the inspectors completed 440 controls in total. Apart from enlisted measures taken as a result of complaint, inspectors rendered 144 administrative decisions and pronounced 103 mandate sanctions and submitted 24 requests for instituting misdemeanour procedure.

b) number and types of measures taken by market surveillance authorities;

In 2008, Market Inspectorate carried out 18,631 inspectorial controls in total, of which 97.66% were carried out ex officio, while for the rest, they carried out acting upon initiatives/complaints of citizens and others. They found 18,197 irregularities, of which 9,931 or 54% were in the field of consumer protection, i.e. violation of provisions of the Law on Consumer Protection and technical regulations.

For the removal of these irregularities, in 1,102 cases, inspectors pointed out to irregularities and determined actions and deadlines for their removal. Apart from this, they rendered 9,586 decisions in total, of which 8,835 contained a warrant of removal of irregularities, and the rest were related to the measure on a temporary ban on performance of an activity, temporary deprivation of goods or contained a warrant to send documentation for inspection.

Out of the total number of decisions requiring removal of irregularities, 7,526 are related to irregularities in the field of consumer protection, where 2,673 also contain a measure concerning a temporary ban on trading goods due to non-declared/irregularly declared goods, non existence or deficient complementary documents (instructions, warranty and others), or due to expiration of use by dates. Having in mind that the total number of temporary bans on trading goods is 3,359, it means that 80% of bans referred to consumer protection, and the rest referred to non-recording of goods in trading book.

There were 9,691 mandate sanctions issued for misdemeanour, out of which 6,512 referred to misdemeanour sanctions in the field of consumer protection. There were 1,249 requests for instituting misdemeanour procedure, which encompassed 1,832 misdemeanours in total. With regard to preventive actions, the inspectors provide information and advice to consumers and cooperate with consumer organizations and traders for the purpose of clarification of legislation.

In 2008, sanitary inspectors, during internal audit, carried out 10,795 inspectorial controls in total and found 2,793 irregularities, which represent 19.68% in relation to the total number of performed controls. There were altogether 2,300 decisions and recommendations made.

Due to determined irregularities, altogether 24 requests for instituting misdemeanour procedure were submitted to the Division for Instituting Misdemeanour Procedure.

During the same time period, health inspectors both ex officio and acting upon consumer complaints carried out 1,186 inspectorial controls in total in health facilities, based on which 92 requests for initiating misdemeanour procedure and 123 administrative decisions on removal of irregularities were submitted.

c) number and types of measures taken by customs authorities;

A customs authority has no records on number and types of measures taken on the basis of enforcement of the Law on General Product Safety. They provided the reasons thereof in the response to the question no. 19 (d).

d) number and types of product safety cases dealt with by the courts, average time-frame for a decision and average time for enforcement;

There are no data available on number and type of product safety cases dealt with by the court. The Division of the Ministry of Economy in charge of misdemeanor procedure institutes misdemeanor procedure upon requests of market inspectors, when during their inspection control, they determine infringement of legislation qualified as a misdemeanor, including misdemeanors concerning products marketed without official declarations, as well as prescribed additional documents attached to a product. The Division does not keep statistics on these types of misdemeanors. The time period for a decision to be rendered and accordingly enforced depends on fulfillment of procedural requirements laid down in the Law on Misdemeanors.

e) number and type of rapid-alert measures notified to and from the central point and documentation on follow-up to such notifications;

Among the internal inspectorate offices, among different inspectorates, as well as among inspectorates and other market surveillance authorities, the information has been exchanged via telephone, fax and e-mail.

The System for the Rapid Exchange of Information (RAPEX) on dangerous products placed on the market has not been established yet. A legal ground for establishment of the System is set forth in the Law on General Product Safety, and more detailed procedures will be laid down in the Decree on the manner of exchange of information on the products posing risk, which determines a contact point for rapid exchange of information. /See more details in the response to the question no. 10/

f) activities undertaken (meetings, information documents etc.) for ensuring co- ordination between authorities and interaction with economic operators and consumer organisations;

Having in mind that the inspection control over the legislation enforcement has been carried out by many inspection authorities from numerous ministries and other state administration authorities, a continuous cooperation between these authorities is required, which is anyhow provided for by the law. Inspectorates organize meetings and exchange the information when needed. An inspectorate is entitled to inform the competent inspectorate of any notifications in areas within the competence of other inspectorate. With regards to consumer complaints, the inspectorate is obliged to submit a received complaint, which is out of its competence, to the competent inspectorate to proceed with it. At the same time, with regards to some special surveillance programmes (movement of certain types of goods, trade in certain territories or in certain time periods – tourist season and others), in which several inspectorates take part, the coordination is ensured by the inspection with prevailing competences in this area.

Coordination of market surveillance authorities is a subject matter of the Market Surveillance Strategy, which provides for mandatory cooperation and identifies specific types of coordination, taking into account the fact that the market surveillance is carried out by an inspectorate within its competences. /for more details see the answer to the question 3(b), 19(b), and 20(h)/.

The Market Inspectorate has established good cooperation with NGO for consumer protection, which is reflected in quick reactions of the inspectorate to their complaints and reporting back on taken measures, participation of Market Inspectorate representatives in informative shows and round tables organized by NGOs, as well as in other types of cooperation with representatives of consumers. At the same time, the cooperation with consumers is ensured in the manner described in the response to the question no. 20 (a), i.e. receipt and urgent processing of complaints, as well as providing advice to consumers.

Besides the cooperation with consumers, this Inspectorate has established good cooperation with the economy, or traders with regards to their education about new regulations, giving opinion on their questions regarding an appropriate enforcement of legislation, organization of meetings upon request of certain traders, or their associations. In the coming period, cooperation with business persons according to the Law on General Product Safety and the Rulebook on contents of notification of dangerous products, which is in the process of drafting.

g) information activities directed to the public;

The Law on Consumer Protection provides for the obligation of informing the public by competent inspection authorities in certain cases. Each market surveillance inspectorate has established communication with means of public communication via press releases, press conferences, interviews, talk shows, answers to journalists' questions and other types of communication with electronic and printed media.

Article 11 of the Law on General Product Safety provides for obligation of competent authorities to submit information relating to risks to health and safety of consumers and other users that may be caused by products at the request of the parties concerned. This Law (Article 12) also provides for the exchange of information on the risks between competent authorities at the national level as well as between national authorities and EC (RAPEX). This information represents notifications on the enforcement of protective clause and taken measures by competent authorities and the enforcement of activities of producers and distributors related to the products that pose a serious risk. A specific Decree defines more detailed procedure and authorities for the exchange of information, /See more details in the response to the question no 19(h)/

h) routines and meetings between product safety authorities and customs to ensure co-ordination of the customs control;

Currently, in Montenegro there is no authority, which would provide for coordination of inspectorates competent for market surveillance and customs authority within the meaning of obligations taken over by the Law on General Product Safety. Cooperation has been developed when necessary/ad hoc. A continuous cooperation and exchange of information on dangerous products in accordance with the said Law will be established by the secondary legislation, i.e. Decree, while the issue related to cooperation will be addressed in line with the Market Surveillance Strategy as well as with the Government's conclusion accompanying the Strategy, which refers to the establishment of the Market Surveillance coordination body. /See more in the response to the questions 3(b) and19 (d)/.

i) details of systems for ensuring a systematic approach to control activities;

The manner and procedure related to the inspection control over the enforcement of legislation, obligations and powers of inspectors, and other issues of importance for performing control activities are laid down in the Law on Inspectorial Supervision.

Competences of inspection authorities, as well as special powers of inspectors are defined in separate sector laws.

A short description of competences, powers and organizations such as Market, Health–Sanitary, Phytosanitary, Tourist and other inspectorates in charge of market surveillance is given in the response to the question A. 3. b) and c)

Apart from the fact that all of these inspectorates are established at the state level, they have a organized in branch offices and they carry out control over the entire territory of Montenegro.

The activities of the inspectors are monitored, analyzed and directed from the headquarters of the inspection run by chief inspector. Through issuance of guidelines and orders the enforcement of control activities on the field has been organized, their enforcement has been monitored, in particular directly and indirectly via reporting on carried out inspection controls, determined requirements and taken measures. Inspectors submit their reports to the inspectorate headquarters via branch units.

This system of control provides for a balanced control over the entire territory of Montenegro, as well as fair proceedings of inspectors and equal enforcement of legislation. /See more details on systematic approach of activity control in the response to the question no. 19 (c)/

j) statistics on injuries related to products;

At the moment, market surveillance authorities don't have a developed system for data collection on injuries related to products, because such an obligation is not stipulated by any piece of legislation for which enforcement these authorities are competent.

Statistics Office of Montenegro does not contain or conduct researches for the purpose of monitoring of statistics on injuries caused by products.

k) systems established to ensure consumer participation in relevant standardisation work;

In accordance with the Law on Consumer Protection consumer organizations may provide the opinion on the national standardization procedure (Article 121 paragraph 1 item 8).

Membership in the Institute for Standardization of Montenegro (hereinafter referred to as: the Institute), in accordance with general and internal acts governing its work, is voluntary and open for all interested parties, including associations and representatives of consumers. By paying annual membership fee (which depends on number of employees) one can become a member of the Institute; a member of the Institute has an opportunity to participate in the management structure of the Institute, and to enjoy favorable conditions (discounts) when purchasing standards, provision of information on standards and standardization process, favorable conditions (discounts) when organizing trainings in the organization of the Institute and others. The Institute has also a good cooperation with the non-governmental organization "ECOM" dealing with consumer protection, which is at the same time a member of the Institute.

At the same time, participation in the work of expert bodies of the Institute (technical committees, working groups and others), working on adoption and development of standards, is also open for all interested parties (including consumer representatives), on a voluntary basis and does not stipulate any financial costs (apart from travel costs for participation in the meetings of the expert bodies).

All the information related to standards and standardization is available on the internet portal of the Institute (www.isme.me). In the coming period, the Institute will continually take additional measures in order to encourage consumer associations to become members of the Institute, as well as to take part in the work of its expert bodies on the adoption and development of Montenegrin standards. The Institute monitors and participates in the work of the Committee on Consumer Policy (COPOLCO), i.e. the ISO Committee dealing with consumer protection issues.

l) statistics relating to sales figures of consumer products, origin of the products etc.

Internal wholesale trade - Product categories in EURO

NAME	Price7	CVPrice7	Price6	CVPrice6
00-In total (01-30)	1 762 142 068.7	4.2	1 297 110 072.9	3.7
01-Agricultural products and live animals (animal fodder, flowers, raw skin and others)	11 696 189.2	21.8	8 145 971.7	28.5
02-Meat, Fish and preparations, oils and fats	92 934 439.8	18.4	77 188 817.8	25.1
03-Milk, dairy products and eggs	61 682 537.4	19.7	47 342 678.6	16.0
04-Fruits and vegetables	26 626 270.6	28.4	22 527 387.4	28.0
05-Sugar, chocolate and sweets	53 765 620.0	16.5	43 963 850.5	15.9
06-Coffee, teas, cacao and spices	22 861 490.3	18.3	18 742 775.3	23.1
07-Non-alcoholic and alcoholic beverages	92 717 061.2	19.9	75 058 601.1	19.2
08-Other products fit for human production	92 076 075.7	29.0	83 897 359.2	23.3
09-Tobacco and cigarettes	61 360 295.2	40.4	34 976 875.5	39.8
10-Textile, linens and other clothing products	41 644 449.0	59.5	25 200 406.1	69.5
11-Footware and leather products	8 765 530.0	97.8	1 249 475.0	97.8
12-Furniture, carpets and other floor coverings	46 703 499.2	54.3	29 765 606.3	47.1
13-Electrical household devices and radio and TV devices	74 485 186.6	25.0	50 266 730.4	28.0
14-Porcelain and glass	13 924 598.7	79.2	6 051 710.0	73.5
15-Varnishes, paints, wall coverings and household cleaning preparations	20 801 450.9	51.2	16 236 823.7	48.6
16- Perfumery, cosmetics or toilet preparations	56 289 988.2	25.9	47 086 572.7	28.8
17-Pharmaceutical products	58 520 829.3	19.2	44 362 608.0	21.3
18-Paper products (books, newspapers, and paper confection)	11 262 103.5	46.6	3 792 834.5	14.9
19-Photographic and optical instruments, bicycles, musical instruments, watches, toys, umbrellas, wooden products and others	4 788 464.8	27.2	2 112 930.0	24.5
20-Solid, liquid and gas fuels	441 895 696.8	9.7	329 991 992.8	7.8
21-Metal products and ores	19 821 748.3	49.4	3 140 338.9	63.4
22-Wood, construction materials and sanitary equipment	144 515 575.6	25.3	94 417 358.8	24.9
23-Metal products, tubes and other installation equipment	24 746 515.5	39.9	13 721 566.6	45.5
24-Chemical products (In industry and agriculture)	13 889 691.4	43.3	40 166 023.6	50.3
25- Offal and residues	17 991 646.0	83.7	14 845 823.0	58.5

26-Machines, devices and accessories (tools, agricultural, office, construction, textile, other classical and computerized accessories, personal computers and equipment and others)	88 932 574.3	21.8	49 916 345.9	27.6
27-Motor vehicles	7 742 910.5	3.0	3 298 908.2	2.5
28- Motor vehicles parts and accessories	28 640 663.6	33.4	14 553 152.7	52.0
29-Motorcycle parts and accessories	17 017 958.0	57.5	440 773.2	96.6
30-Others (please list)	104 041 009.4	41.2	94 647 775.5	37.0

Source: Statistics Office of Montenegro (hereinafter referred to as: MONSTAT)

Internal wholesale trade - Main activity, in EURO

Activity	Turnover 2007	Turnover 2006
512-Wholesale trade in agricultural products and live animals	10 251 460	7 960 559
513- Wholesale trade in foods, beverages and tobaccos	165 877 856	121 045 240
514- Wholesale trade in household utensils	144 580 184	86 408 472
515- Wholesale trade in raw materials and offal and residues except for agricultural products	531 981 042	403 828 572
516-Wholesale trade in machines, utensils and accessories	60 084 422	36 560 195
517- Other wholesale trade	794 458 342	6 269 45 318
50 Sale, maintenance and repair of motor vehicles and motorcycles	54 908 763	14 361 717
50100-Sale of motor vehicles	14 886 840	5 914 294
50300-Sale of motor vehicles parts and accessories	25 452 921	8 006 650
50401 Sale of motorcycle parts and accessories	14 569 002	440 773
In total	1 762 142 069	1 297 110 073

Source:MONSTAT

Internal retail trade- Products listed in commodity groups, in EURO

		Companies	Independent trader	Total 2006
	Products listed in commodity groups	2006	2006	In total 2006
00	Total (01- 41)	597 068 403.7	43 138 978.1	640 207 381.8
01	Bread, cereals, pasta, pastry (rice, biscuits, sandwiches, pizzas, cookies and others)	28 128 042.5	2 251 267.0	30 379 309.5
02	Meat and fish products	45 406 714.1	3 814 960.9	49 221 674.9
03	Milk, dairy products and eggs	28 806 285.5	1 581 678.9	30 387 964.4
04	Oils and fats	13 000 173.8	1 178 963.6	1 417 9137.5
05	Fruits and vegetables (fresh and frozen)	9 938 694.6	976 455.5	10 915 150.1
06	Sugar, chocolate and sugar products (jam, honey, ice cream, compotes, confectionary, gums and others)	22 030 567.6	3 877 947.7	25 908 515.3
07	Non-alcoholic beverages (coffee, tea, cacao, all types of juices, mineral and spring water and others)	34 180 648.9	3 919 229.8	38 099 878.6
08	Other products fit for human production non elsewhere specified	17 266 458.6	2 771 097.5	20 037 556.1
09	Alcoholic beverages	37 790 739.2	2 826 789.5	40 617 528.8

10	Tobacco and cigarettes	19 275 104.3	1 268 131.4	20 543 235.7
11	Clothing fabrics of all types	835 618.9	229 966.0	1 065 584.9
12	Men, women, children clothing and other clothing accessories	26 320 632.9	3 080 876.4	29 401 509.3
13	Footwear (men, women, children and sports)	14 216 218.5	742 228.1	14 958 446.6
14	Preparations for household cleaning and maintenance (paints, varnishes, parquet, ceramics tiles, wall coverings, cement, window glasses and others)	24 423 013.0	172 9512.2	26 152 525.3
15	Light distillate oil , butane-gas, coal and wood for household	1 344 298.8	0.0	1 344 298.8
16	Furniture and products for household furnishing, decoration and lighting	34 824 584.8	459 168.3	35 283 753.1
17	Carpets and floor coverings	653 054.0	23 567.5	676 621.5
18	Textile products and textile for households (linens, curtains, table cloths and others)	6 1896 71.8	103 893.2	6 293 565.1
19	Basic household utensils (refrigerators, washing and dishwashing machines, stoves, vacuum cleaners, thermo-accumulation furnace, air conditioners and others)	2 2981 633.7	455 732.7	23 437 366.4
20	Other electrical household devices (irons, mixers, juice makers, toasters and others)	3 729 991.8	545 038.2	4 275 030.1
21	Glass, dishes, silverware, cutlery, mechanic cutlery and others)	4 217 704.0	678 295.0	4 895 999.0
22	Household devices and accessorize, electrical and manual (drills, lawn mowers, saws, hammers, spades, shovels and others)	10 756 052.6	579 163.6	11 335 216.2
23	Household cleaning and maintenance preparations (detergents, softeners, insecticides, pesticides, and others)	20 867 958.8	1 488 287.6	22 356 246.4
24	Pharmaceutical products (medicines, vitamins, shots and other medical products)	16 883 370.4	193 029.0	17 076 399.4
25	Medical equipment, therapy appliances and equipment (sanitary materials, thermometers, corrective glasses, orthopaedic appliances, auricular appliances and others)	283 116.9	0.0	283 116.9
26	Motor vehicles (new and second hand)	53 175 109.5	0.0	53 175 109.5
27	Motorcycled, bicycles, tricycles and other transport vehicles	116 6070.3	0.0	1 166 070.3
28	Parts and accessorize for motor vehicles maintenance, motorcycles, and other transport vehicles	18 104 516.0	2 240 144.5	20 344 660.5
29	Fuels and coal for motor vehicles, motorcycles and other transport vehicles)	22 654 875.1	1 248.8	22 656 123.8
30	Telephone and facsimile machine	751 417.5	607 641.2	1 359 058.7
31	Radio and TV devices, video recorders, CD players, stereo systems, and additional equipment	4 628 697.2	186 845.0	4 815 542.2
32	Photographic and optical equipment (cameras, digital cameras and others)	717 922.6	4 300.0	722 222.6
33	Computers, special software, printers, keyboards, calculators and others)	1 860 639.5	0.0	1 860 639.5
34	Instruments for recording and recorded (records, CDs, VSH, tapes and others)	32 535.0	144 001.1	176 536.1
35	Durable goods for recreation and culture (camping trailers, trailers, boats, all types of musical instruments and others)	0.0	0.0	0.0
36	Toys: equipment for sports, camping, recreation and hunting, weapons and ammunition	2 890 539.0	363 762.8	325 4301.8
37	Flowers, seedlings, seeds, and all types of fertilizers	1 123 013.4	450 439.6	1 573 453.0
38	Pets, food, medicines and auxiliary devices for care thereof	361 546.8	31 150.4	392 697.2
39	Books, newspapers, and writing materials	277 942 00.3	1 459 846.6	29 254 046.9
40	Apparatus and preparations for personal care (hairdryers, creams, soaps, shampoos, perfumes and others)	11 627 978.5	663 447.6	122 91 426.2
41	Other products for personal use (jewelry, watches, bags, wallets, equipment for babies and others)	5 828 992.8	2 210 871.1	8 039 863.9

Source: Monstat

Internal retail trade, in EURO

		Companies	Independent Trader	Total 2007
	Products listed in commodity groups	2007	2007	Total 2007
00	Total (01- 41)	844 588 003.8	56 415 540.7	901 003 544.4
01	Bread, cereals, pasta, pastry (rice, biscuits, sandwiches, pizzas, cookies and others)	37 045 571.4	3 242 474.3	40 288 045.7
02	Meat and fish products	61 247 336.6	4 867 938.3	66 115 274.9
03	Milk, dairy products and eggs	36 785 828.7	2 489 158.0	39 274 986.8
04	Oils and fats	18 789 228.3	2 090 556.4	20 879 784.7
05	Fruits and vegetables (fresh and frozen)	15 270 069.3	1 358 392.3	16 628 461.6
06	Sugar, chocolate and sugar products (jam, honey, ice cream, compotes, confectionary, gums and others)	29 928 373.0	4 243 571.6	34 171 944.6
07	Non-alcoholic beverages (coffee, tea, cacao, all types of juices, mineral and spring water and others)	43 507 900.8	4 398 459.1	47 906 359.9
08	Other products fit for human production non elsewhere specified	21 084 860.5	2 954 617.2	24 039 477.7
09	Alcoholic beverages	45 029 764.4	3 839 077.2	48868841.6
10	Tobacco and cigarettes	22 755 530.5	2 936 157.5	25 691 688.0
11	Clothing fabrics of all types	1 602 045.0	625 420.5	2 227 465.5
12	Men, women, children clothing and other clothing accessories	39 911 248.0	3 257 357.3	43 168 605.4
13	Footwear (men, women, children and sports)	30 602 143.8	1 948 535.9	32 550 679.7
14	Preparations for household cleaning and maintenance (paints, varnishes, parquet, ceramics tiles, wall coverings, cement, window glasses and others)	45 095 779.6	1 716 040.3	46 811 819.8
15	Light distillate oil , butane-gas, coal and wood for household	1 644 180.4	0.0	1 644 180.4
16	Furniture and products for household furnishing, decoration and lighting	46 436 513.8	1 318 526.8	47 755 040.6
17	Carpets and floor coverings	863 532.5	250.0	863 782.5
18	Textile products and textile for households (linens, curtains, table cloths and others)	10 001 054.5	83 095.8	10 084 150.4
19	Basic household utensils (refrigerators, washing and dishwashing machines, stoves, vacuum cleaners, thermo-accumulation furnace, air conditioners and others)	34 336 706.1	919 196.3	35 255 902.4
20	Other electrical household devices (irons, mixers, juice makers, toasters and others)	5 661 940.2	359 109.8	6 021 050.0
21	Glass, dishes, silverware, cutlery, mechanic cutlery and others)	5 168 259.2	668 673.3	5 836 932.4
22	Household tools and accessorize, electrical and manual (drills, lawn mowers, saws, hammers, spades, shovels and others)	15 693 985.8	1 229 403.3	16 923 389.0
23	Household cleaning and maintenance preparations (detergents, softeners, insecticides, pesticides, and others)	24 652 201.6	1 757 798.5	26 410 000.1
24	Pharmaceutical products (medicines, vitamins, shots and other medical products)	21 082 341.6	342 553.0	21 424 894.6
25	Medical equipment, therapy appliances and equipment (sanitary materials, thermometers, corrective glasses, orthopaedic appliances, auricular appliances and others)	310 566.3	0.0	310 566.3
26	Motor vehicles	100 055 068.9	0.0	100 055 068.9
27	Motorcycled, bicycles, tricycles and other transport vehicles	2 967 559.7	2 763.7	2 970 323.4
28	Parts and accessorize for motor vehicles maintenance, motorcycles, and other transport vehicles	24 739 755.7	1 561 436.4	26 301 192.1
29	Fuels and coal for motor vehicles, motorcycles and other transport vehicles)	28 755 203.3	12 681.8	28 767 885.0
30	Telephone and facsimile machine	624 504.0	99 964.1	724 468.1
31	Radio and TV devices, video recorders, CD players, stereo systems, and additional equipment	6 009 740.7	972 981.7	6 982 722.4
32	Photographic and optical equipment (cameras, digital cameras and others)	852 641.8	34 798.2	887 439.9

33	Computers, special software, printers, keyboards, calculators and others)	3 792 435.0	6 370.0	3 798 805.0
34	Instruments for recording and recorded (records, CDs, VSH, tapes and others)	108 088.0	17 038.5	125 126.5
35	Durable goods for recreation and culture (camping trailers, trailers, boats, all types of musical instruments and others)	0.0	0.0	0.0
36	Toys: equipment for sports, camping, recreation and hunting, weapons and ammunition	3 497 016.1	273 486.3	3 770 502.4
37	Flowers, seedlings, seeds, and all types of fertilizers	1 117 225.0	164 160.1	1 281 385.1
38	Pets, food, medicines and auxiliary devices for care thereof	422 586.6	32 425.7	455 012.3
39	Books, newspapers, and writing materials	34 473 640.4	1 994 401.8	36 468 042.2
40	Apparatus and preparations for personal care (hairdryers, creams, soaps, shampoos, perfumes and others)	14 768 902.0	665 329.6	15 434 231.6
41	Other products for personal use (jewellery, watches, bags, wallets, equipment for babies and others)	7 896 674.6	3 931 340.6	11 828 015.2

Source: Monstat

Internal retail trade-main activity, in EURO

Activity	turnover 2006	turnover 2007
521- retail trade in non specialized stores	333 039 389	440 093 310
522- trade in food, beverages and tobacco in specialized stores	25 791 179	35 650 789
523-trade in pharmaceuticals, medical, cosmetics , toilet products	22 424 070	28 960 763
524- retail trade in non-alimentary products	125 306 254	188 534 415
525-retail trade in second hand goods	548 077	1 150 077
526-trade in stores dispatching ordered goods via mail	2 663 324	3 833 226
50-sales, maintenance, repair of motor vehicles and motorcycles, retail trade in motor fuel	87 296 102	146 365 424
50100,50401-trade in parts and accessorize of motor vehicles and motorcycles	58 396 548	108 727 200
50300- sale of parts and accessorize of motor vehicles	10 826 587	14 093 801
50500-retail trade in motor fuels	18 072 967	23 54 423
In total	597 068 395	844 588 005

Source: Monstat

Note: As of 2006, wholesale and retail trade is conducted according to the new methodology.

As of 1 January, 2009 Statistics Office of Montenegro monitors consumer prices index (CPI),

Statistics Office of Montenegro has no data available on origin of products.

21. For which of these product categories have you carried out specific market surveillance activities in the last three years?

a) Child-care articles (e.g. teething rings, pacifier chains, babywalkers, folding cots);

Child-care articles (e.g. teething rings, pacifiers and gummy toys) are controlled in accordance with the Rulebook on requirements concerning safety of marketed products for general use (Official Gazette of the Socialist Federal Republic of Yugoslavia 26/83, 61/84, 56/86 and 50/89).

In accordance with this Rulebook, the said products are tested to the presence of dangerous migrants. Apart from these products, childcare toys of physical characteristics (pointy, sharp and jaggy edges, varnished surfaces, hair and similar) that may endanger child health and safety are also controlled.

b) playground equipment;

There is no data available that specific market surveillance activity is carried out for playground equipment. Control over these types of products has been carried out as a part of administrative control, in particular with regards to origin of products (purchase invoice and others), required documents accompanying marketed products and determined manner of declaring and designating products

c) furniture (e.g. bunk beds, flammability of upholstered furniture);

There is no data available that specific market surveillance activity is carried out for furniture (e.g. bunk beds, flammability of upholstered furniture). Control over these types of products has been carried out as a part of administrative control, in particular with regards to origin of products (purchase invoice and others), required documents accompanying marketed products and determined manner of declaring and designating products.

d) do-it-yourself equipment (e.g. ladders);

There is no data available that specific market surveillance activity is carried out for do-it-yourself equipment (e.g. ladders). Control over these types of products has been carried out as a part of administrative control, in particular with regards to origin of products purchase invoice and others), required documents accompanying marketed products and determined manner of declaring and designating products.

e) leisure equipment (e.g. bicycles, climbing equipment, bounce castles);

There is no data available that specific market surveillance activity is carried out for leisure equipment (e.g. bicycles, climbing equipment, and bounce castles). Control over these types of products has been carried out as a part of administrative control, in particular with regards to origin of products purchase invoice and others), prescribed documents accompanying marketed products and determined manner of declaring and designating products.

f) clothing (flammability risks, strangulation risks);

There is no data available that specific market surveillance activity is carried out for leisure clothing (flammability risks, strangulation risks). Control over these types of products has been carried out as a part of administrative control, in particular with regards to origin of products purchase invoice and others), prescribed documents accompanying marketed products and determined manner of declaring and designating products.

g) decorative articles (e.g. imitation fruit, Christmas decorations, candles);

There is no data available that specific market surveillance activity is carried out for decorative articles (e.g. imitation fruit, Christmas decorations, candles). Control over these types of products has been carried out as a part of administrative control, in particular with regards to origin of products purchase invoice and others), required documents accompanying marketed products and determined manner of declaring and designating products.

h) products containing chemical

All products – items that come into direct contact with food and that are made of different materials (plastics, metal, wood, paper and others) have been tested to presence of dangerous migrants, and PVC-products, including child-care products to presence of phthalates.

i) products for children, other than toys (e.g. products attractive to children, children's swim seats, playpens);

There is no data available that specific market surveillance activity is carried out for products for children, other than toys (e.g. products attractive to children, children's swim seats, playpens). Control over these types of products has been carried out as a part of administrative control, in particular with regards to origin of products (purchase invoice and others), required documents accompanying marketed products and determined manner of declaring and designating products.

j) cigarette lighters;

There is no data available that specific market surveillance activity is carried out for cigarette lighters. Control over these types of products has been carried out as a part of administrative control, in particular with regards to origin of products (purchase invoice and others), required documents accompanying marketed products and determined manner of declaring and designating products.

k) laser pointers;

There is no data available that specific market surveillance activity is carried out for laser pointers. Control over these types of products has been carried out as a part of administrative control, in particular with regards to origin of products (purchase invoice and others), prescribed documents accompanying marketed products and determined manner of declaring and designating products.

l) medicines.

In accordance with the Law on Pharmaceuticals (Official Gazette of the Republic of Montenegro 80/04 and Official Gazette of Montenegro 18/08), market surveillance of pharmaceuticals quality is ensured by the Agency for Pharmaceuticals and Medical Devices of Montenegro and Health Inspectorate of Ministry of Health, and the ministry in charge of market affairs, through the Market Inspectorate, carries out control over the prices of marketed pharmaceuticals.

In 2008, a systematic control over 226 pharmaceutical samples taken from maxi drug stores, pharmacies and other health facilities was carried out. After obtained control results from authorized laboratory, the competent Inspectorate in line with the law, took appropriate measures on pharmaceuticals that did not comply with quality standards. At the same time, on the basis of the information from other agencies, an ad hoc control and withdrawal of specific series of pharmaceuticals, for which it was proven in other countries that there were omissions with regards to quality, was carried out.

Currently, pharmaceuticals have been imported in Montenegro on the basis of import licenses issued by the Agency in accordance with the Law, and a prerequisite for obtaining such a license is to have a pharmaceutical registered in the European Union countries, USA, Canada, Switzerland, Norway and ex -Yugoslav countries. According to the Law, this sort of import is possible until March 2120.

Concurrently, as of the end of 2008, the process of registration of pharmaceuticals has been started in line with the Law and Rulebook on more detailed requirements for issuance of a license for putting pharmaceuticals into circulation. Thus, after March 2010, the Montenegrin market needs to keep only those pharmaceuticals containing the license for marketing pharmaceuticals issued by the Agency for Pharmaceuticals and Medical Devices of Montenegro (CALIMS) and pharmaceuticals, which will be imported emergently in accordance with the Rulebook on emergency import of pharmaceuticals.

The Agency ensures that all pharmaceuticals correspond to current quality standards, upon the assessment of documentation on pharmaceuticals, laboratory quality control and control procedure conducted by the Agency in accordance with mentioned legislation.

Pharmaceutical quality control is carried out by means of the following:

- The assessment of the certificate on conducted quality control of pharmaceutical and/or (producer and/or authorized laboratories, which must be in compliance with European and other distinguished pharmacopoeia or tested methods of analysis);
- Laboratory inspection in authorized laboratories.

Pharmaceutical laboratory quality control is conducted by a control laboratory for pharmaceutical testing of drugs, in accordance with principles of good laboratory control practice.

Pharmaceutical laboratory quality control is carried out in compliance with European, national pharmacopoeia or other distinguished pharmacopoeia or other validated methods of analysis.

In accordance with the Law, the Agency may establish its own quality control laboratory or may, on contractual basis, entrust a laboratory in Montenegro with pharmaceutical quality control or a national quality control laboratory of pharmaceuticals in charge other country.

The Agency currently does not have its own laboratory for quality control; instead it uses services of the National Control Laboratory of the Agency for Pharmaceuticals and Medical Devices of Serbia as well as Agency for Pharmaceuticals and Medical Products of the Republic of Croatia, on the basis of signed treaties, i.e. Protocol on Cooperation. The Agency also recognizes certificates issued by laboratories, which are members of the Official Medicines Control Laboratory Network (OMCL).

The Ministry of Health performs inspection control over producers, bearers of license for wholesale trade to pharmacists, veterinary pharmacists and other persons to which the Law on Pharmaceuticals applies, as well as inspection control over pharmaceutical announcements. The Inspectorate within the Ministry, also, prohibits sale or orders suspension or withdrawal from the market of pharmaceuticals, which do not correspond to quality standards, safety and efficiency.

The Agency can carry out a sample control of each pharmaceutical if deemed necessary for provision of the respective quality, provided that legal persons who have license for production and distribution of pharmaceuticals do not lead one each other into unequal position.

Pharmaceutical market quality control is carried out on the basis of a planned systematic control, which is made of different indicators (pharmaceutical consumption, information about pharmaceuticals received from other agencies, EMEA, FDA; UPSAL, monitoring of side effects of pharmaceuticals and others)

22. For product-categories for which no activities were carried out: what was the reason that no activities were carried out?

Apart from controls described in the responses to follow-up questions to the question no. 21, no other activities were conducted for the rest of product categories due to the following reasons:

- non-existence of specific legislation;
- poorly defined competences of the state administration authorities;
- lack of financial resources for possible inspections.

23. For categories for which activities were carried out: choose randomly some of the products falling under the categories of products under question 21 as examples to provide answers to the following questions:

a) Why did you choose these products?

Examples:

We chose the following products:

1. Child-care toys – due to potential risk to children safety and information on non-safety from other countries.

2. PVC packing - due to possible increase in concentration of phthalates and the information on

potential damage to health from other countries.

Accidents involving the product.

Risk reported by the manufacturer.

Risk reported by conformity assessment (testing, certification) bodies.

Risk reported through an alert network.

Risk reported through a national alert network (e.g. hospital services).

Action by consumer associations or an individual consumer.

Complaint from a competitor.

Information from another country (bilateral contact).

Risk reported by customs.

Special risk covered by a sectoral or seasonal surveillance programme.

b) How was the surveillance organised for these products?

Prior to customs clearance, the listed imported products are controlled in the importer's warehouse by the competent inspection that checks supporting documents and conducts sensor check, including the method of declaration, labeling and packing of products. On the basis of these controls, the inspector conducts a risk assessment and decides to take samples of products and refer them to further safety checks to an authorized laboratory. The completion of the procedure depends on the results of controls. The surveillance over these products is also carried out after their placement on the market (ex officio and at the requests of consumers and other persons).

Timing and frequency of checks (e.g. before placing on the market, during customs clearance, after placing on the market, in use)

Locations where the checks were carried out (e.g. places of design, manufacture, packaging, storage, sale, in use, goods transport vehicles, roadside checks, customs control)

Control procedures (e.g. documentary or in-situ checks, visual checks (marking, etc.), requests for technical documents, sampling, testing in government laboratories, testing in private laboratories)

- Control is carried out according to the following procedures: in-situ checks of documents, visual checks, sampling and testing in authorized laboratories.

Resources used (e.g. administrative and judicial authorities involved, numbers of staff assigned, spending) as follows:

- The following recourses were used during the control: competent inspections, competent judicial authorities, authorized laboratories.

Time elapsing between the first check and final decision:

- The procedure from the first check to final decision, depending on the type of a product and the testing methods, last from 3 to 15 days.

c) Which measures were taken as a result of the checks? (If the measures were temporary, for how long did they apply?)

Examples:

If, during the market surveillance of the imported products, it is established that the products do not conform to prescribed legislation, the import and distribution of the said products are banned and the product is referred back to the distributor or destroyed, depending on the type of the product, importer's requirements and decision of competent inspection authorities.

If market inspectorate finds that the product is not in conformity with prescribed measures it acts as follows:

- Temporarily bans distribution of the product and orders removal of determined irregularities within a specified time period;
- If the irregularities can not be removed, permanently prohibits distribution of the product and orders its destruction;
- and requires the destruction of the product
- Ensures that the competent inspection informs the public on the presence of non-safe products on the market;
- Initiates appropriate procedure before the competent authorities, which, after determining responsibilities, issue punitive measures;

Product deemed compliant.

Party responsible merely required to bring the product into compliance.

Product banned from the market until brought into compliance.

Product withdrawn from the market until brought into compliance.

Product impounded.

Product ordered to be destroyed.

Product recalled.

Information and warning for consumers (how?)

Recall of the product from consumers (how?)

Civil or penal sanctions (to whom?)

24. Have the results of these activities and the experience acquired influenced subsequent market surveillance activities?

Yes, the results of the enforced activities have provided for stronger surveillance of products determined to be in non-conformity with the existing legislation.

25. Who were informed about the activity and/or the outcome – in general or with regard to specific products (e.g. media, other countries, etc.)?

The public is informed in several ways depending on the type of information and target population by placing the information in the media via press releases, alerts, reports and briefings, as well as by putting the information on the web pages.

26. What practical difficulties were encountered in carrying out the activities? C. Non-safety related measures (protection of economic interests of consumers) Legislation

Practical difficulties in performing these activities are a result of the fact that neither the inspection authorities nor testing laboratories have sufficient technical equipment.

C. Non-safety related measures (protection of economic interests of consumers)

Legislation

27. In the framework of your consumer protection policy, indicate whether the following sectors are covered and to what extent they are in line with the relevant EC acquis:

- certain aspects of the sale of consumer goods and associated guarantees (*Directive 1999/44/EC*)

Directive 1999/44/EC concerning certain aspects of the sale of consumer goods and associated guarantees is transposed into the Law on Consumer Protection and Law on Obligations.

The Law on Consumer Protection in Article 2 paragraph 1 item 14 defines the warranty, and in Chapter III – Protection of Economic Interests of Consumers, Articles 19-22 sets forth the obligation of warranty issuers (producers, distributors, and traders), contents of the warranty, fulfilment of obligations deriving from the warranty and the manner of enforcement of the rights deriving from the warranty.

Article 127 item 6 of the Law defines an administrative measure imposed to ban the distribution of the product, which is not accompanied by the warranty certificate, when so required by technical or other regulations and when the warranty certificate does not contain the prescribed data. Furthermore, Article 129 item 10 prescribes a pecuniary fine for the reported cases.

The Law on Obligations, Subtitle 3, Section 2 – III Warranty for the Correct Functioning of the Object Sold, in Articles 509-515 regulates in more details liability of seller and manufacturer, demanding repair or replacement, extending warranty period, contract termination and reduction of prices, expenses and risks and liability of subcontractor and forfeiture of rights.

- unfair terms in consumer contracts (*Directive 93/13/EEC*)

Directive (*Directive 93/13/EEC*) concerning unfair terms in consumer contracts is transposed into the Law on Consumer Protection (Chapter III – Protection of Economic Interests, Articles 63-66). Apart from defining the term unfair provision in consumer contract, these Articles also provide for a list of provisions regarded as particularly unfair, as well as interpretation of blanket contracts (standard form) or provisions, and consequences of unfair provisions in consumer contracts.

- indication of the prices of products offered to consumers (*Directive 98/6/EC*)

Directive on consumer protection in the indication of the prices of products offered to consumers is transposed in the Law on Consumer Protection (Chapter III – Protection of Economic Interests, Article 12 paragraph 1 item 5, Articles 13 and 14; Chapter IV Raising Awareness and Educating Consumers, Articles 68 and 75. In Chapter VII – Supervision, Article 127 paragraph 1 items 4 and 10 prescribes that an administrative measure imposed to ban distribution if the prices are not indicated in a proper manner, and Chapter VIII – Sanctions, Article 129 paragraph 1 items 5 and 6, 21 and 25 prescribes offences in the case the listed provisions are not respected.

- contracts negotiated away from business premises (*Directive 85/577/EEC*)

Directive to protect the consumer in respect of contracts negotiated away from business premises is transposed in the Law on Consumer Protection (Chapter III – Protection of Economic Interests, Article 48-54, which define the term contract concluded out of the trader's business premises, trader's liability towards consumers related to his identification and prior notification. The consumer's right to unilaterally terminate the contract, along with the consequences of unilateral termination of the contract and the scope of application are also laid down in these Articles. Article 129 paragraph 1 item 16 prescribes a pecuniary fine imposed on the trader failing to notify the consumer about the important elements of the contract before concluding the sales contract outside the business premises within the meaning of Article 50. This type of trade is regulated in the Law on Internal Trade.

- distance contracts (*Directive 97/7/EC*)

Directive on the protection of consumers in respect of distance contracts is transposed into the Law on Consumer Protection (Chapter III - Protection of Economic Interests, Articles 37-47, which, besides the definition of the distance contract term, sets forth restrictions on the use of means of distance communication, as well as obligations of the trader towards consumer in respect of prior notification and issuance of a written notice on important elements of the contract, the right of

consumer to unilaterally terminate the contract, the manner of unilateral termination of the contract, the consequences of unilateral termination of the contract, as well as the effects of unilateral termination of the contract on the credit arrangement). In addition, it prescribes the enforcement of the distance contract and its scope of application. Article 129 paragraph 1 items 13, 14 and 15 sets forth a pecuniary fine for the offence of the trader failing to meet the obligations deriving from Articles 38, 39 and 40. This type of trade is also regulated by the Law on Internal Trade.

- distance marketing of consumer financial services (Directive 2002/65/EC amending Directives 90/619/EEC, 97/7/EC and 98/27/EC)

Directive concerning distance marketing of consumer financial services is not transposed into the Law on Consumer Protection, save for partially in the provisions related to consumer credits (Articles 33 – 36), and consumer support in Article 83, which prescribes that the trader providing public and financial services must provide a consumer support for the receipt of complaints and provision of necessary information to the consumers, in the business premises or in other designated place. The trader is obliged to put up, at a visible place in his business premises, the working hours of the consumer support established in agreement with consumer organizations. The consumer support must decide within 15 days after receiving the complaint and notify the consumer thereof in writing. In the complaint resolution procedure, the customer support is obliged to cooperate with consumer organization. Item 9 of the Article 130 stipulates that the trader who fails to provide conditions referred to in Article 83 will be fined.

Distance marketing of consumer financial services within the banking regulation system is not tackled as a separate issue. However, the banking legislation in Montenegro does not recognize instruments of electronic payment as distance marketing instruments, and defines this issue in the Law on Payment Operations in Chapter IV – Electric Payment Instruments, articles 21 to 28. According to provisions of this Law, the issuer of electronic marketing instruments can only be a bank or branch of a foreign bank whose license or approval implies issuance of distance marketing instruments. At the same time, the Law defines in details duties and responsibilities of the issuer of distant marketing instruments, mutual rights and obligations of the issuers of distant marketing instruments and receiver. These provisions created general preconditions and legal grounds concerning consumer protection in respect of use of distant marketing instruments, while further regulations regarding this issue should be encompassed by secondary legislation of the Central Bank.

The Law on Insurance (Official Gazette of the Republic of Montenegro 78/06 and 19-07 does not provide for the rules concerning provision of distance insurance services.

The legislation governing securities of Montenegro does not contain any specific provisions in relation to the conclusion of financial services contracts or provision of financial services concerning distance sale and purchase of securities.

The contract on sale and purchase of securities within the meaning of the initial contract services in accordance with Directive 2002/65/EC of the European Parliament and the Council can be concluded by electronic communication, according to general provisions on conclusion of contracts by electronic communication laid down in the Law on Obligations.

Upon the conclusion of the initial contract (general contract on representation in performing securities operations) individual orders for trade in securities can, according the existing legislation governing performance of securities operations, be issued by means of distance communication.

- Credit agreement for consumers (Directive 2008/48/EEC)

Directive 2008/48/EEC concerning credit agreements for consumers is adopted in 2008, and the Law on Consumer Protection is adopted in 2007, so that Directive concerning consumers credit (87/102/EEC) is partially transposed into provisions on consumer credits in this Law (Chapter III – Protection of Economic Interests, Articles 33 to 36). According to the definition laid down in item 15, Article 2 of the Law on Consumer Protection, creditor means a business organization or another entity that within its activity approves consumer loans. Article 131 prescribes a pecuniary fine will be imposed for the offence on the trader if, prior to conclusion of the credit contact, he fails to deliver to the consumer the notice referred to in paragraph 2 of Article 33, or he advertises the consumer credit in the manner that is contrary to the to requirements laid down in paragraph 4 of

the Article 34, or fails to notify the consumer about the change in annual interest rate or any other cost within the meaning of the Article 35 of the Law.

The analysis of the national legislation in the field of consumer credits with the European legislation, including Directive 2008/48/EEC is conducted, within the EU funded TRIM MNE project, on the initiative of the Ministry of Economy, as the body competent for consumer protection. /See more details on the analysis and harmonization plans in the response to the question no. 28/.

The Law on Obligations, also, contains provisions concerning consumer credits (Articles 1168 to 1171).

Consumer protection in the banking sector is governed by the provisions of the Law on Banks, in particular by a specific chapter of this Law. Namely, Chapter 6, Articles 87 to 91 relate to establishing banks' responsibilities in relation to their clients, including consumer credits. Thus, Article 87 prescribes a general obligation of a bank to inform the client, upon his request, on state of the loan or deposit account and provide him with the access to other information that may be available to the client in accordance with this Law. According to Article 88, a bank is obliged to post on a visible location its general business operating conditions. Furthermore, according to Article 89 of the Law a bank is obliged to calculate and report lending effective interest rate on loans granted and effective deposit rate on deposits taken and inform clients and public on the amount of effective interest rates. With the aim to provide for full implementation of these provisions, the Central Bank rendered Decision on the unique manner of calculating and disclosing the effective interest rate on loans and deposits. At the same time, the client may require additional explanations from the bank referring to the application of requirements of general operations. According to Article 90 of the Law, a bank may not condition its credit granting by the use of its other services or the services of any of the bank related parties, which are not in relation with the main business. Finally, according to the Law a client that deems that the bank does not meet obligations from the signed contract may introduce a complaint to the bank, and the bank is obliged to respond to the complainant not later than 30 days as of the day of introduction of complaint.

The Central Bank controls the enforcement of prescribed legal obligations for client protection through a permanent supervision, and it is authorized to undertake measures against the bank violating provisions of the Law for removal of determined irregularities.

- Misleading and comparative advertising (*Directive 2006/114/EEC*)

Directive concerning misleading and comparative advertising is transposed in the provisions of the Law on Consumer Protection (Articles 84 to 93), which encompass misleading advertising, discriminatory advertising, advertising that propagates violence, concealed advertising, advertising intended to underage persons, comparative advertising, identification of sponsors, special telephone tariff, publishing in professional publications, and recording the data about the advertiser.

In the broadcasting sector (electronic broadcasting) the standards in respect of advertising are regulated with the following legislation: the Media Law (see more in the Appendix 10-52-1), Broadcasting Law (see more in Appendix 10-52-2), Law on Ratification of the European Convention on Cross-Border Television (see more in Appendix 10-52-3), as well as the Rulebook on Advertising and Sponsorship in Electronic Media (see more in Appendix 10-65-1) and Decision on Minimum Programme Standards in Electronic Media (see more in Appendix 10-65-1). /See more on electronic media advertising in the response to the question no. 28/.

This area is also regulated by other sector legislation related to food safety, restriction on use of tobacco products, spirituous beverages and others.

As the line authority for consumer protection, the Ministry of Economy, within the National Programme for Consumer Protection and Action Plan for its implementation, in the amount of resources allocated in the budget for this purpose, sponsored the development of the project "Analysis of the Montenegrin National Legislation with the European in the Area of Advertising". This Analysis was conducted by the NGO Centre for Consumer Protection (CEZAP) and referred to the Ministry, on the basis of which this Ministry along with other line ministries will determine further harmonization of the legislation with Directive concerning misleading and comparative

advertising. Namely, it will be decided whether or not this area will be fully harmonized through amendments to the existing sectoral legislation or adoption of a separate law on advertising.

- unfair commercial practices (*Directive 2005/29/EC*)

Directive concerning unfair commercial practices is transposed into the Law on Consumer Protection (Chapter III – Protection of Economic Interests Article 67), which defines conduct of a trader deemed to be particularly banned, including conduct of a trader deemed to be aggressive and which is also sanctioned in Article 129 of the Law;

- certain aspects of timeshare, long term holiday product, resale and exchange contracts (*Directive 2008/122/EC*)

The Law on Consumer Protection defining time-sharing is adopted in 2007, which means prior to the adoption of Directive *2008/122/EC.* Thus, this Directive (94/47/EC) on the protection of purchasers in respect of certain aspects of contracts relating to the purchase of the right to use immovable properties on a timeshare basis is transposed into this Law (Articles 55-62). The Law defines the definition and the form of the contract, a previous notification that the trader is obliged to deliver to every interested consumer, content of the contract, the right of consumer to unilaterally terminate the contract and the consequences thereof, as well as the effects of unilateral termination of the contract on credit arrangement and ban on advance payment request.

According to Article 129 of the Law, a pecuniary fine is imposed on the trader failing to deliver to the consumer the prescribed notification (the offer) about the requirements for time limited use of immovable property (Article 57 paragraph 1,3, 4 and 5), and also if advertising the right to time limited use of immovables in irregular manner (Article 77, paragraph. During the amendments to the Law, the new Directive (2008/122/EC) will be transposed in the amended Law.

- package travel, package holidays and package tours (*Directive 90/314/EEC*)

Directive concerning package travel, package holidays and package tours is transposed into the Law on obligations and Tourism Law.

The Law on Obligations defines the contract on organizing travels (Articles 953 to 976), the intermediary contract of travel (Articles 977 to 981), and the contract on engaging catering capacities/contract on allotment (Articles 982 to 993).

According to the Tourism Law (Article 6), a tourist package travel (flat rate travel) is a previously confirmed combination of at least two offered individual services that are sold at a total previously set price, and the total service lasts more than twenty four hours or includes at least one overnight stay, i.e. accommodation. Tourist agency – tour operator is a tourist agency that organizes tourist package travels and directly sells it or offers for sale by way of an agent.

The obligations of tourist agencies are determined by this Law (Articles 4 and 12). The activities of organizing tourist trips can be performed by tourist agencies, which apart from the work permit (Article 11 paragraph 3) also have the licence issued by the Ministry of Tourism.

According to the Law, the travel operator is obliged to establish general terms of travel and provide for the travel program in written form, with detailed description of the contents (Article 16).

A tourist agency providing for the services of tourist package travels, excursion programs or transfer of passengers is obliged to use means of transport in which the passengers and baggage are insured, as well as hospitality industry facilities in which the service users are insured (Article 21). Besides the above mentioned, Article 22 of the Law stipulates that a tourist agency – tourist operator is obliged to, for every tourist travel package, provide a guarantee for compensation of travellers (paid travel price, if due to insolvency of the tourist agency, the travel services are cancelled; expenses as a result of insolvency of tourist agency for return of travellers to their place of departure and damages due to failure to fulfil travel program, owing to type, range, quality, and in the method given in the program.

A tourist agency is obliged to provide for a guarantee in the amount of 10 000 Euros, in the form of a cash deposit laid to a separate account of a business bank, or bank certificate, issued by business bank licensed from the Central Bank of Montenegro, payable on the first call and without the right to complaint within the validity period of the length of the license.

A tourist agency – travel operator is obliged to reimburse a traveller within the period stipulated under general conditions for travel, i.e. according to travel program, which cannot last longer than 30 days from the day of a traveller submitting a claim. The tourist agency – travel operator is not liable to the traveller for incurred damages or insurance company if the established error with regard to not fulfilling the contracted services is attributed to the traveller, or if unpredictable and unavoidable omissions are attributed to a third party which has not participated in the realization of contracted services and omissions occur due to a force major.

- injunctions for the protection of consumers' interests (*Directive 2009/22/EC*)

Directive 2009/22/EC is adopted this year and could not have been implemented in the Law on Consumer Protection, which is adopted in 2007. However, Orders concerning consumer protection deriving from Directive 98/27 EC of the European Parliament and the Council of 19 May 1998 on judicial and administrative injunctions are transposed in the Law as follows: judicial injunctions in provisions of Articles 113t o 114, and administrative injunctions in provisions of Articles 81,126 and 127. Alignment with the injunction on consumer protection (Directive 2009/22/EC) will be performed during the amendments to the Law on Consumer Protection.

- principles applicable to the bodies responsible for out-of-court settlement of consumer disputes (*Commission Recommendation 98/257/EC*)

Principles applicable to the bodies responsible for out-of-court settlement of consumer disputes and bodies involved in consensual settlement of consumer disputes are transposed in the Law on Consumer Protection (Chapter V, Articles 97 to 111) and in the Rulebook on Arbitration Committee for settling consumer disputes (Official Gazette of Montenegro 28/08). In addition, the Law on Arbitration regulates in more details the rules of arbitration procedure in civil-legal disputes of legal and natural persons.

- principles for out-of-court bodies involved in the consensual resolution of consumer disputes (*Commission Recommendation 2001/310/EC*)

The response to this question is given in the previous question.

- pre-contractual information to be given to consumers by lenders offering home loans (*Commission Recommendation 2001/193/EC*)

The Central Bank has not adopted specific legislation or secondary legislation for the purpose of regulating consumer protection issues related to home loans. In respect of home loans, the banks are obliged to respect the rules on client protection laid down in the Law on Banks, as well as the rules on calculating and disclosing effective interest rate prescribed by the Decision on the unique manner of calculating and disclosing the effective interest rate for loans and deposits.

28. Please indicate for each of the above listed pieces of legislation the basic features of the respective legislation, including enforcement mechanisms, and plans for reform. For implementing regulations, please specify which regulations have already been adopted and give an indicative timetable for those that still need to be adopted.

A part of the response to this question concerning basic characteristics of the Law on Consumer Protection, Law on General Product Safety and other legislation, including enforcement mechanisms is given in the responses to previous questions.

Reforms in the field of consumer protection or further harmonization of the Law on Consumer Protection is planned to be continued in 2010. This procedure will provide for transposition of the Directive concerning the distance selling of financial services (a part not transposed into other sector legislation) as well as of other consumer directives which are partially transposed or passed after the adoption of the Law on Consumer Protection.

In order to meet the above-mentioned reforms, the Ministry of Economy as the body in charge of consumer protection, during the implementation of certain activities deriving from the National Programme for Consumer Protection and Action Plan for its Implementation, has launched the development of the analysis of the national consumer legislation in relation to the European one, in the field of consumer credits and advertising. Both analyses were submitted to the Ministry, on the

basis of which this Ministry along with other line ministries will determine further harmonization of the legislation with the Directive concerning misleading and comparative advertising. Namely, it will be decided whether or not this area will be fully harmonized through amendments to the existing sectoral legislation or adoption of a separate law on advertising. /See more in the response to the question no. 27, where appropriate/.

The new Directive on package travel, package holidays and package tours (Directive 90/314/EEC) will be fully transposed into the planned amendments to the Law on Tourism, and the new Directive 2008/122/EC (time-sharing) will be fully transposed into the amendments to relevant laws. The characteristics of the legislation governing package travel and time-sharing, as well as the enforcement mechanisms are given in the response the previous question.

Characteristics and enforcement mechanisms of the Broadcasting Law: in accordance with the provision of Article 112 of the Law, any broadcasting of hidden advertising aimed at convincing the audience that a particular advertisement is not actually an advertisement is forbidden. Both the ordering party and the broadcaster bear the responsibility for hidden advertising. Any hidden advertising is assumed to be intentional. The Rulebook on sponsorship and advertising in electronic media, in Article 3, sets forth that advertising and sponsorship in electronic media is based on principles as follows: freedom of expression and sponsorship, truthfulness, fullness and explicitness; recognition of advertiser; prohibition of misuse of trust; prohibition of discrimination; prohibition of morale breach, protection of children's rights and respect for and competition protection. In accordance with the provisions of Articles 5 to 9, an advertisement forbids the use of unspecific and ambiguous expressions and other information that could cause delusion about the identity of the advertiser and features, quality, origin and other data concerning a product or a service. Any advertising and recommending products and services during the programme that is not intended for advertising, as well as all other forms of hidden advertising are prohibited. An advertisement may not misuse trust, relation of dependence and affection, credulity, lack of experience and knowledge, and prejudice of receivers of the advertisement. It is prohibited to reject broadcasting of advertisement if the rejection creates or maintains monopoly or other dominant positions of participants in the market competition, or establishment of unfair competition. In accordance with provisions of Articles 16 to 19, an advertisement may not present any offer as "free of charge" if it implies any consumer expenses. These expenses have to cover all fees, taxes and other obligations for the buyer. An advertising message cannot contain untruthful claims that the product or service has positive or negative influence on protection of health and environment; may not discredit or underestimate a competitor, its product or service; may not present a competitive product or service as a bad copy or reproduction. It is prohibited for an advertising message to broadcast a copy of an advertisement of another advertiser, its activities, products or services, as well as unauthorized use of logo or other feature that belongs to the competitor. Chapters 1.2/ Protection of Children and Minors (Articles 24, 25, 26, 28, 31, 33), 1.3. Medicines and Medical Services (Articles 35 to37) and Alcohol Beverages (Articles 38 – 40), define specifically obligations in respect of certain aspects of advertisement content.

In June 2009, a public discussion has been started on the Draft Law on Electronic Media, which is expected to be adopted by the end of 2009. This Law should provide for the basic legislative framework for harmonization of the national legislation with acquis communautaire, and *inter alia*: Council Recommendation from 1998 on the development of the competitiveness of the European audiovisual and information services industry by promoting national frameworks aimed at achieving a comparable and effective level of protection of minors and human dignity (98/560/EC); Recommendation of the European Parliament and of the Council from 2006 on the protection of minors and human dignity and on the right of reply in relation to the competitiveness of the European audiovisual and on-line information services industry (2006/952/EC); Directive 2005/29/E on unfair economic practice; and Directive 2006/114/EC concerning misleading and comparative advertising in the part related to advertising in electronic media.

The legislation aimed at protecting clients in banking sector that have been adopted until now, and for whose enforcement is competent and authorized the Central Bank of Montenegro are as follows: The Law on Banks (Chapter 6 – Client Protection, Articles 87 to 92), Decision on the unique manner of calculating and disclosing the effective interest rate on loans and deposits and in relation to thereof the Decision on bank ombudsman.

The Chapter of the Law on Banks concerning client protection and its characteristics are described in details in the response to the previous question. Decision on the unique manner of calculating and disclosing the effective interest rate on loans and deposits contains provisions directly related to bank's liability to inform the public and clients when approving credits. The Decision sets forth that the bank is obliged to inform the public and clients of the effective interest rate, that commercial advertisements published in the public media must also contain information on interest rates, and that the bank is obliged to inform client on effective interest rate in writing prior to the conclusion of the credit contract. At the same time, the bank is obliged to make repayment plan with clearly indicated effective interest rate and that one copy must be given to the client. The bank is obliged to introduce into the credit contract a provision indicating clearly that the client is familiar with the terms of repayment of the loan and that he was given a repayment plan.

As an important form of protection of clients' rights in the banking system, the Law on Banks provides grounds for the introduction of the institute of bank ombudsman. Ombudsman is a person not related to the bank and with a significant experience from the area of banking operations; upon the complaint of a client who is not satisfied with an act, action or banking procedure, the ombudsman is obliged to participate in out-of-court settlement of disputes between the bank and client. For this purpose, the Ombudsman considers clients' complaints and proposes to disputing parties settlement or other way of resolving the dispute, gives banks recommendations for improving their relationship with customers, gives advice to clients for further conducts of the dispute and performs other tasks that contribute to achieving the protection of clients' rights of clients. The Decision on Bank Ombudsman defines in more details requirements that the Bank Ombudsman needs to meet, his main working principles, powers and responsibilities, manner of provision of material-technical conditions for work and procedure for protection of clients' rights before the Bank Ombudsman. The Central Bank of Montenegro adopted all the regulations needed for the Ombudsman to start working, and the Parliament has already appointed the Ombudsman.

In terms of further regulatory activities of the Central Bank in the field of drafting and the adoption of regulations concerning protection of clients' rights in the banking system, by the end of 2009, Central Bank planned to render Decision on public disclosure of bank data, in order to further enhance the position of clients, particularly in terms of choosing the best bid, estimates of bank security and other elements that may be of interest for the client.

29. Please indicate whether within the framework of your consumer protection policy there are in place public authorities that are capable of assuming the obligations imposed by Council Regulation 2006/2004 on Consumer Protection Cooperation.

Montenegro has competent public authorities capable of assuming obligations deriving from Regulation 2006/2004 of the Council on Consumer Protection Cooperation, however, these capacities will be enhanced continuously. A part of the response to this question may be found in the responses to the questions concerning capacities and powers of authorities in charge of consumer protection.

30. Specify which authorities are competent for drafting the relevant legislation and how legislation is passed (primarily through parliamentary procedure or ministerial orders or decrees).

Preparation of draft legislation (laws, decrees, rulebooks, orders, decisions, instructions and other secondary legislation) is within the competence of Government, line ministries and other relevant authorities, and the adoption procedure depends on the type of legislation.

Parliament of Montenegro is a legislative branch of the government and it performs its legislative function by adopting the Constitution and laws.

Constitution and laws are adopted following the procedure laid down in the Constitution of Montenegro and the Rules of Procedure of Parliament. These legislations, in relation to the procedure, stipulate that the procedure of adoption of a law is initiated by submission of a proposal for a law. The proposal for adoption of a law (the right to propose legislation) may be initiated by Government and an MP. The right to propose legislation is also vested in 6000 voters, through an

authorized MP. The proposal for a law must be submitted in the form of the law and must be justified; the justification encompasses the following: constitutional grounds, reasons for adoption of the law, compliance with the European legislation and ratified international conventions, definitions of basic legal institutes and assessment of budgetary resources needed to enforce the law. The proposed law is submitted to MPs, competent committees (Committee for Constitutional Affairs and Legislation and the lead committee) and also to Government, in case Government is not a proposer, the law is considered in Parliament in a three-stage procedure known as three readings:

- first reading/consideration of the proposed law at the sitting of competent committees;
- second reading/ general debate of the proposed law at the sitting of Parliament; after the debate, Parliament decides on the proposed law in details, and if it accepts the proposed law in general, Parliament proceeds to third reading;
- third reading/debate in details at the session of Parliament that includes debate on concrete in the proposed law, submitted and disputable amendments and opinions and proposals of committees.

After detailed debate, Parliament votes on amendments rejected by the initiator of the proposal for a law (proposer), and then proceeds to vote on the proposed law in its entirety.

After the proposed law is adopted in its entirety, Parliament adopts the concrete piece of legislation that the Speaker of Parliament, not later than within three days after its adoption, refers the law to the President of Montenegro for promulgation. The President of Montenegro promulgates the law by Decree.

Government adopts decrees, decisions and other acts for enforcement of legislation (Article 100 of the Constitution).

The Law on State Administration prescribes operations of the state administration including normative affairs (Article 111). Ministries adopt rulebooks, orders and instructions for enforcing the laws and other regulations within its competence (Article 38).

Also, competences of line ministries and other authorities enacting secondary legislation for specific areas are laid down in specific laws, such as:

In the area of consumer protection, on the basis of the Law on Consumer Protection, Government adopts appropriate secondary legislation (decrees, national programme) on the basis of the proposal of the Ministry of Economy as the authority in charge of consumer protection, and the Ministry adopts other secondary legislation for the enforcement of the Law on Consumer Protection (rulebooks, decisions, instructions).

The Central Bank of Montenegro, taking into consideration that it is one of relevant institutions, which, within competences laid down by the law also exercises a function aimed at consumer protection (Law on Banks – Chapter 6; Consumer protection, Articles 87 to 92), is empowered to draft and adopt legislation within its competences. In accordance with the Law on Central Bank (Article 11 paragraph 1 item 8), it has powers to draft and participate in drafting laws and other regulations in the sphere of the monetary, foreign exchange and banking system, in accordance with international standards, including establishing reserves for different types of deposits. However, Article 1 paragraph 2 of this Law determines: “The Central Bank is an independent organization of Montenegro and it is solely responsible for monetary policy, establishing and maintaining a sound banking system and efficient payment system in Montenegro”. in the Republic.

At the same time, Article 17 paragraph 1 of the Law on Central Bank, establishes powers of the Council of Central Bank as a managing authority of the Central Bank, and accordingly in item 2) defines that the Council enacts regulations, recommendations and orders issued by the Central Bank. Item 3) of this Article prescribes that Council decisions, having a character of general act, are published in the Official Gazette of Montenegro.

The Central Bank of Montenegro prepares draft laws and participates in drafting thereof and submits them to the Ministry of Finance of the Government of Montenegro, which is empowered and responsible for further procedure related to the enforcement of the laws.

The Council of the Central Bank independently establishes and adopts secondary legislation (decisions concerning regulation of all segments of banking operation).

The Broadcasting Agency Council is competent for drafting secondary legislation (rulebooks, decisions, instructions and others) in the area of broadcasting in relation to the programme and advertising standards for electronic media. The Broadcasting Law sets forth that these acts are to be adopted after public discussion and published in the Official Gazette of Montenegro. Ministry of Culture, Sports and Media is in charge of the Law on Electronic Media.

Consumer protection within the Ministry of Transport, Maritime and Telecommunications is regulated in a way that the Ministry proposes laws and secondary legislation, which are in compliance with international conventions and other regulations with the aim to protect consumers using services in all means of transport.

Likewise, line ministries and other state administration authorities are responsible for preparation of legislation as regards consumer protection in other areas (environmental protection, tourism and others).

Laws, decrees and other legislation, having a character of general act, are published in the Official Gazette of Montenegro.

31. Please indicate additional existing legislation protecting consumers' economic interests (e.g.: rules on sales promotions, rules on advertising, rules on price reductions, general labelling requirements on products

In addition to already mentioned legislation concerning protection of consumers' economic interests, there are also other legislation containing appropriate measures such as follows: the Law on Internal Trade, Law on Food Safety, Law on Tourism, Law on Electronic Communication, Broadcasting Law, Law on Road Transport, Law on Limiting Use of Tobacco Products, Law on Tobacco, Law on Contracts of Carriage by Road, Law on Contracts of Carriage by Rail, Law on Basics of Ownership Relations in Air Transport, Law on Maritime and Inland Navigation and others.

Implementation and enforcement

32. If public authorities exist to protect the economic interests of consumers, please specify the powers at their disposal and give some examples of activities carried out, including the powers and activities in cross border cases.

The Law on Consumer Protection contains provisions concerning protection of economic interests of consumers, which are contained in Chapter III (Articles 12 to 67), while the provisions governing protection of consumers' economic interests in specific areas are also contained in sectoral legislation. Measures ensuring protection of these rights are laid down, both in the above-mentioned laws and in the Law on Inspectorial Supervision (see more in the response to the question no. 3 (b) i (c).

Specific powers vested in competent inspectorates aimed at protecting economic interests of consumers, are laid down in the Law on Consumer Protection (Articles 126 and 127) and specific sectoral legislation, as well as sanctions for persons not abiding by provisions concerning protection of economic interests of consumers. Protection of economic rights of consumers when buying goods and using specific services within competence of Market Inspectorate, is exercised *ex officio* and upon complaints or at the requests of consumers.

Market Inspectorate's procedure upon consumer complaints due to the flawed product/services (Articles 24 to 27, 83 and 126 of the Law on Consumer Protection), as well as on requests for enforcement of consumer rights deriving from the warranty (Articles 12 to 22) is explained in the response to the question no. 20 (a). Several examples of enforced activities are as follows:

Example 1: A seller advertised the sale of products under the advertisement entitled "lowest price" in three daily printed media. In the process of *ex officio* control of other retailers selling the same products, the inspector found that prices of certain items were lower than the prices advertised by the seller using the advertisement. Due to these reasons, the inspector established that the advertisement was of a deceptive character due to which it would probably affect economic conduct of consumers. Therefore, he rendered a decision imposing a ban on further advertising. The seller abided by the inspector's decision.

Example 2: During the control procedure conducted *ex officio*, the inspector found that a seller had put on a visible place of his retail store an advertisement "Total sale" and "Loans without warrantors and going to the bank". When he checked the facility, he established that, by advertising of the total sale in the above-mentioned manner, specific provisions of the Law on Consumer Protection were violated, i.e. in this case, it was a typical example of discounted prices conducted contrary to Article 75 of this Law and not of a total sale. At the same time, the inspector also determined that the advertisement concerning loans was also misleading. Therefore, he rendered a decision to impose ban on further advertising. The seller abided by the inspector's decision.

Example 3: During the control conducted *ex officio*, the inspector found that a seller advertised sale of computers on a retail store by putting inscription "Super Computer". By means of further inspection of the store, he found out that it is about distribution of the same computers as in other retail stores trading in this type of goods, which means that there are no super computers. Therefore, the inspector concluded that it was the type of advertisement, which could deceive consumers with regards to computer specifications, and rendered decision to impose ban on further advertising and required from the seller to remove disputable advertisement from the object. The seller abided by the inspector's decision.

Example 4: Consumer complaint about the electricity bill. During the control, the inspector determined that the prices per items contained in the bill were formed in accordance with the decision, however, the bill did not contain the item code common consumption, although this item was calculated in the total price of the service. Also, the service provider neither appropriately informed consumers on alteration of conditions when calculating the existing compensations and tariffs, nor obtained the opinion of the consumer organization when forming new prices, which is required by the Law on Consumer Protection. The inspector rendered decision on removal of irregularities within the specified time period and submitted a request for instituting misdemeanour procedure.

Example 5: Consumer complaint against the price of the service concerning connection to the water supply network, which was calculated according to a different or even higher tariff just because the consumer did not have residence in that municipality. During the control, the inspector found out that the service provider acted contrary to the following provision of Article 31 of the Law on Consumer Protection: the seller providing for public service through a distribution network is obliged to allow the consumers to connect to the distribution network and use the connection, the network and the services under conditions that were known and agreed in advance, and without discrimination. The inspector rendered decision on removal of irregularities within the specified time period and submitted a request for instituting misdemeanour procedure.

Example 6: Consumer complaint against a seller's refusal to terminate the contract (typical – standard form) based on a postponed instalment payment for the purchase of the product (cleaner), as well as to refund the amount paid in advance. Having checked provisions of the contract, the inspector found out that they were not in accordance with the following provisions of the Law on Consumer Protection:

- Deadline for filing a complaint in case of a flawed product by the contract is not later than three days after taking over the product, which is in contrary to Article 26 of the Law;
- No determined deadline according to which the is obliged to provide to the consumer the maintenance of the product (servicing), which is contrary to Article 21;
- Establishing the right of the to retain the funds paid by the consumer who has given up the conclusion or execution of the contract, where the same right is not established for the

consumer if the seller gives up the conclusion or enforcement of the contract, which is within the meaning of Article 64 paragraph 1 item 4 of the Law deemed to be unfair contract provision.

For these reasons, the inspector rendered decision imposing on the obligation to remove the irregularities, i.e. to harmonize disputable provisions of the contract with the provisions of the law, thus meeting the basic consumer request. The controlled subject abided by imposed measures arising from the inspector's decision.

Example 7: Consumer complaint of the fact that the seller did not fulfil obligations deriving from the warranty, because the purchased product (computer – notebook) was sent several times to the repairer in the authorized service, and the product was not fixed, and the rejects to deliver consumer the new notebook or to refund him paid amount. During the control procedure, the inspector determined that the request of the consumer is grounded and rendered decision ordering the seller to fulfil obligations deriving from the warranty regarding the consumer in the manner prescribed in Articles 21 and 22 of the Law on Consumer Protection, i.e. deliver the consumer the new product or to refund him the paid amount. The seller abided by the inspector's decision and provided the consumer with the new notebook.

Example 8: Consumer complaint of the fact that the seller did not deliver purchased furniture within 30 days as agreed by the contract. During the inspection control, the inspector determined that the did not deliver the purchased product to the consumer within the agreed time period, which is in contrary to Article 17 of the Law on Consumer Protection. For these reasons, the inspector rendered decision to order the trader to send the delivery immediately. The trader abided by the inspector's decision and delivered the furniture to the consumer.

Complaints and appeals concerning tourist services, as well as consumers' words of appraisal, are to be reported to Call Centre Montenegro, via special number 1300, and authorized operator forwards calls to competent inspectorates. Via this Centre, in the period from 1 July to 31 December 2008, there were 1286 calls, out of which 836 complaints, 446 calls asking for different information and 5 calls referred appraisals in work. Complaints of dissatisfied consumers are submitted to Tourist Inspectorate, which immediately acts upon them. Guests dissatisfied by hotel services (accommodation, food and drinks), as well as tourist services, have opportunity to express their dissatisfaction directly in the Book of Complaints, which must be put on a visible place in the facility and sealed and signed by an authorized person in charge of local government. The cover page of the "Book of Complaints" must also be printed out in several other languages besides the Montenegrin language. The response to the submitted complaint is written in the language in which the complaint was written in the Book of Complaints. The provider of the service will promptly respond to the complainant, which means not later than three days from the day when the complaint was written in the Book of Complainants. The copy of the response must also be referred to the Tourist Inspectorate. The provider of the services will be sanctioned in case of violation of due provisions.

In order to protect economic interests of consumers, Tourist Inspectorate cooperates with other inspectorates, as well as with tourist authorities and organizations (Montenegrin Tourism Association, National Tourism Organization, local tourism organizations and others).

Since 90% of tourism turnover, especially during the summer season, is realized from foreign tourists, special attention and efficiency control is aimed to address their complaints and appeals. Cross-border consumer protection cases are resolved by means of: constant telephone communication, written notices, and requests for legal assistance to the competent authorities of countries from the region and beyond. Protection of economic interests of consumers in the area of electronic communications is regulated by the Law on Electronic Communications (Official Gazette of Montenegro 50/08), in Article 114, which defines the procedure in respect of filing complaints and appeals by the user, as follows:

The user of public communications services has the right to file a complaint against the operator on the access and quality of services, as well as on the bill for provided services. The user submits the complaint concerning the access and quality to the operator, immediately after establishing these circumstances, while the complaint against the bill is to be submitted from the eighth day following that of the receipt of the bill in witting. Operator/provider of communications services must

decide within 15 days as of the day of the receipt of complaint and submit the user thereof the appropriate notice in writing.

Until the decision on the complaint is rendered, the user is required to pay undisputed amount of the bill or the amount corresponding to the average amount of bill for the three previous accounting periods. If the operator rejects the complaint or it does not render decision within 15 days from the day following that of the receipt of the complaint, the user has the right to, within 15 days, file a complaint to the Agency, which will days decided on the complaint within 30 days. If the user is dissatisfied with the decision of the Agency upon his complaint, he has the right to lodge an appeal to the Ministry of Transport within 15 days following that of the acceptance of the decision.

Universal postal service as the service of public interest is regulated by the Law on Postal Services (Official Gazette of the Republic of Montenegro 46/05). This service is provided with the Post of Montenegro and the quality of service is defined by Article 56 of the Rulebook on general conditions for provision of postal services (Official Gazette of the Republic of Montenegro). The Post is obliged to ensure the quality of reception and delivery of postal items in accordance with standards laid down in the said Rulebook and Rulebook on the organization of postal network. The Post is also obliged to perform annually measuring of the quality of transfer of postal items, as well as to publish annual data on the quality of transfer of postal items and information on the total number of complaints received and processed through its newspapers and the website.

Consumer protection in the sector of maritime transport is regulated by Articles 463 to 791 of the Law on Maritime and Inland Navigation (Official Gazette of the Federal Republic of Yugoslavia 12/98, 44/99, 74/99 and 73/00). In order to protect consumers (users of services in the maritime transport), the rights arising from the ship building contract, ship exploitation contract, agreement on maritime operations, agreement on naval agency operations and naval insurance contract are protected. Consumer protection in the sector of air transport is regulated by Articles 3 to143 of the Law on Basic Ownership Relations in Air Transport (Official Gazette of the Socialist Republic of Yugoslavia 12/98). The rights arising from the contract of carriage of passengers, contract of freight carriage, contract on medical transportation and provision of services from the air, aircraft lease agreement, air transport insurance agreement and relations arising in the event of damage caused to third parties by the aircraft in flight are protected. This Law is based on the Warsaw Convention from 1292. Having in mind the changes occurred in the commercial aviation in that period of time, Montenegro ratified the Convention for the unification of certain rules for international carriage by air (Montreal Convention, 1999), which also defined the liability of the carrier and other carriage entities to consumers. The Warsaw Convention will cease to be effective following the day of the ratification and entry into force of the Montreal Convention expected by the end of the current year.

In addition, the Law on Air Transport (Official Gazette of Montenegro 66/08), within the activities of the Agency for Civil Aviation laid down in Article 6, paragraph 13 stipulates that the Agency, among other things, is in charge of "resolving issues and complaints, reviewing initiatives and instituting procedures and norms arising from protection of interests and rights of service users", in a way that its services perform supervision and control of passengers concerning the security and level of services provided for in the international standards in the field of civil aviation.

Protection of economic interests of consumers in rail transport is regulated by the Law on Railways (Official Gazette of the Republic of Montenegro 21/04 and Official Gazette of Montenegro 54/09), Law on Safety in Rail Transport (Official Gazette of Montenegro 4/08), the Law on Contracts on Carriage in Rail transport (Official Gazette of the Socialist Republic of Yugoslavia 26/95) and other regulations and general acts deriving from them.

Inspector for Rail Transport, in addition to powers established by the Law on Inspection Control, is required and empowered to review and control: fulfilment of conditions for the carriage of passengers, persons and things in rail transport; carriage of passengers, persons and things in rail transport in the manner and under conditions prescribed by this Law and regulations governing the safety in rail transport; if the established and published timetables in rail transport are properly and regularly implemented; whether a carrier or company organized internal control over the safe development of the rail transport and whether or not the control is carried out regularly and

effectively; as well as if the efficient protection of people, property and environment in the field of rail transport is conducted in the prescribed manner.

In case the prescribed measures are not respected, the user may lodge an appeal to the inspector in charge of rail transport. The appeal against the decision of the inspector may be lodged within eight days following that of the delivery of the decision in writing. A minister or head of administration authorities decides on the appeal.

The Law on Contracts of Carriage by Rail regulates contractual and other obligation relations in the area of carriage of passengers and goods in rail transport. This law defines that "the right holder may exercise the claim deriving from the contract of carriage by submitting the request in writing to the carrier or filing claims to the court if the carrier does not pay for the requested damages within 30 days following that of the submission of the request".

The new Law on Contracts of Carriage by Rail is also planned to be adopted and the Regulation (EC) No 1371/2007 on rail passengers' rights and obligations will be transposed in the new Law. In addition, the Law on Ratification of Protocol of 3 June 1999 for the Modification of the Convention concerning International Carriage by Rail (COTIF) of 9 May 1980 (1999 Protocol) and the Convention concerning International Carriage by Rail (COTIF) of 9 May 1980 in the version of the Protocol of Modifications of 3 June 1999, which contains Uniform Rules concerning the Contract of International Carriage of Passengers by Rail (CIV - Appendix A to the Convention) unique rules for agreement on international railway transport of passengers (CIV-Appendix A of the Convention) and Uniform Rules concerning the Contract of International Carriage of Passengers by Rail (CIM Convention Appendix B) are referred to parliamentary procedure.

Control of the provision of services of carriage by road is carried out by the Inspectorate of Road Transport, pursuant to the Law on Carriage by Road (Official Gazette of the Republic of Montenegro 72/05) and the Law on Inspection Surveillance. In addition to other powers, the Inspectorate has authority to order the removal of deficiencies in relation to: meeting the prescribed conditions for performing public transport of passengers and cargo; transportation for its own needs, bus station requirements, major bus stops and freight stations; proper technical correctness of vehicle control; keeping to the timetable, performing the tasks and operations of professional and driving staff.

In addition, the protection of users of transport services by road, i.e. passengers, is the subject matter of the Law on Contracts in Road Transport, which provides for the liability of the carrier to treat the passenger with respect and dignity and to carriage passenger in accordance with the published timetable, under conditions in terms of comfort and hygiene, which are, depending on the type of transport, vehicle, and the length of the journey, prescribed by general conditions of carriage of passengers. This Law governs contractual and other obligation relations in the area of carriage of passengers by road, in accordance with the recommendations in the European and international practice, i.e. clearly defines rights and obligations of the carrier and the user of the transport services, meaning the passenger. The ticket means the contract between a carrier and passenger, in accordance with Article 10 of the Law, based on which the passenger may demand a series of rights, and the carrier has specific established liabilities in accordance with Article 7 of this Law.

The Law provides for the liability of the carrier for the damage in case of death of, personal injury to or damage to health to, the passenger caused by an accident during the transport and happening while the passenger is in, or entering the vehicle or alighting from the vehicle in the amount of €75000, in accordance to Article 16 paragraph 1 of the Law, when the court is obliged to, unless having reached consent arrangement, determine the amount of the damage in each case separately.

The passenger is entitled to compensation for the damage in case of delays or interruption of the journey, by fault of the carrier in the amount of three-fold to six-fold price of the ticket, in accordance to paragraph 2 of this Law.

The Law provides for the liability of the carrier for damage resulting from the total or partial loss of, or damage to, registered luggage between the time of taking over by the carrier and the time of

delivery, as follows for the hand-luggage up to the amount of 300 000 EUR per passenger, while the liability for the luggage stored in the bus trunk amounts up to 150 000 EUR per item of luggage or per passenger up to 600 000 EUR in case there are more luggage items lost or damaged, Article 26 of the Law.

The Law on Contracts by Road defines the rules in respect of exercising claims in all prescribed cases when the passenger is dissatisfied with the transport service, or the sender of the freight is not satisfied with the freight carriage service. The passenger or the sender of the freight may exercise claim arising from the contract of carriage by submitting a request to the carrier in writing or filing a claim before the court in case the carrier does not pay the compensation for the damage within 30 days following that of the submission of the request, in accordance to Article 94 paragraph 1 of the Law.

In the field of broadcasting, Article 26 of the Decision on the minimum programme standards in electronic media (Appendix 10-65-2) stipulates that commercial broadcasters, within their organization of affairs, in accordance with the Media Law, must have an authorized officer for the archiving of broadcast program content and an authorized officer for handling appeals and complaints. Commercial broadcasters are obliged to provide for the procedure for handling appeals and complaints to broadcast programming content. When a legal or natural person present a reasonable claim that the published program content damages his reputation or is false, the electronic media is obliged to submit to the injured party a written explanation of an apology. In case of each appeal and complaint procedure, the electronic media is obliged to inform the complainant or appellant that the complaint or appeal may be referred to the Broadcasting Agency. If no agreement is reached between a submitter of complaint or appeal and electronic media, the electronic media is obliged to refer recordings and other documents to the Broadcasting Agency. When considering appeals and complaints, Broadcasting Agency Council will particularly take into account the sensitivities of the problems of expressing views and ideas in the electronic media, especially when it comes to violence, sexual orientation, etc.., acknowledging, to the extent possible, the differences in tastes and opinions resulting from multi-layeredness of the entire audience.

The example of the conducted activities is as follows:

Example 1: Broadcasting Agency of Montenegro, based on the findings of the Sector for Monitoring, stated that almost all the TV stations (including the public service of the TV Montenegro) broadcast special shows during which the viewers may send SMS (text) messages, while on certain TV stations it is possible to send SMS during the larger part of the programme. The Agency accepted such practice with understanding, taking into consideration the financial position of TV stations and the fact that SMS messages represent a source of income for them. However, the Agency, at some point, noticed an increase in the number of SMS messages of the content which is against the provisions of the Media Law and Decision on minimum programme standards, and as such, absolutely unacceptable to be broadcasted publicly. It was evident that all the TV stations do not use the possibility of control and selection of received messages, and in that way they avoid their obligation to edit programmes they broadcast and thus have to assume the responsibility for the consent thereof. For that reason, the Agency warned all the electronic media that it is unacceptable to keep on with such practice and sent them a request to immediately ensure that the content of broadcasted SMS messages is in accordance with positive legislation. In addition, broadcasters are also warned that otherwise the Agency would proceed with proper sanctions from its competences against broadcasters whom decide to broadcast prohibited contents both in this and other segments of their programme.

Example 2: After a viewer lodges an appeal that a certain broadcaster violates rules on the manner of marking prices of telephone calls for take part in the programme, the Broadcasting Agency warned a specific broadcaster and referred to the need to remove detected irregularities. All mentioned measures had positive effects and led to giving up the practice endangering the interests of viewers.

A bank ombudsman will be in charge of protection of economic interests of consumers in the area of banking services, who has been appointed by the Parliament. / See more on ombudsman competences in the response to the question 28/.

33. Please provide details on enforcement of legislation in the area of financial services, in particular on consumer credit.

Obligations of banks arising from provisions of the Bank Law concerning client protection are controlled by the Central Bank through a continuous supervision of banks. Control of respect for provisions concerning client protection is reflected in the control of obligations to inform clients, publish general operating conditions, calculate and disclose effective interest rates, possible conditioning of clients and bank's procedure upon client complaint. When acting against legislation, the Central Bank is, in accordance with the Bank Law, empowered to undertake measures against such a bank, which range form issuance of a warning in writing, conclusion of agreement with the bank aimed at removal of established irregularities to issuance of a written order to the bank to remove established irregularities. Failure to comply with orders imposed by its decision, the Central Bank has the right to introduce a temporary bank management or to revoke license.

II. Public Health

A. Horizontal aspects

34. Document COM(2007) 630 final, and the second programme of Community action in the field of health 2008-2013 (Decision No 1350/2007/EC) sets out the health strategy of the European Community. Does your country have a health strategy set out in a legal document? What are the main priorities? Are activities being implemented in these areas? If so, give a brief description.

In 2003, the Government of Montenegro adopted the Strategy for Health Care Development in Montenegro, which sets out basic guidelines for the health system reform. The new health policy is aligned with the health policies of developed countries that Montenegro strives to join, and it is in line with the aspirations for democratic development of the society and prosperity of all citizens of Montenegro.

Health policy has been changed in terms of placing an accent on health rather than focusing on disease.

The implementation of the policy is contingent on the reorganization of health services, adequate planning and education, development of research and science in health care, study of health determinants and influence on risk factors, improvement of measures for promotion of health and prevention of disease, preventing and counteracting health conditions, higher quality treatment and rehabilitation.

Adoption of healthy life styles is a prerequisite for the prevention of health risks and improvement in the quality of life by way of ensuring proper diet, improvement in living and working conditions, as well as improvement to traffic safety and reduction of the risks from injuries.

Common factors of risk from certain diseases also include the health risks relating to environmental determinants, which comprise regular water supply, waste disposal, microbiological and chemical pollution, genetically modified food, air pollution, noise and other determinants.

General Objectives of Health Policy

The bases of the Strategy for Health Care Development aim at improvement and preservation of health of population, vulnerable groups in particular. Health policy of the Republic of Montenegro until 2020 sets out general objectives of health policy:

Extending Life Expectancy

Preventing premature death and thus increasing life expectancy is the primary objective of health policy and the basic task of the health care system, which is achieved through measures for prevention of disease and treatment of the ill. The Strategy for healthy life style comprises the prevention of respective health risks that have an important influence on extending life expectancy. This pertains to the measures for preventive health care for motherhood, pregnant women and children, with a view to ensuring a healthy start in life, undisturbed growth and development, as well as optimum physical and psychological maturation of the young and their becoming capable of controling their own health, preservation of functional abilities of the elderly persons aged 65 years and above, with less frequent health disorders and with an appropriately active role in the community they live in.

Improving the Quality of Life in Relation to Health

Health problems affect the quality of life of citizens and reduce their working and functional abilities. Health problems also affect the functioning of a family, community and the society as a whole. Improvement in the quality of life and prevention of a decrease in the quality of life due to health problems is the second primary objective of health policy.

Decreasing Health Inequities

Inequities in the state of health and in the access to the health care system among socioeconomic classes of a society exist in all societies. The objective of health policy is to influence these differences not to become more profound, but decrease through targeted and active measures for reallocation of health assets and resources in favour of vulnerable groups of the society.

Insurance from Financial Risk

Health problems may cause considerable negative financial consequences for citizens and their families. Medical science and the expenditure for treatment and prevention concurrently grow faster than the economic basis of the society. It is, therefore, necessary to introduce adequate forms of health financing that will provide for an access to the health care required and distribute the financial risk, so that the citizens should not be exposed to considerable financial strain in the event of a disease.

Objectives of the Reform

The health reform comprises far-reaching changes in the systems of health and health insurance in Montenegro. The primary objective of the reform is to bring the health system to a state of optimum functionality in order to achieve, within the resources available, the maximum positive effect on the state of health of the population of Montenegro.

Operational targets of the Montenegro health system reform include:

- Development of health policy that should make citizens aware of health consequences of their own decisions and of their responsibility for health,
- Improvement to health care in the most acceptable and equality-based manner,
- Development of health system in line with the EU health development trends,
- Increase in the efficiency of the health system through rational and available resources,
- Improvement in the quality of services,
- Employment of modern health technologies,
- Financial stability of the system.

Health mainstreaming

In the strategy of the WHO Regional Office for Europe, »Health for All in the 21 Century», nearly all of 21 regional targets are directly or indirectly related to public health, while in the EU programme (2003-2008), integrated health strategies hold a special place through the following fundamental objectives:

- Improvement in information and knowledge related to public health,
- Strengthening the capacity of public services and health system for swift response to health threats, and
- Promotion of health and prevention of disease through actions aiming at health determinants, across all policies and social activities.

Taking into account the aforesaid documents and the new public health approach, strategic lines of development arise from multisectoral and participatory strategies for creation of sustainable health of the population of Montenegro in the twenty-first century. Such strategies accept public health as a science and art of preventing disease, extending life expectancy and enhancing mental and physical health through organized efforts of the community. Public health strategies also constitute support for pursuit of social interests through providing conditions in which people may be healthy. For the implementation of such strategies, the efforts put into the prevention of disease and promotion of health must be based on scientific and technological knowledge, while public health activities should reflect the values of a community and build upon the consensus in the community.

„New Public Health“

Public health comprises the programmes and activities oriented towards the community level, whether they contribute to all (e.g. clean air and water), or contribute to those individuals who are not currently under protection (different screening programmes, guidance centres for sexually transmitted diseases, guidance centres for nutrition, and the like). Concurrently, the responsibility for the implementation of public health activities pertains to the Government, at all levels of administration. The modern concept of public health, the new public health, implies such strategies, through efforts on mobilizing thousands of communities, their public health developers and political leaders, around health promotion projects.

Significant support along those lines is provided by the national Public Health Institute that enhances and encourages ongoing education in public health, provides technical consults to the Ministry of Health and performs priority research on public health in Montenegro. Promotion of health represents one of the leading directions in the strategic plan of the Public Health Institute of Montenegro.

Health Promotion Activities

Every year, the Ministry of Health and the Health Insurance Fund pass a Decision based on which the Public Health Institute develops the Plan and Programme of Health Care for the Population of Montenegro, whereby the priorities and areas of public health are set out.

The aforesaid measures imply health promotion activities with a view to extending life expectancy and improving the quality of life.

In terms of primary prevention, these are the measures and procedures to decrease the exposure of an individual and the community to preventable risk factors, including the application of measures for the elimination of the risks. In addition, measures of secondary prevention are specified, which includes early diagnostics, treatment for disease in early stages, prevention of further progress of disease and onset of complications, onset of disability and premature death.

Priority objective of health promotion is to increase the level of health and it pertains to the overall population of Montenegro and to distinct vulnerable groups. Basic measures for the promotion of health in Montenegro relate to the activities of providing information to and education for population on the importance of healthy life styles. The Public Health Institute has developed health promotion programmes that will be implemented through guidance centres in all primary health centres (i.e. at the primary health care level) in Montenegro. These programmes aiming at the increase in the quantum of health, especially relating to the sensitive groups of population, have been adopted by the Ministry of Health and funded by the Health Insurance Fund, while chosen doctors have started to implement the programmes at guidance centres.

Promotion of health, as well as the practical implementation of the new public health concept, is a process of rendering individuals and communities capable of increasing control over the health determinants and thus improve their health. Health promotion activities strengthen physical and emotional well-being and extend life expectancy and quality, acknowledging the fact that many diseases are not associated with unknown factors, but with personal life styles that may be modified. It is believed that modifications to life styles (such as unhealthy eating habits, physical inactivity, sexual intercourse without protection, failure to use prenatal protection, failure to use safety belt while driving, use of tobacco, alcohol and drugs) may reduce all causes of acute inability by a third, all causes of chronic inability by two thirds and all premature deaths by nearly a half.

Surveillance and Preparedness Activities

Statutory Regulations

Surveillance and inspection in the health care system are set out in the Law on Health Care (the Official Gazette of the Republic of Montenegro 39/2004) in terms of providing heath care to the population in accordance with the principles of good medical practice, monitoring the state of health of the population and undertaking appropriate measures in cases of disorders in the state of health of wider population, especially in the events of extreme weather conditions and other disasters when emergency actions are included, disorder in the epidemiological situation in the

country or in a part of the country, compliance with the prescribed rules of conduct within health institutions, as well as duties in the area of sanitary inspection and other responsibilities of the Ministry of Health.

The Law on Protection of Population from Communicable Diseases, promulgated by the Government of Montenegro in 2005, sets out communicable diseases that threaten the health of the population of Montenegro, infections that arise as a consequence of performing medical practice, determines measures for the prevention and combat against the diseases and clearly defines the manner of the implementation of the measures, the entities responsible for the implementation, the manner of providing resources for the implementation, conducting surveillance over the enforcement of this Law.

By way of setting out communicable diseases in the aforesaid manner, as well as by defining general and special measures, and methods for the implementation of the measures, legal conditions of consequence for governing the system of protection, preservation and improvement of health of the population of Montenegro, are provided. The Law is in line with the EU regulations, primarily with the Directive 2119/98 EC of the European Parliament and of the Council and with the decisions arising from the regulations subsequently promulgated in this area.

The Law specifies the scope of the rights and responsibilities of all participants in the procedures for exercising the right to the protection from communicable diseases, as well as the competence of the state administration authority the scope of work of which includes the control of the application of the proposed law. The list of communicable diseases established by this law was compiled based on the recommendations of the World Health Organization, Commission of the European Union, as well as on the current epidemiological situation and analysis of the quality of surveillance over particular communicable diseases registered on the territory of Montenegro, based on the cases reported so far.

Monitoring the state of health and planning measures for improvement and preservation of health of the population fall within the competence of the Public Health Institute. The Public Health Institite is a highly specialized health institution at the tertiary level of health care, the activity of which is oriented towards the preservation and improvement of health of all citizens.

Epidemiological surveillance and control of communicable diseases are conducted through the following measures and activities:

- Immunoprophylaxis and chemoprophylaxis,
- Medical examinations of certain categories of population with provision of guidance,
- Health surveillance and quarantine,
- Laboratory testing for detection of agents of communicable diseases and agents of epidemics of communicable diseases,
- Early detection and reporting of communicable diseases,
- Transport, isolation and treatment of the ill with communicable diseases,
- Epidemiological examination,
- Health education for the ill, members of their families and other persons at risk from falling ill with communicable diseases,
- Disinfection and disinfestation upon epidemiological indications.

Epidemiological surveillance is organized through a network of sanitary/epidemiological services in primary health centres and at the Public Health Institute. Doctors who diagnose the communicable diseases that must be reported are obliged to complete an appropriate form and report such diseases, and deliver the form to the locally competent epidemiological service and to the Public Health Institute.

In accordance with the Law on the Protection of Population from Communicable Diseases (the Official Gazette of the Republic of Montenegro 32, 2005) and the Rulebook on Reporting Communicable Diseases and Hospital Infections (the Official Gazette of the Republic of

Montenegro 45, 2007), the diseases that must be reported in Montenegro are those listed within the answer to the question 50a.

Innovation in Health/Health Technology

It is known that the growth of health expenditure depends to a great extent on the innovations relating to new medical technology. According to some assessments, the »new technology« increases the expenditure in public health systems of developed countries per approx. 2% every year. Employment of new medical technology exists in Montenegro, especially if taking into account the isolation that lasted for several decades and the need for an update in modern technological and scientific achievements in medicine and health. Under the given circumstances in Montenegro, it is not possible to recognize the impact yet, but from the viewpoint of the state of affairs, it may be concluded that the impact will be more discernible in the following period. Introduction and consequences of the introduction of new medical technology will be increasingly more reflected in the health care system, especially in an increase in the quality of services, but also in expenditure.

Due to the significance that new medical technology has within the framework of the overall health care development, evaluation of consequences of new technology, by the method of analysis and results based on scientific evidence (»evidence based medicine«), and the benefits and cost-effectiveness of using the technology, will be introduced. This approach is widely taken in highly developed countries, and therefore the introduction of the approach is even more significant in the countries with low gross domestic product and scarce capacity for financing the health protection of population.

With a view to the implementation of new medical technology, it has been envisages that the Ministry of Health should:

- Develop proposals for and supplements to the standardization of equipment per level of health care activity and specialty,
- Develop proposals for the standardization of preoperative, operative and other procedures in hospitals, as well as recommendations for common efficient and successful pharmacotherapy in health institutions,
- Monitor the development of new technology in medicine and health, experiences relating to costs and benefits of the introduction of a technology to the improvement in health and monitor the evidence on the justifiability of the employment of the technology in practice,
- Evaluate the proposals of health institutions for the procurement of new equipment and introduction of new treatment methods and medical devices in practice, based on the evidence of the benefits and cost-effectiveness arising therefrom. The integral part of an analysis shall be the evidence on: epidemiological requirements; the number of patients to use the new equipment; the number of examinations; benefits of and possibilities for the use of new equipment instead of the equipment or curative method currently used; capacity of human resources to use the new equipment; method of payment for services, etc.

The Ministry of Health of Montenegro has established the Agency for Drugs and Medical Devices that conducts the registration of drugs and issues licences for placement of the drugs in circulation, and performs other duties set out in the Law on Drugs and Law on Medical Devices that governs this area.

In respect of the drug cost management, the Ministry of Health, in conjunction with the Health Insurance Fund and respective Chambers of Medicine and Pharmacy, passes the decisions on:

- The control of the prices of drugs, which is based on comparative prices of the same drugs in the countries with approximately equal generated gross domestic product per capita,
- The introduction of reference pricing for drugs, as a model and a method for setting the prices of the medicines included in the Positive List and funded by the Republic Health Insurance Fund, based on the Financial Plan,

- The development of clinical guidelines in pharmacotherapy for respective diseases and conditions; separate working groups for respective specialties will propose specific solutions as to the most successful and most rational use of drugs in health institutions and as to prescription drugs.

The Ministry of Health is considering the possibility for establishing regional centres for diagnostics (X-ray and laboratory), which, based on modern information/communication solutions and technologies, may reduce the costs of the procurement and maintenance of equipment, overcome the problem of the lack of medical staff in certain parts of Montenegro and, most importantly, increase the quality of diagnostics in the whole territory of Montenegro.

Along those lines, consideration is given to the implementation of a project relating to teleradiology, where all images produced by diagnostic devices (X rays, mammograms, CTs, MRIs, angiograms, ultrasound images) would be transmitted to one central point, since Montenegro has a good communications infrastructure and most of the medical equipment is fully digital. The final solution to this issue will be provided in the revised Master Plan for Health Care System Development, the revision of which is in progress.

Gender Dimension

Gender equality implies equal participation of women and men in all areas of public and private sectors, equal position and equal opportunities to exercise all rights and liberties and to use personal skills and competences for the development of the society, as well to equally benefit from the results of labour.

Pursuant to the Constitution of Montenegro, the Law on Health Care and Health Care Development Policy of Montenegro, women and men have an entirely equal access to the services in the area of health care. Furthermore, the health care system reform provided for women to have two chosen doctors (one to be in charge of the protection of health in general, and the other – a gynaecologist, to be in charge of the protection of reproductive health). All health care services provided to women during pregnancy, child birth and puerperium are free, even the services not associated with pregnancy, if a woman is in that condition.

All citizens of Montenegro have entirely equal rights to health care.

Health policy of Montenegro recognized promotion, improvement and protection of women's health as significant objectives. Through its policy (making laws and secondary legislation, initiating, defining and implementing strategies, planning and programming activities), the Ministry of Health displayed clear commitment to the harmonization of health policy objectives of Montenegro with the Millennium Development Goals, particularly in respect of vulnerable groups of population. Daily medical practice and positive legal solutions in this area indicate progress in the health protection of women.

Over the last years, there has been an indicated need for health policy to draw attention to and reflect the position of women from the viewpoint of their health protection, in terms of associating the health problems of women with their family relationships, social status and working/economic activity. Thus, health policy would have an opportunity to take a more realistic and real-life approach in establishing and reaching its goals.

The area of women's health protection constitutes a part of a wider context of general protection of human rights and it is brought into focus through: the promotion of health of the female part of the population, preventive protection of women's health, family planning and birth control in terms of high and low birth rates, control of pregnancy, childbirth and motherhood, sexual activity and the risk of communicable diseases, the change of life and problems of women's health in old age. With reference to the aforesaid, the basis for the protection of health is the prevention of the onset of disease.

Women have absolute rights to all types of health care.

The health care system in Montenegro is devised in such a manner that all women have absolute rights to all types of health care at all levels. This includes the health care at the primary level, where care is provided by the chosen gynaecologist and where every woman has an option to choose her own doctor. Then, the system comprises the services provided at secondary and

tertiary levels, i.e. hospital health care services. There are separate wards in hospitals for women's protection (obstetrics ward and ward for the treatment of reproductive system diseases, respectively). In addition, there is a developed home care service in Montenegro, which provides an appropriate range of services to women in relation to pregnancy, childbirth and reproductive health, and conducts home visits to the newborn, pursuant to the Law on Health Care.

The country exerts influence on diet through health education processes, while the assistance to mothers who are not able to provide for adequate nutrition during pregnancy and breastfeeding, is rendered through social protection processes.

Basic indicators of women's health are presented in the answer to question 36.

Rights to Prenatal Care

All women in Montenegro enjoy the right to prenatal care provided by their respective chosen doctors at the primary healthcare level, or provided in general hospitals or the Clinical Centre, according to indications. All health care services in that period are entirely free.

General fertility rate represents a ratio between the total number of the liveborn and women child-bearing population (15 to 49 years of age) within a year, and it amounted to 49.6 in 2007. With reference to the total number of women population, the share of women child-bearing population is 25.28% of the total population of Montenegro.

Contraception

In respect of the provision of services relating to contraception, a need is not fulfilled only if not expressed through a request for fulfilment, in case of the contraception methods that women are entitled to free of charge. All known methods of contraception are available to women in Montenegro, but some of them are funded from own resources, at reasonable prices.

According to the only available information (the UNICEF data from 2001), 52.7% women in Montenegro used contraception, while the research conducted by the Ministry of Health in 2005 indicated that:

- 13.9% used condom,
- 8.2% used the coil (intra-uterine device),
- 4.7% used the pill,
- 6.6 % used some other contraceptive,
- 20.5 % used other contraceptive methods.
- Remaining respondents would not answer the question.

Abortion is one of the most unacceptable and expensive methods of contraception, i.e. family planning. Montenegro passed the Law on Conditions and Procedure for Termination of Pregnancy, which admits abortion under specific conditions.

Legal provisions (Law on Conditions and Procedure for Termination of Pregnancy, the Republic of Montenegro 53/09 dated 07/08/2009) regulate the cases when consent from a third person is required for termination of pregnancy and provide for the obligation of keeping professional secret, ensuring the protection and dignity of a pregnant woman, as well as the right of a pregnant woman to be informed of possible adverse effects on health that may arise as a consequence of termination of pregnancy, and also of the medical methods and devices used during the intervention. Furthermore, conditions under which a termination of pregnancy may be conducted, which is 10 weeks from conception, are also set out, as well the exception to these conditions. In addition, the procedure for termination of pregnancy is set out in detail and it has been specified that an individual doctor approves a termination of pregnancy within 10 weeks of the conception, First-Instance Medical Commission in the period between 10 and 20 weeks of the conception, and the Ethical Committee between 20 and 32 weeks of the conception; the manner of formation and composition of bodies authorized to make decisions on termination of pregnancy are also prescribed. The above mentioned provisions govern the manner of submitting a request, time frames for the submission, the right of a pregnant woman to complain, the right of a pregnant woman and her spouse or partner, parent, adoptive parent, guardian or representative of

guardianship authority, to attend the sessions of the First-Instance or the Second-Instance Commission, i.e. the Ethical Committee, at which the decision on approving the termination of pregnancy is reached.

With a view to the protection of reproductive health, a termination of pregnancy may be conducted only in secondary and tertiary level institutions.

Prenatal tests are available and conducted in accordance with the recommendations arising from medical doctrine. Use of early genetic tests (until the tenth week of pregnancy) for gender identification is prohibited by the Law. There is not any information on the incidence of miscarriages following prenatal testing, or the reasons for the miscarriages.

Health Literacy Programmes

Over the last years, Montenegro has accepted the modern concept of health promotion that reflects the desire for the improvement in the health of population. The primary health care system reform provided for the implementation of programmes for promotion of health and prevention of disease directly at the first level of health care for all citizens of Montenegro in a uniform manner. In this case, the principle of availability, accessibility and equality has been honoured. Health promotion aims at the overall population, but also refers to the environment that has an unquestionable impact on health.

Action measures in terms of promotion and prevention refer, primarily, to health determinants and the most significant of those measures include: provision of full and timely information, reaching the adequate quantum of knowledge, modifications to the behaviour with a view to accepting healthy life styles such as non-smoking, appropriate diet, physical activity, non-consumption of alcohol and all other psychoactive substances, as well as a non-risky sexual behaviour. In this campaign, promotion of health should be accepted as a process that enables people to improve their health and become capable of taking responsibility for their own health.

Multisectoral and Partnership Approach to Preservation and Improvement of Health of Population

In Montenegro, for the purpose of health education, it is provided that the information and the quantum of knowledge relating to the significance of healthy life style and reduction to the risk of the onset of a disease are increased through the activity of guidance centres at the primary health care level. Stemming from the fact that health care is only one of health determinants which, per se, cannot be solely accountable for the health of the population, a wide range of strategies and other documents have been developed in Montenegro, which provide for multisectoral and partnership approach to preservation and improvement of health of population. Such strategies include the Strategy for Mental Health (that comprises the segment of social protection, the segment of education and other segments), Strategy for Reproductive Health (that also comprises the aforesaid segments), Strategy for the Control of Smoking (that comprises the segment of economic development, the segment of education, the segment of integrations, etc.), Strategy for Prevention and Control of Chronic Non-Communicable Diseases, Strategy for Safe Blood, Strategy for Food Safety, National Strategic Response to Drugs, National Strategy for HIV/AIDS, etc.

The basic approach in respect of the promotion of health and prevention of disease gives priority to integrated programmes that address the improvement of health concurrently with a reduction to the extent of respective risk factors, and therefore the action based on the approach aims at the prevention of several diseases, or groups of diseases.

Consultation Mechanisms

Ministry of Health formed working groups for respective areas of public health, which consist of, apart from the representatives of the Ministry, the representatives of other ministries and Government institutions, business organizations, as well as the representatives of the non-government sector and non-government organizations that are engaged in the activities relating to a specific area of public health. Working groups and committees of the Ministry of Health define strategic documents and monitor the implementation of the documents through programmes and action plans.

Each working group is chaired by the coordinator of the working group, and in most cases, coordinators are the focal points appointed for cooperation with the World Health Organization and other international organizations, who are experts in given fields.

The public is also included in the process of passing legal and strategic documents through public debates organized during the development of each of these documents. The programme of a public debate is announced in the media and this mechanism provides for the wider public to become informed and involved in the process of passing documents.

35. Health status analysis and reporting (to support national health policy cycles, as public health problems and their determinants –in different population groups) are important for policy makers.

For the purposes of planning and organizing the health care system in Montenegro, the following activities are carried out:

- Every year, appropriate statistical processing of data on morbidity and mortality of the population of Montenegro is conducted, which is presented in statistical yearbooks published at one year intervals. The last published Statistical Yearbook on the Health of Population and Health Care in Montenegro refers to the data from 2007 (the data included in the statistical yearbook is available in Montenegrin/English on the web site of the Public Health Institute – Podgorica: www.ijzcg.me).
- Every year, the Public Health Institute publishes the annual Report on the Trend of Acute Communicable Diseases in Montenegro. The last published report is for 2008.
- Every year, the Public Health Institute publishes the annual Report on Immunization Conducted in Montenegro. The last published report is for 2008.
- Every year, the Public Health Institute publishes the annual Report on the Hygiene and Safety of Food and Objects of Common Use. The last published report is for 2008.
- Every year, the Public Health Institute publishes the annual Report on Hygiene and Safety of Drinking Water in Montenegro. The last published report is for 2008.
- In addition to the above listed regular annual reports, there are specific surveys occasionally conducted and published in the form of appropriate reports:
- In 2008, National Health Survey for the population of Montenegro was conducted (the report is available in English in the electronic form). The Strategy for Prevention and Control of Chronic Non-Communicable Diseases adopted by the Government of Montenegro provides for such surveys to be conducted at five year intervals;
- In cooperation with UNICEF, surveys on multiple indicators for the status of women and children (Multiple Indicator Cluster Survey, MICS), developed in response to the World Summit for Children, are conducted every five years. Until now, three surveys have been conducted, for which there are reports MICS1, MICS2 and MICS3. The first two reports refer to SR Yugoslavia, while the third report for 2007 refers to Montenegro only. The reports are available in hard copy (MICS1 and MICS3 in English, and MICS2 in Montenegrin);
- In cooperation with UNICEF, a survey within the programme of „Sustainable Elimination of Disorders Caused by Insufficient Intake of Iodine in Montenegro" was conducted in 2007. The report was printed in Montenegrin.
- In cooperation with ESPAD and CAN, a survey on the use of tobacco, alcohol and drugs among school children was conducted in accordance with ESPAD's methodology in 2008. The report is available in printed form in Montenegrin.
- Until now, three surveys on the consumption of tobacco among the young have been conducted in Montenegro (2003, 2004 and 2008). One of the reports is available in English: Center for Disease Control and Prevention, Global Youth Tobacco Survey. [displayed 20 November 2006].Available at: http://www.cdc.gov./tobacco/global/GYTSintro-htm.

- For the purpose of better understanding of the behaviour of the population groups at a higher risk of sexually transmitted diseases, including HIV infection, with the support of the Global Fund and the UNDP office in Podgorica, in 2007 and 2008, appropriate surveys were conducted on the risky behaviour associated with the HIV infection in the population of:

1. The young between the ages of 18 and 24,
2. Sex workers between the ages of 18 and 59, and
3. Intravenous drug users between the ages of 18 and 59.

The reports on the surveys conducted are available in printed form both in Montenegrin and English.

36. Please provide information on the health status of the population in your country. This should include gender specific and combined information on key health indicators such as infant mortality and life expectancy; patterns of mortality and morbidity; situation with regard to communicable and sexually transmitted diseases, healthy life years. To this end, please see DG Health and Consumers website on European Community Health Indicators (ECHI) and consider as an example to follow this first set of key health indicators. (http://ec.europa.eu/health/ph_information /dissemination/echi/echi_en.htm). With reference to descriptive data, please specify also:

Health Status

Vital Indicators

The health status of the population, its structure and demographic trends such as natality, mortality, population growth and migration trends, represent general indicators for vitality and the potential for economic and social growth and development of a society. At the same time, these indicators reflect and measure the health care practice and organization in whole, and reflect and determine the overall relations in a wider socio-economic community within the context of the human resources available in the country.

The data on the natural movement of the population of Montenegro in 1991 and 2007 indicates that the aforesaid period is featured by the tendencies for aging of population, decrease in the birth rate, fertility rate and natural growth.

Basic vital indicators for the population of Montenegro in 1991 and 2007

Indicator	1991		2007	
	Number	Rate/1000	Number	Rate/1000
Liveborn	9 606	16.50	7 834	12.46
Total Mortality	3 970	6.80	5 979	9.51
Infant mortality	107	11.14	58	7.40
Population Growth	5 636	9.70	1 855	2.95
Vital Index	9 606/3 970	2.42	7 834/5 979	1.31

Source: MONSTAT

In contrast to the last decade, when a significant tendency for a decrease in the birth rate was perceived, the period 2004-2007 is featured by the stabilization of this rate (the value of the birth rate in 2004 amounted to 12.60, 11.85 in 2005, 12.14 in 2006, and 12.46 in 2007).

The growth of total mortality rate also stabilized in the period 2004-2007 (total mortality rate in 2004 amounted to 9.2, 9.37 in 2005, 9.56 in 2006 and 9.51 in 2007).

Reduction to the infant mortality rate and natural growth rate in relation to 1991 (resulting from the decrease in birth rate and increase in death rate), with concurrent reduction in the value of the vital index from 2.42 to 1.31 in 2007 are the features of the period 1991- 2007.

Life Expectancy

According to the latest available data of the Statistical Office of Montenegro, life expectancy at birth for both genders in Montenegro in 2007 was 73.77 years, 76.06 for women and 71.22 for men, respectively.

In 2001, this indicator for Montenegro amounted to 73.91 years, or 76.45 years for women and 71.37 years for men, respectively. The gender difference did not change considerably in the period 2001 – 2007.

Life expectancy at birth per gender in the period 2001-2007

Life Expectancy	2001	2002	2003	2004	2005	2006	2007
Men	71.4	70.9	70.4	71.0	70.4	70.7	71.2
Women	76.5	75.7	74.9	75.3	74.9	74.8	76.1

Source: MONSTAT

Mortality in Montenegro

According to the data of the Statistical Office of Montenegro, the total number of deaths in 2007 was 5979 (51% men and 49% women), according to which the total mortality rate that amounted to 960/100,000 population (990 for men and 920/100,000 for women) shows growth in relation to 2000 (880 per 100,000 population), or modest growth over the last years (940 in 2005).

The leading causes of death in Montenegro are almost identical to the leading causes of death in developed parts of the world, primarily in European countries.

On the top of the list of the leading causes of death, there are circulatory system diseases that account for a growing number of women deaths over the past years. It is important to highlight that the share of these diseases in the structure of mortality of the population of Montenegro is higher than 50%. In the second place, there are tumors, with a tendency for an increase in the number of deaths, as in respect of the aforesaid cause. The number of women deaths from tumours also increases. These are the leading causes of death in other developed and developing countries as well. It should be underlined that the third place is still held by symptoms, signs and abnormal clinical and laboratory findings as insufficiently defined states of causes of death. Due to such high share of symptoms and insufficiently defined conditions in total mortality in Montenegro, some deliberation in analyzing ranks and reaching conclusions is necessary. The fourth and fifth place of the leading causes of death are alternately held by two groups of diseases: respiratory system diseases, and injuries and poisoning, with approximate numbers of deaths. The leading five causes of death accounted for more than 90% of mortality of the population of Montenegro.

Leading Causes of Death 2003 – 2007

Groups of Diseases		2003		2004		2005		2006		2007	
		Number	%	Number	%	Number	%	Number	%	Number	%
IX	Diseases of the circulatory system (I00-I99)	2 873	50.3	2 961	51.9	3 086	52.7	3 389	56.8	3 336	55.8
II	Tumours (C00-D48)	967	16.9	971	17.0	1 026	17.6	974	16.3	943	15.8
XVIII	Symptoms, signs and abnormal clinical and laboratory findings (R00-R99)	837	14.7	842	14.7	768	13.1	558	9.3	800	13.4
XIX	Injuries, poisoning and consequences of external causes (S00-T98)	233	4.1	214	3.7	232	4.0	293	4.9	233	3.9

Groups of Diseases		2003		2004		2005		2006		2007	
		Number	%	Number	%	Number	%	Number	%	Number	%
X	Diseases of the respiratory system (J00-J99)	272	4.8	231	4.4	235	4.0	256	4.3	236	3.9
	Other causes of death	755	13.2	488	8.5	492	8.4	497	8.3	431	7.2
	Total:	**5 704**	**100**	**5 707**	**100**	**5 839**	**100**	**5 968**	**100**	**5 979**	**100**

Source: MONSTAT

Infant Mortality

According to the data of the Statistical Office of Montenegro, 58 infants died in 2007 (36 male infants and 22 female infants), i.e. the total infant mortality rate amounted to 7.40 per 1000 live births, while in 2006 the rate was considerably higher (11.02 per 1000 live births). Fluctuations in the infant mortality rate in Montenegro are a consequence of the small population of infants, where a few cases significantly increase, or decrease the rate.

Infant mortality in Montenegro in the period 1990-2007

Indicator	1990	2000	2001	2002	2003	2004	2005	2006	2007
Infant deaths	156	102	129	92	92	61	70	83	58
Deaths - male infants	81	60	73	51	50	33	39	41	36
Deaths - female infants	75	42	56	41	42	28	31	42	22
Deaths per 1000 live births	16.6	11.1	14.6	10.8	11.0	7.8	9.5	11.0	7.4

Source: MONSTAT

In 2007, 31 infants died at the age between 0 and 6 days, i.e. the early neonatal mortality rate amounted to 3.95 per 1000 live births.

The most frequent causes of death of infants in Montenegro in 2007 were respiratory diseases (29.31%), followed by intrauterine hypoxia and birth asphyxia (25.86%).

Perinatal Mortality

According to the data of the Statistical Office of Montenegro, the largest number of children dies in perinatal period, and in 2007 there were 53 cases of perinatal death, i.e. the perinatal mortality rate amounted to 6.74 per 1000 births. Out of the total of 53 cases of perinatal death, 22 were stillbirths (10 male and 12 female stillborn), i.e. the stillbirth rate amounted to 0.3 per 100 live born, while 31 infants died at the age of up to 7 days.

Postneonatal Mortality

In Montenegro, in 2007, there were five cases of postneonatal death with the rate of 1.6 per 1000 liveborn, which is a record of a decrease in the given 2000 – 2007 period.

Values for the Infant Mortality Rates in Perinatal, Neonatal and Postneonatal Periods

	2000	2001	2002	2003	2004	2005	2006	2007
Perinatal mortality	10	13.23	10.8	10.1	9.3	9.1	9.0	6.7
Neonatal mortality	7.5	11.2	8.2	7.8	6.1	7.4	8.2	6.1
Postneonatal mortality	3.5	4.52	2.8	3.2	1.7	2.2	2.8	1.6

Source: MONSTAT

Mortality of the Elderly Aged 65 and Above

In 2007, the share of the deaths of the elderly aged 65 years and above in total mortality was 74%, i.e. the mortality rate at the age of 65 years and above amounted to 5498/100,000 population of this age (according to the assessment of population in 2007).

Maternal Mortality

Since 2003, there have not been any recorded cases of death associated with pregnancy, child birth and puerperium in Montenegro, through to 2007, when one case was recorded as having occurred due to aforesaid reasons (12.76/100,000 live births).

Diseases of the Circulatory System

Diseases of the circulatory system present the leading cause of morbidity and mortality in the world. As assessed by the World Health Organization (WHO), in 2006, 17.5 million people across the world died from circulatory system diseases, which constitutes 30% of all causes of death.

According to the data of Statistical Office of Montenegro, in the same year in Montenegro, 3389 people (1621 men and 1768 women) died from circulatory system diseases, which presented 56.8% of all causes of death, a share somewhat higher than the European average (52%). Within the group of circulatory system diseases, the most frequent cause of death in Montenegro are other forms of heart disease, followed by cerebrovascular diseases and ischaemic (coronary) heart disease

The share of women in the total mortality caused by circulatory system diseases is somewhat higher than the share of men (52.2%: 47.8%). However, differences are more significant if seen through cerebrovascular diseases (diseases of blood vessels of the brain) and ischaemic (coronary) heart disease, respectively. Namely, the share of women in the total mortality caused by cerebrovascular diseases is considerably higher in relation to the men's share (59.8% : 40.2%), whereas in respect to the total mortality from ischaemic heart disease, the situation is practically the reverse, i.e. the share of men is more significant compared to women (58.7% : 41.3%).

Shares of Respective Diseases of the Circulatory System in the Total Mortality in Montenegro, According to Gender, 2006

Rank	Disease Groups (codes according to ICD-10)	Men		Women		Total	
		Number	%	Number	%	Number	%
1	Other forms of heart disease (I26-I51)	1 056	47.8	1 154	52.2	2 210	37.0
2	Cerebrovascular diseases I60-I69	282	40.2	420	59.8	702	11.8
3	Ischaemic heart diseases (I20-I25)	260	58.7	183	41.3	443	7.4
4	Other diseases of the circulatory system	23	67.6	11	32.4	34	0.6
5	All other diseases	1 471	57.0	1 108	43.0	2 579	43.2
	TOTAL (all diseases)	3 092	51.8	2 876	48.2	5 968	100.0

Source: MONSTAT

In respect of the number of deaths from circulatory system diseases in Montenegro in the last six years, there is a record of a growth trend in the number of the ill, as well as in their group's share in total mortality.

Share of Circulatory System Diseases in the Total Mortality in Montenegro, 2001-2006

Disease Group	Number of deaths and share in total mortality in Montenegro (%)					
	2001	2002	2003	2004	2005	2006
All diseases	5 412	5 513	5 704	5 707	5 839	5 968
Circulatory system diseases	2 912	2 706	2 873	2 961	3 086	3 389
Circulatory system diseases - share (%)	53.8	49.1	50.4	51.9	52.9	56.8
Diseases of blood vessels of the brain	669	701	687	699	742	702
Diseases of blood vessels of the brain - share (%)	12.4	12.7	12.0	12.2	12.7	11.8
Ischaemic heart disease	446	450	429	481	485	443
Ischaemic heart disease - share (%)	8.2	8.2	7.5	8.4	8.3	7.4

Source: MONSTAT

The standardized rate of mortality from diseases of the circulatory system (heart and blood vessels) in Montenegro in 2006 amounted to 611.5 for men and 485.5 for women per 100,000 population. Values for the standardized rates of mortality from ischaemic (coronary) heart disease in Montenegro in 2006 amounted to 96.1 for men and to 50.6 for women per 100,000 population. Respective values for the rate of standardized mortality from cerebrovascular diseases in Montenegro in 2006 amounted to 106.1 for men and to 114.6 for women per 100,000 population.

Out of the total number of deaths from diseases of the circulatory system in 2006, 1550 or 45.7% people died before reaching 75 years of age (approximate average value for life expectancy at birth in Montenegro), while 586, or 17.3% of the people died before reaching 65 years of age.

For the time being, i.e. until the registers have been established and the programme introduced for conducting regular national representative studies of health of the population of Montenegro every five years, it is not possible to provide precise information on the number of new cases of circulatory system diseases, or for respective entities (e.g. the number of new cases of acute coronary syndrome or cerebrovascular insult – stroke), but based on the current health statistics, it is possible to determine which diseases adult persons most report to doctors.

According to the available health statistics for 2006, the share of circulatory system diseases in the total number of diseases for which people had hospital treatment is in the first place (16.7% of all cases of hospital discharge, while digestive diseases, as a cause for hospitalization, are in the second place with 11.5%). In respect of the outpatient healthcare services, in the course of 2006, by far the largest number of cases registered pertained to the group of respiratory system diseases (47.2%), whereas circulatory system diseases were in the third place (6.2%), preceded by urogenital diseases (6.8%).

Hypertension

Elevated systolic blood pressure is one of the leading risk factors for the onset of chronic non-communicable diseases, especially cardiovascular disease. According to WHO estimates, at the global level, systolic blood pressure accounts for 7.1 million deaths per year.

According to the WHO data, 15-37% adult population in the world has elevated blood pressure, while the prevalence of hypertension in persons older than 60 years of age amounts to 50%. Based on the information from the national health survey of the population of Montenegro from 2000 that was conducted among a nationally representative sample, it was estimated that the prevalence of elevated blood pressure in adult population (persons over 20 years of age) amounted to 40.8% (39.9% in women population and 41.7% in men population).

The health survey of the population of Montenegro from 2008 indicates that there was a decrease in the prevalence of measured hypertension to 27.2 % (25.7% in women population and 28.7% in men population). The frequency of elevated blood pressure also increased with years of age, so that the lowest prevalence was registered in the age group of 20-34 years (7.8%), and then at the age of 35-44 years (20.2%), with slightly progressive growth in the age groups of 45-54 (32.0%) and 55-64 years (42.5%). Highest values for prevalence were recorded among persons in the age group 65-74 years (51.6%) and among the persons older than 75 years of age (53.2%).

Diabetes

Diabetes mellitus (sugar disease) pertains to the five leading causes of death in most countries across the world.

With the standardized mortality rate that amounts to 19.1 per 100,000 population both for men and women respectively, Montenegro falls into the group of countries with a medium-high rate of mortality from this disease.

Out of the total number of deaths from diabetes mellitus in 2006, 58.7% of the persons died before reaching 75 years of age, while 20.7% of them died before reaching 65 years of age. The data on the age-specific mortality rates indicates that there is ample opportunity, through the implementation of appropriate measures for prevention, early detection and adequate treatment, to considerably decrease the number of premature deaths from diabetes mellitus among the population in Montenegro.

Generally, if we look at the number of deaths from diabetes in Montenegro during the last six years, we can see that the number of deaths, as well as the relating share in total mortality, have not changed significantly.

Share of Diabetes Mellitus in the Total Mortality in Montenegro, 2001-2006

	Number of Deaths and Share in Total Mortality in Montenegro (%)					
Disease Group	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**
All diseases	5 412	5 513	5 704	5 707	5 839	5 968
Diabetes mellitus	138	121	128	120	122	121
Diabetes mellitus - share (%)	2.5	2.2	2.3	2.1	2.1	2.0

Source: MONSTAT

Currently, the prevalence of diabetes in Montenegro is estimated at around 3%, which places Montenegro in the group of the European countries with lower prevalence.

Laboratory tests done within the National Health Survey of the population of Montenegro conducted in the course of 2008, indicate that about 10.8% of adult population (older than 20 years of age) have elevated values for glycaemia, which confirms the assumption that a large number of adult persons in Montenegro do not know that they have elevated sugar in the blood. This concurrently indicates a need to organize a systematic screening of the population for diabetes mellitus in order that the disease be diagnosed at an early stage whereby the onset of complications would be significantly reduced by appropriate educational and therapeutic measures.

According to the available health statistics for 2006, the share of diabetes mellitus in the number of persons treated in hospitals amounted to 2.9%, while the concurrent share in the initial diagnoses in outpatient health care services constituted 1.4%.

Malignant Neoplasms

Following the circulatory system diseases, malignant neoplasms (cancer) constitute the most frequent cause of death in Montenegro. In 2006, 974 persons died from malignant neoplasms. The standardized mortality rate in 2006 amounted to 209.3 for men and 119.3 for women per 100,000 population. The share of men in the total mortality is significantly higher compared to women (573 men, or 58.8%: 401 women or 41.2%).

In Montenegro during 2006, men died in most cases from cancer of the lung, colon and rectum, stomach, prostate, while the most common causes of death among women were cancer of the breast, lung, colon and rectum, pancreas, stomach and uterine cervix.

Most common malignant neoplasms as the cause of death among men and women respectively, Montenegro, 2006

MEN			WOMEN		
Site	Mortality Crude Rate per 100,000	Mortality Standardized Rate per 100,000	Site	Mortality Crude Rate per 100,000	Mortality Standardized Rate per 100,000
Lungs	68.0	74.9	Breast	28.9	27.8
Colon and rectum	13.9	15.0	Lungs	22.5	21.0
Prostate	11.2	13.1	Colon and rectum	8.3	7.4
Stomach	11.5	13.1	Mal Neo CNS	7.1	6.5
Liver and bile duct	10.9	11.9	Pancreas	6.4	5.7
Pancreas	10.2	11.2	Lymphoma and leukemia	6.1	5.2
Larynx	9.9	10.7	Stomach	5.4	5.0
Mal Neo CNS	9.2	10.2	Liver and bile duct	5.4	4.8
			Uterine cervix	4.5	4.5

Source: MONSTAT

Generally, the number of deaths from malignant neoplasms in Montenegro during the last six years, as well as their ratios in the total mortality, have not changed significantly.

Among men in Montenegro, by far the highest mortality rates are for lung cancer (standardized rate of mortality from lung cancer amounted to 74.9 per 100,000 men), while the highest rate of mortality for women is the rate for breast cancer (standardized rate of mortality amounted to 27.8 per 100,000 women). However, the problem of lung cancer as the cause of death becomes increasingly pervasive among women in Montenegro (standardized rate of mortality in 2006 was 21.0 per 100,000 women), which may also be encountered in other countries where tobacco consumption is common among women.

Out of the total number of deaths from malignant neoplasms in 2006, 742 or 76.2% of the persons died before reaching 75 years of age, while 417 or 42.8% of them died before reaching 65 years of age, which indicates premature death as a significant problem. This is also supported by age-specific mortality rates.

Upon viewing respective age-specific mortality rates for most common sites of malignant neoplasms, it may be observed that there are significant differences among them regarding the age at which the relating deaths occur. Namely, the respective rates of mortality from malignant neoplasms of bronchi, lungs and breasts are significantly high already at the age of 45-54 years, while mortality rates for malignant neoplasm of prostate become distinct only after reaching 65 years of age, with progressive growth at the age of above 75 years. In respect of the malignant neoplasm of colorectum, age-specific mortality rates are somewhat more equally distributed with a significant increase only after reaching 65 years of life.

According to the available health statistics for 2006, the share of malignant neoplasms in the number of persons treated in hospitals in Montenegro is very high. With the share of 8.7% of all cases of hospital discharge, this constituted the fourth most common reason for hospitalization in 2006 (circulatory system disease – 16.7%, digestive system disease – 11.5%, respiratory system disease 11.0%).

Regarding the workload of the outpatient health care service, in the course of 2006, they coped, to by far the highest extent, with health problems relating to the group of respiratory diseases (47.2%), while malignant neoplasms with a share of 0.53% were at the very bottom of the scale of the reasons for visiting outpatient health service.

Injuries

Injuries represent one of the leading causes of death in European countries. Injuries occur in a very wide range of situations: at home, during recreation and sports activities, in traffic, at work, etc. Unintentional and intentional injuries constitute one of the most significant causes of disability among young people, which leads to a substantial loss of “healthy years of life”.

In Montenegro, the value for standardized rate of mortality from injuries and consequences of external causes in 2006 amounted to 47.5/100,000 population. In the total mortality from injuries and consequences of external causes, the share of men is more significantly expressed compared to women (72.7% : 27.3%). Standardized mortality rate for men was equal to 72.0 per 100,000 population, while for women it amounted to 25.3 per 100,000. The largest number of cases of death within this group of conditions (50.7%) result from injuries to the head, neck, thorax and abdomen, while the so-called other injuries account for 47.6%.

According to the data of the Statistical Office of Montenegro, out of all deaths by accident in 2006, traffic accidents accounted for 83.6%, while in 2007 the share was lower (73.83%).

Out of the total number of deaths from the consequences of injuries and external causes in the course of 2006, around 90% of the persons died before reaching 75 years of age, while around 77% of them died before reaching 65 years of age. An extremely important piece of information is that the age of up to 35 years accounts for around 26.5% total number of deaths from the consequences of injuries and external causes. The aforesaid data indicates that there is ample opportunity to considerably decrease the number of premature deaths from injuries among the population in Montenegro through the implementation of, primarily, appropriate measures for prevention of injuries. Generally, if we look at the number of deaths from the consequences of injuries and external causes in Montenegro during the last six years, we can see that the number of deaths, as well as the relating share in the total mortality, have not changed significantly, except for the jump recorded in 2006, while in 2007 the share stabilized.

The share of injuries in the total mortality in Montenegro, 2001-2006

	Number of deaths and share in total mortality in Montenegro (%)					
Disease Group	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**
All diseases	5 412	5 513	5 704	5 707	5 839	5 968
Injuries	294	236	225	211	225	290
Injuries - share (%)	4.5	4.3	4.1	3.8	4.0	4.9

Source: MONSTAT

In Montenegro during 2006, around 9% of all hospital discharge diagnoses referred to injuries and consequences of external causes. Outpatient healthcare services also frequently register a significant number of patients who come for injuries and consequences of external causes, so that in 2006, there was a record of somewhat more than 20,500 initial visits to outpatient healthcare services for injuries and consequences of external causes. This accounts for 2.7% total number of the diagnoses established in outpatient healthcare services. Within this group, the most frequnt reason for visiting a doctor constituted the so-called “Other Specific Injuries, Non-Specific Injuries and Multiple Injuries”, with relating share of 78.1%. Unfortunately, due to the lack of existence of specific registers for injuries, it is not possible to obtain more detailed information from the existing system of health statistics on the manner in which injuries occurred, i.e. whether they occurred as consequences of traffic accidents, injuries during recreation or sports activities, at home or at work, as well as if they led to a certain degree of disability, i.e. a chronic condition.

Chronic Obstructive Airways Diseases

Due to the lack of existence of a national register for bronchial asthma and other chronic obstructive pulmonary (airways) diseases, in Montenegro, for the time being, it is not possible to determine the incidence and prevalence of bronchial asthma and other chronic obstructive airways diseases. It is only possible to say that, in the course of 2006, outpatient health care services registered somewhat more than 18,000 initial diagnoses of the health problems associated with bronchial asthma and other chronic obstructive airways diseases (2.4 % total number of the diagnoses established in outpatient healthcare services), and also that the number of those registered diagnoses has not significantly changed in the last five years.

Mortality from the above mentioned diseases is very low in Montenegro, but these diseases produce considerable adverse effects on the society, which is reflected in the chronic course of the disease per se and in the large expenses resulting from the inability to work, absenteeism and use

of the health care and social welfare resources for the treatment and rehabilitation of the ill, as well as in the indirect costs incurred by the absenteeism of parents in case of the illness of children.

Mental Health

During 2007, 25 persons died of mental and behavioural disorders (out of that, in two cases death was caused by drug abuse and in 23 cases by other mental disorders), which constituted 0.42% of the total mortality in 2007.

Out of the five indicators of the WHO European health for all database, which are published in health statistics, the only available data is for the indicator relating to “Hospital discharges, mental and behavioural disorders” that amounted to 2188 in 2007, constituting 3.6% of all discharges. In relation to all hospital discharges, this share recorded growth in the period as of 2003, when it was 2.85%, until 2007.

In outpatient healthcare services in Montenegro, in 2007, registered cases of mental and behavioural disorders constituted 1.29% of the total outpatient morbidity. The most common diseases in the structure of the outpatient morbidity were from the group of “Neurotic, stress-related and somatoform disorders” (F40-F48), followed by the disorders pertaining to the group of “Schizophrenia, schizotypal and delusional disorders” (F20-F29), and the category of “Mood (affective) disorders” (F 30-F39).

Communicable Diseases

In respect of communicable diseases, all diseases (except for the West Nile virus infection, SARS and small-pox) subject to compulsory registration in the EU are also registered in Montenegro in line with the WHO registration system and the application of definitions of diseases for the diseases individually reported by WHO (HIV, AIDS, TBC, diseases against which vaccination is conducted – EPI).

Leading Communicable Diseases

In 2008, in the Republic of Montenegro, 14380 of persons ill with communicable diseases subject to compulsory registration (influenza not included), with the incidence of 2223.3 per 100,000 population, were reported to the Public Health Institute. The increase in the incidence of communicable diseases in 2008 is a result of higher registration of new cases of respiratory, intestinal and parasitic diseases.

In the course of 2008, there was one registered case of death from communicable diseases subject to compulsory registration and reporting (exclusive of AIDS covered by a separate report), with the mortality of 0.15/100,000 and lethality of 0.01 % in respect of acute communicable diseases subject to compulsory registration (AIDS and influenza not included). There was one registered case of death from sepsis. The table below shows mortality trend over the last ten years relating to accute communicable diseases subject to compulsory registration (AIDS and influenza not included).

Communicable Diseases, Exclusive of Influenza and AIDS, in Montenegro, in the period 1999-2008

YEAR	NUMBER OF CASES	Inc/100 000	NUMBER OF DEATHS	Mt/100 000
1999.	10 107	1 579.2	2	0.31
2000.	9 583	1 455.4	0	0.00
2001.	7 610	1 073.0	2	0.28
2002.	7 225	1 020.4	5	0.70
2003.	7 621	1 080.9	1	0.01
2004.	11 247	1 741.0	3	0.04
2005.	8 172	1 317.0	6	0.96
2006.	9 873	1 535.0	2	0.31
2007.	8 417	1 301.4	1	0.15
2008.	14 380	2 223.3	1	0.15

Source: MONSTAT

With reference to the respective groups of communicable diseases, the number of new cases reported in 2008 was highest for the group of respiratory communicable diseases (influenza not included) that constituted 49.7% of the total number of reported cases of communicable diseases, whereby this group remained on the top of the scale as in the year before.

Intestinal communicable diseases are in the second place with the share of 45.1% of the total number of cases, where the third place is occupied by parasitic diseases with the share of 3.2%. Other groups of communicable diseases (anthropozoonoses, genital, vector-borne, carrier state and other diseases) are present with very low respective shares (all of them together constitute 1.87% of the total number of registered cases of communicable diseases).

In the structure of the 10 most common communicable diseases in 2008, acute enterocolitis is on the top, which may be accounted for by an increase in the number of cases registered during the epidemic of gastroenterocolitis in Podgorica.

The second place is held by chickenpox that used to be on the top of the scale, while the third place is occupied by streptococcal angina, followed by food poisoning in the fourth place. In the fifth place, there is scabies that is significantly present and almost always among the most frequent diseases, while salmonella infections hold the sixth place. Viral meningitis is in the seventh place, which is accounted for by an outbreak of this disease in the form of an epidemic in the municipalities of Podgorica and Danilovgrad. Infectious mononucleosis occupies the eighth place, herpes zoster is in the ninth, and scarlet fever holds the tenth place.

Number of cases and incidence of ten most common communicable diseases in Montenegro in 2008

ORD. NO.	DISEASE	NUMBER OF CASES	Incidence / 100 000
1.	ENTEROCOLITIS ACUTA	5 544	857.0
2.	VARICELLA	4 607	712.3
3.	ANGINA STREPTOCOCCICA	2 106	325.6
4.	TOXIINFECTIO ALIMENTARIS	426	65.9
5.	SCABIES	371	57.4
6.	SALMONELLOSES	198	30.6
7.	MENINGITIS ENTEROVIROSA	189	29.0
8	MONONUCLEOSIS INFECTIOSA	149	23.0
9.	HERPES ZOSTER	148	22.9
10.	SCARLATINA	108	16.7

Source: MONSTAT

The first five most frequently reported communicable diseases constitute 91% of the total of the reported communicable diseases, whereas the share of the first ten in the cases of acute communicable diseases is 96.3%.

Sexually Transmitted Infections (AIDS not included)

In 2008, there were 31 cases of sexually transmitted diseases with the incidence of 4.61 / 100,000. The incidence was the same as in the year before. Generally, registered rates of morbidity from gonorrhea, syphylis and genital chlamydiasis did not change significantly. The number of registered infections is far below the actual number, primarily as a consequence of the failure of doctors to report these infections, although the concern over AIDS and consequent increase in the use of condom could have influenced to a certain extent the lower rate of infections pertaining to this group of diseases.

Sexually transmitted infections (AIDS not included) in Montenegro in the period 1999-2008

YEAR	NUMBER OF CASES	INCIDENCE / 100,000
1999.	14	2.2
2000.	14	2.2
2001.	11	1.5
2002.	16	2.3
2003.	7	1.1
2004.	50	7.7
2005.	44	7.0
2006.	37	5.8
2007.	30	4.6
2008.	31	4.6

Source: MONSTAT

The list of sexually transmitted infections and diseases subject to compulsory registration was extended a few years ago by the introduction of an obligation to report genital chlamydiasis.

In 2008, the registered sexually transmitted infections included gonorrhea, hepatitis B and syphilis.

Prevalence of respective sexually transmitted infections in Montenegro in 2008

ORD. NO.	VENEREAL DISEASE	NUMBER OF CASES	%
1.	Hepatitis B	24	77.4
2.	Gonorrhoea	3	9.6
3.	Syphilis	4	13.0
4.	Chlamydiasis genitalis	0	-
	TOTAL	31	100.0

Source: MONSTAT

Gonorrhoea

In 2008, there were 3 reported cases of morbidity from this disease, which represents the incidence of 0.46 / 100,000 that is by 1.5 times lower than in the year before.

Gonorrhoea in Montenegro in the period 1999-2008

YEAR	NUMBER OF CASES	INCIDENCE / 100,000
1999.	14	2.2
2000.	14	2.1
2001.	8	1.2
2002.	12	1.8
2003.	6	0.9
2004.	8	1.2
2005.	6	0.9
2006.	7	1.1
2007.	5	0.7
2008.	3	0.4

Source: MONSTAT

This low values of incidence probably result from inadequate reporting of morbidity from this disease.

During 2008, the infection was registered in adult persons (19-59 years of age), as in the years before.

The registered average morbidity rate for the period 1999-2008 is considerably higher for men in comparison to women, which is logical to a certain extent for a higher level of promiscuity among men, but is also a consequence of the difference in clinical manifestations of this disease that more frequently develops without clinical manifestations in female persons, which very often represents the reason why female persons do not even report the discomfort to a doctor.

Syphilis

In 2008, there were 4 registered cases of morbidity from syphilis. It is assumed that this infection, as well as other sexually transmitted infections, is not registered in the volume that actually exists, and therefore an adequate analysis may not be made. However, the very fact that the disease is registered indicates a need for an improvement in surveillance of sexually transmitted diseases.

Syphilis in Montenegro in the period 1999-2008

YEAR	NUMBER OF CASES	INCIDENCE / 100,000
1999.	-	-
2000.	-	-
2001.	3	0.4
2002.	4	0.6
2003.	-	-
2004.	2	0.3
2005.	-	-
2006.	2	0.3
2007.	4	0.6
2008.	4	0.6

Source: MONSTAT

Hepatitis B

In 2008, there were 24 registered cases of viral hepatitis B with the incidence of 3.7 / 100,000, which is a 16% higher value in relation to the year before.

Hepatitis B in Montenegro in the period 1999-2008

YEAR	NUMBER OF CASES	INCIDENCE / 100,000
1999.	27	4.2
2000.	26	4.0
2001.	31	4.8
2002.	31	4.8
2003.	31	4.8
2004.	36	5.6
2005.	38	6.1
2006.	24	3.7
2007.	20	3.1
2008.	24	3.7

Source: MONSTAT

Since the immunization for hepatitis B was introduced in the Compulsory Immunizaton Programme in 2003, it is to be expected that a better control of this disease will be established in the foreseeable future, although due to the better diagnostic capacity there may even be an increase in the number of registered cases in the following period (for the overflow of a number of cases of diagnosed viral hepatitis, the agents of which could not have been differentiated in recent years).

For the time being, the largest number of infections is registered in adult persons, in 88% of the cases (persons above 20 years of age), while a significantly lower share of morbidity is registered in children of school age (12 %).

In respect to gender distribution, it may be perceived that the infection is approximately two times more frequently registered in male persons.

The current problem is the immunization of persons from the groups at higher risk, primarily the so-called hard to reach groups at risk (intravenous drug addicts, commercial sex workers, homosexuals, etc).

The relevant data on HBsAg carrier state for the territory of Montenegro is insufficient. In 2008, there were 3 registered cases of HBsAg carrier state.

HIV/AIDS

In the period from 1989 until the end of 2008, there were 89 persons in total registered as infected by HIV. The ratio between all men and women with HIV/AIDS from the beginning of the epidemic in the Republic of Montenegro is 4.7:1. This piece of data supports the fact that in Montenegro the level of promiscuity among men is higher, but it must not be overlooked that men are predominant in certain risk groups, e.g. men who have sex with men, sailors, etc. In the light of these facts, it may be concluded that the ratio between genders has been somewhat more balanced in respect of the overall population. If the number of registered persons with HIV infection is viewed in relation to the years when the infection was first detected, a mild growth trend may be perceived.

In the period as of 1989, when first cases were diagnosed, through until the end of 2008, 47 cases of AIDS were reported in Montenegro, out of that 37 men and 10 women (gender ratio is 3.7:1).

From the beginning of the epidemic until the end of 2008, there were 29 registered cases of death from AIDS in Montenegro (23 men and 6 women), with the gender ratio of 4:1.

In 2008, there were six registered cases of asymptomatic HIV infection and three cases of AIDS. The incidence of the new cases of infection was 0.92/100,000, and of the cases of the disease 0.46/100,000 population. The total incidence of newly detected infections in 2008 was 1.38/100,000 population. In this year, there was one registered case of death from AIDS, mortality being 0.15/100,000 population.

According to age distribution, all newly registered persons with HIV infection and persons with AIDS are between 20 and 37 years of age, except for one person who is 5 years of age.

According to the data from the submitted reports of the cases, one person was infected by HIV through vertical transmission (from mother to child), while other persons with HIV/AIDS became infected through sexual contact, out of which in 50% of the cases it was bi/homosexual contact.

The analysis of the epidemiological data obtained from infected persons indicates that there were five new registered cases of HIV in the population groups more exposed to HIV infection, four cases of men who had sex with men and one case of female sex worker in 2008.

Out of the persons with HIV/AIDS registered in 2008, three were female, or 33.3%.

In 2008, according to the data delivered by health institutions to the Public Health Institute, 18221 persons in total were tested for HIV, which was by 7.7% more in relation to the year before. Out of the aforesaid number of the tested, 17782 persons were tested in transfusion units. There were 13553 of voluntary blood donors tested, out of which 3365 were new donors. There were not any HIV positive persons among new blood donors, whereas among the old donors, one HIV positive person was found who had been HIV negative on previous tests. The number of citizens tested on other various grounds (voluntarily, anonymously, upon referral, etc.) was 4229. Out of this number of the tested, there were 8 persons with HIV infection detected.

Tuberculosis

In 2007, there were 159 reported cases of morbidity from active tuberculosis, which represents the incidence of 24.5 per 100,000 population and a lower value compared to 2006, although in the course of 2007, in difference to 2006, active TBC entered the group of ten most frequently diagnosed communicable diseases.

Incidence of TBC per 100 000 population in the period 1997-2007 Source: MONSTAT

Year Observed	TBC incidence per 100 000 population
1997.	32.9
1998.	34.1
1999.	37.7
2000.	30.5
2001.	24.8
2002.	25.8
2003.	34.8
2004.	26.7
2005.	27.4
2006.	27.3
2007.	24.5

Self-Assessment of Health

In addition to the aforesaid data on morbidity available in health statistics of Montenegro, morbidity of the population was also explored through a national health survey of the population of Montenegro conducted in 2008.

According to the results of this survey, in 2008, 9.6% of adults (20 years of age and above) in Montenegro assessed their health to be very poor or poor, 32.6% rated their health to be fair, while the remaining 57.8% perceive their health to be good or very good. A significantly higher proportion of women perceived their health as fair or poor (in total 47.3%, as opposed to 36.6% for men), contrary to men who tended to perceive their health as good or very good (in total 63.4%, as opposed to 52.7% for women). People older than 55 were more likely to assess their health as poor and those above the age of 65 were more likely to describe it as very poor.

It was found that in 2008, 42.8% of adult population in Montenegro reported having one of the 27 listed chronic diseases. According to the survey respondents, seven most common chronic diseases affecting the health of the Montenegrin population were found to be the following: hypertension, rheumatic joint diseases, elevated blood lipids, chronic cardiac diseases, allergies (except for asthma), kidney diseases and diabetes.

Female adult population (47.5%), those who are older than 45 and those with elementary education or less (62.9%) had a significantly higher prevalence of all reported diseases. On the other hand, a significantly lower prevalence was observed among men (37.7%), population in age groups below 44 years of age, the richest wealth index quintile of the population (36.1%), as well as among those with secondary education (37%), or college or university (35.9%).

In the 12 months preceding the 2008 survey, the listed chronic diseases were initially diagnosed in 11.1% of adults (incidence).

Most of Montenegrin children and adolescents (90.7%) defined their health as good or very good. There were no significant variations over geographic or demographic factors, gender, age groups or wealth.

a) What data is produced nationally, who has access to them and to what degree are they comparable to other EU countries?

Demographic data and vital indicators that comprise the data on the population, birth rate and death rate (the indicators listed within the answer to question 36) are available nationally and kept by the Statistical Office of Montenegro. It may be said that the aforesaid indicators are partially aligned with other EU countries, considering that the improvement and revision of the methodology that will provide for a higher degree of international comparability of the aforesaid and required indicators are currently in progress.

The data on standardized death rates (per gender and age) that provide for international comparisons is not processed through a regular statistical procedure. Certain documents (Strategy for the Prevention and Control of Chronic Non-Communicable Diseases adopted by the Government of Montenegro in 2008) contain calculations relating to the standardized death rates in 2006 (in accordance with the standard EU population) for cardiovascular diseases, malignant neoplasms, injuries, diabetes, which are given above in the section on the health status of Montenegro.

All data for monitoring and surveillance of the health status, which is delivered by health institutions and processed at the Public Health Institute of Montenegro, is published at the national level (outpatient and inpatient morbidity, communicable diseases). As stated above in the analysis of the health status, based on the existing method of collecting and processing of the data, it is not possible (except for communicable diseases in part) to obtain the data on the incidence and prevalence of respective diseases, especially of leading chronic non-communicable diseases (cardiovascular diseases, malignant neoplasms, traumata, etc), which is necessary for comparison.

Health surveys in one part are in the process of being aligned with certain WHO indicators from the HFA-DB database.

Montenegro is in the WHO system for monitoring indicators relating to immunizations (EPI). Monitoring of communicable diseases has been aligned with the WHO Communicable Disease Annual Reporting.

b) What is available on access to and use of health care, funding of primary and secondary care, morbidity, mortality, incidence rates, hospital facilities, health personnel, healthy life years, regional differences?

Data on Utilization of Health Care

Health care in Montenegro is provided in state-owned and private health institutions.

In public sector, health care is organized at the primary, secondary and tertiary levels.

Primary Health Care

Primary health care is a priority in the development of the health care system, while the promotion of healthy life styles and preventive health care are the priority within the primary health care.

At the end of 2008, all primary health centres changed the organizational structure and contents of work, as well as job systematization, registration of insurees was conducted, etc. Pursuant to Article 19 of the Law on Health Care, citizens exercise their right to primary health care through a selected team of a doctor or medicine, or a doctor of stomatology.

The data on the use of health care is given for the period until 2007, during which time the health care departments of the Public Health Centre ("Dom zdravlja") were still operating under the system of PHC departments that would correspond to the current organization of selected doctors for adults, children, women, etc. Due to the gradual introduction of primary health care reform and reorganization of PHC departments that had already been introduced in some institutions, some of the indicators given below are different to a lower or to a higher extent in relation to the state of the affairs in the period compared (1998).

Department of General Practice and Specialist Departments

In 2007, the department of general practice included 119 organizational units in 18 primary health care centres, which is by 16.6% more than in 1998, when there were 102 units. In the same year, there were 219 organizational units in supporting specialist departments, which is by 25.86% more than in 1998, when there were 174 units. The number of visits conducted within the department of general practice to doctors and other health workers in medical offices, as well as their home visits in 2007, was 3 456 700, which is by 17.65% more than in 1998. The number of visits to doctors in medical offices increased in 2007 by 44.26%, and the increase in visits to other health workers was 5.16% compared to 1998. In specialist department, as a supporting department for general

practice, the number of visits to doctors and other health workers increased between 1998 and 2007 by 22.18%.

Out of all conducted visits to doctors in medical offices of the department of general practice, there were 43.39% initial visits in 1998, and 34.36 such visits in 2007.

In specialist department, the respective shares of the initial visits in the total number of visits in the aforesaid years were 40.57%:57.91%. The number of initial visits in 2007 compared to 1998 increased by 63.13%.

Department of Health Care for Preschool Children

In 2007, there were 28 organizational units in the department of health care for preschool children, the same as in 1998.

In 2007, there were 391 800 of conducted visits to doctors in medical offices and guidance centres, which was by 29.15% less than in 1998. Out of the aforesaid number of all visits in 2007, there were 59.62% of initial visits. In the department of health care for children, there were 340 864 of visits to doctors in medical offices in 2007, which was by 25.58% less than in 1998.

In 2007, the share of the initial visits in the aforesaid visits to doctors in medical offices was 61.03%. There were 272 300 visits to other health workers in 2007, which is by 25% less than in 1998.

In 2007, there were 20 529 routine/regular general medical examinations and 11 100 follow-up examinations conducted in the department of health care for preschool children. Also, in 2007, there were 75 220 conducted visits of children to guidance centres, which is by 20.82% less than in 1998.

Department of Health Care for School Children and Youth

In department of health care for school children and youth, outpatient health care is provided to school children and students at the age of 7 to 24 years.

In 2007, this department operated through 20 organizational units, which was 16.6% less than in 1998. In 2007, the activity in this department was performed by 81 health workers, out of which there were 31 (38.27%) doctors and 50 (61.72%) other health workers.

There were 266 900 conducted visits to doctors in medial offices, and 199 600 visits to other health workers.

Out of the conducted visits to doctors in medical offices in 2007, there were 164 961 (61.80%) registered initial visits.

Department of Health Care for Women

In department of health care for women, outpatient health care is provided to the women population above 15 years of age. This group includes women of childbearing age 15-to-49 years old.

The department of health care for women comprised 25 organizational units in 2007, which was by 13.63% more than in 1998.

In 2007, the activity of this department was performed by 82 health workers, out of which there were 31 (37.8%) doctors and 51 (62.19%) other health workers. Out of 31 doctors in 2007, there were 87.1% specialists and 12.9% residents (doctors undergoing specialization).

In 2007, there were 111 300 visits of women to doctors in medical offices and guidance centres, out of which there were 37 500 (33.7%) initial visits.

In 2007, there were 91 405 conducted visits to doctors in medical offices. The share of initial visits therein was 36.43%. There were 41 200 conducted visits to other health workers in 2007. There were 26 476 visits of pregnant women to pregnancy guidance centres.

Hospital Health Care

Inpatient health care is provided in 7 general hospitals, Montenegro Clinical Centre, 3 specialist hospitals and 5 in-patient clinics of Primary Health Centre.

The number of patients discharged after treatment amounted to 71 504, or 11.41% of the total population in 2007. There were 642 193 bed days, or 8.98 days per discharged patient on the average.

The rate of utilization in all inpatient facilities was 71.26%, so that 709.57 out of 2 469 beds were available per day on the average. Out of that number of available beds, there were 34.58 beds in inpatient clinics of primary health centres, 386.87 in general hospitals, 86.56 in specialist hospitals and 201.56 in Montenegro Clinical Centre.

The number of beds in inpatient health institutions in the Republic of Montenegro in 2007 amounted to 2 469, not including 48 beds of day clinic for hemodialysis and 22 beds for neonatology.

The number of beds per type of inpatient institutions is as follows:

- General hospitals 1 127 (45.64%),
- Specialist hospitals 560 (22.68%),
- Clinical Centre 709 (28.71%),
- In-patient clinics of primary health care centres 73 (2.95%).

Structure of Outpatient and Inpatient Morbidity

Outpatient morbidity of the population of Montenegro in 2007 was dominated by the respiratory system diseases constituting 49.73% thereof. The shares of diseases of the genitourinary system and circulatory system diseases were 7.80% and 7.61%, respectively. In the structure of outpatient morbidity, the aforesaid is followed by diseases of the skin and subcutaneous tissue (4.70%), then diseases of the digestive system (4.24%) and diseases of the musculoskeletal system and connective tissue (4.26%). The share of other diseases in total moribidity was 21.67%.

Inpatient morbidity was dominated by diseases of the circulatory system, the share of which in the overall structure of morbidity of hospital patients in 2007 was 17%, followed by diseases of the digestive system with the share of 12.5%, diseases of the respiratory system constituting 11.3%, tumours with 9% and diseases of the genitourinary system with the share of 7%. The five leading groups of diseases constitute 57% of all diseases registered in inpatient morbidity.

Incidence

The existing method of keeping health system records does not provide for obtaining data on the incidence of respective conditions pertaining to chronic non-communicable diseases (ischaemic heart diseases, malignant neoplasms, diabetes), but these records will be governed by the subordinate legislation being drafted, which sets out the keeping of registers in accordance with the new regulations governing health system record-keeping (Official Gazette of the Republic of Montenegro 80/08). Certain assessments may be provided based on some population surveys that are still not conducted on a continuing basis (the latest population health survey was conducted in 2008), but by the adoption of the Strategy for Prevention and Control of Chronic Non-Communicable Diseases (December 2008), it has been provided that they be conducted at five year intervals.

Human Resources

Out of the total of 7 569 workers employed in public health care institutions (JZU) in the Republic of Montenegro in 2007, there were 5 697 (75.26%) health workers and associates, and 1 872 (24.73%) non-medical staff (ratio 3.04:1). Out of 5 697 health workers and associates, there are 1 656 (29.06%) with university education, out of which 1 233 (21.64%) are doctors, 248 (4.35%) stomatologists, 105 (1.84%) graduate pharmacists, while the remaining 70 (1.22%) are health associates. Out of health workers and associates, there are 236 (4.14%) with college (two-year post-secondary) education, 3 800 (66.7%) with secondary education and 5 (0.08%) workers with primary education.

Out of 7 569 workers, 3 348 (44.23%) worked in outpatient health care (primary health care centres and constituent units, the Institute of Public Health), 3 902 (51.55%) worked in in-patient

institutions (general and specialist hospitals and Montenegro Clinical Centre) and 319 (4.21%) worked in the pharmaceutical institution "Montefarm".

Doctors

Out of 1 233 doctors, there are 889 (72.10%) specialists, 106 (8.59%) general practitioners and 238 (19.30%) residents (undergoing specialization). The data on the trend relating to the number of doctors as of 1998 to 2007 indicates that the number of doctors increased from 1 120 in 1998 to 1 233 in 2007, i.e. by 9.16%. In the aforesaid period, the number of population per one doctor in Montenegro ranged from 581 in 1998 to 508 in 2007. With regard to gender, there are 501 (40.63%) male doctors and 732 (59.36%) female doctors.

According to the age of doctors, 259 (21%) are aged up to 34, 365 (29.6%) are 35-44 years of age, 439 (35.60%) are aged 45-54 years, while 170 (13.78%) are above 55 years of age.

Stomatologists

Out of 1 656 health workers and associates with university education in public health care institutions in Montenegro in 2007, there were 248 (14.97%) stomatologists. Out of the aforesaid number, there were 131 (52.82%) specialists, 8 (3.22%) residents and 109 (43.9%) general stomatologists. Their number decreased from 1998, when there were 264 of stomatologists, by 16 in 2007 (6.06%). The ratio between men and women among stomatologists in 2007 was 48.38%:51.61%.

Graduate Pharmacists

In 2007, in public health care institutions in Montenegro, there were 105 employed pharmacists, or 6.34% of the workers with university education, out of which there were 8 pharmacists holding specialization.

Health Workers With College (Two-Year Post-Secondary) and Secondary Education

The total number of health workers with college, secondary and primary education amounted to 4 041 in 2007. The number of workers with college ecucation was 236 in 2007, and of those having secondary education 3 800. Out of the total number of health workers, there were 54.83% of those with college and secondary education in 2007.

The number of population per one health worker with college or secondary education was 170 in 1998, and 155 in 2007.

Funding of Primary and Secondary Care

In Montenegro, the capacity is still funded and there is not any contracting between the Health Insurance Fund and health institutions (except for stomatologists' activity, following the reform of stomatological care). Capitation is defined as a model for financing primary health care. Institutions of the secondary and tertiary levels of health care are financed from pre-appropriated funds defined in the Financial Plan of the Health Insurance Fund.

More detailed information on funding of health care per level is provided within answers to other questions addressing this subject matter.

c) What is the number of health staff physicians, nurses and dentists other staff per capita?

The provision of the population of Montenegro with health workers and associates in public health care institutions (state ownership) and the Institute of Physical Medicine, Rehabilitation and Rheumatology „Dr Simo Milošević“ Igalo, joint stock company (state-private ownership), per 1,000 population at the end of 2007 was as follows:

- 2. 04 doctors,
- 0.40 stomatologists,
- 0.17 pharmacists,
- 0.12 health workers with university education, and
- 6.9 medical staff with college and secondary education.

The indicators listed above do not include employees in private health institutions. New Law on Health Data Collections (the "Official Gazette of the Republic of Montenegro“ 80/2008) provides for the establishment of a register of human resources in health care system in Articles 8 and 11 thereof.

d) What is the average length of stay in hospitals and institutions?

The Law on Health Care (the «Official Gazette of the Republic of Montenegro» 39/2004) and Master Plan for Development of Health Care System in Montenegro for the period 2005- 2010 (adopted by the Government of Montenegro in 2005) provide for the types and network of hospital capacity.

Beds and all indicators arising thereof (including the average length of stay in hospitals) are given in aggregate, since there has not been a division into acute and chronic beds. In the course of 2009, it is planned that the reform to the secondary and tertiary levels of health care should be conducted, whereby standards relating to acute and chronic beds will be defined.

The indicator relating to the average length of stay is presented according to the structure of ownership.

Average length of stay per public (state owned) hospital and institution:

Public Health Institution	Average Length of Stay
In-patient clinics of primary health care centres	3.7
General hospitals	7.2
Bar (catchment areas Bar and Ulcinj)	6.2
Berane (catchment areas Berane, Andrijevica, Rožaje and Plav)	6.8
Bijelo Polje (catchment areas Bijelo Polje and Mojkovac)	8.1
Kotor (catchment areas Kotor, Tivat and Herceg Novi)	5.9
Nikšić (catchment areas Nikšić,Šavnik and Plužine)	8.8
Pljevlja (catchment areas Pljevlja and Žabljak)	8.7
Cetinje (catchment areas Cetinje and Budva);	6.3
Specialist hospitals	30.5
SB for Lung Disease and TBC Brezovik - Nikšić	21.3
SB for Psychiatry Dobrota – Kotor	77.3
SB for Orthopaedics, Neurosurgery and Neurology Risan	15.3
Montenegro Clinical Centre	6.6
TOTAL	8.6

Source: MONSTAT

The Institute of Physical Medicine, Rehabilitation and Rheumatology „Dr Simo Milošević“ Igalo, a joint stock company, is under state-private ownership, and in 2008, the average length of treatment provided in the Institute was 12.72 days.

e) What are the main determinants of diseases?

Unfavourable demographic trends over the past several decades had an adverse effect on the total number and age structure of the population of Montenegro, and therefore it may be said that we pertain to the countries with old population and negative rate of natural growth of population.

Leading causes of death and morbidity of the population of Montenegro are chronic non-communicable diseases and specific grups of diseases the diagnoses of which still indicate a growth trend. On the top of the scale of mortality in 2007, there were diseases of the circulatory system, followed by the group of tumours, while symptoms, signs and abnormal clinical and laboratory findings were in the third place. Injuries, poisoning and external causes were in the fourth place, whereas diseases of the digestive system occupied the fifth place.

The indicator od premature death are lost years of life. The largest number of lost years of life has been caused by basic causes of death of the population of Montenegro.

Basic causes of mortality and morbidity of the population of Montenegro are given in the answer to question 36.

Health Determinants (Factors)

Socioeconomic Determinants

Health status of population is a significant determinant of socioeconomic development, but socioeconomic factors also have considerable influence on the health status. Unemployment, loneliness, harmful habits, but also concerns, uncertainty, the lack of supportive environment (existence of social network and social support), long-term stressful situations, etc. pose a threat to health and should be the focus of special attention in the future.

Macroeconomic Determinants

Macroeconomic and structural reforms have resulted in modest economic recovery and transition. In recent years, Montenegro has achieved modest economic progress: the real GDP has increased, the inflation went down, consolidated budgetary deficit in Montenegro has been reduced, the current deficit, although still high, is getting better; and the main indicators of well-being such as poverty, life span and literacy of adults remained moderate and stable.

According to the data of the Ministry of Finance, Montenegrin economy recorded dynamic growth in 2008, which produced effect on health determinants. The data on economic flows in Montenegro is given in answers to the questions addressing that subject matter.

These determinants condition the allocation of budgetary resources for health care and health expenditure per capita which is explained in the section on health financing.

Education

Education is a significant health determinant. In Montenegro, there is a record of a growing trend of persons who received college or university education. According to the data from the last census in 2003, there were 12,617 illiterate persons registered in Montenegro, which constituted 2.3% of the total population of Montenegro. Generally, at the level of the whole of Europe, the share of the illiterate ranges around 1.5%. Out of the total number of the illiterate, there are 8 714, or 69% of the persons above 65 years of age. Out of that, 7 882, or 90.4% are female persons. Among younger population, literacy is very high and equally distributed in relation to gender. In addition to positive trends relating to the level of literacy of the population, it is important to mention that the process of reforming the education system has considerably advanced and that the basic postulates thereof are compliant with programmes for prevention and control to a large extent (adoption of the strategy for inclusive education with an emphasis placed on the children with special needs, which has already been implemented in a number of schools; teaching programme for healthy life styles; school day care centres, etc.).

Households

According to the 2003 census, the average Montenegrin household comprised 3.43 members, which was less than in the period before.

Employment

Employment is a very important determinant of health. Recently, there have been reported changes in the trend relating to the number of the employed, which is presented in the section on employment in Montenegro.

At workplace, the employed are exposed to a range of harmful effects, the most common of

which, according to reported occupational diseases, are the following: noise, vibrations, non-physiological position of body at work, inorganic and organic dust, ionizing radiation, as well as different chemicals' harmful effects.

Unemployment

Unemployment, as an economic determinant, influences health in many aspects. According to the data of the Employment Agency, the unemployment rate in Montenegro is lower compared to the previous period, which is presented in the answers addressing employment and unemployment.

Habits as Health Determinants

Smoking – the Main Avoidable Health Risk Factor

Smoking tobacco products increases the risk of morbidity (with regard to the diseases such as specific forms of malignant conditions, then diseases of the heart and blood vessels, especially myocardial infarction, stroke and peripheral artery occlusive disease, as well as chronic obstructive pulmonary disease) and premature death. Smoking during pregnancy is associated with a higher risk of miscarriage and lower birth weight. Exposure of infants to passive smoking increases the risk of sudden infant death syndrome, while small children are at a higher risk of diseases of the respiratory system.

According to Global Youth Tobacco Survey, the share of smokers among the young at the age of 15 decreased in 2008 compared to the previous survey conducted in 2003 (in 2003, 5.6% children were regular smokers, out of which 5.6% boys and 6% girls, and then the number of regular smokers among children decreased in total to 5.1%, among boys 5.7%, while the share of girls was reduced to 4.4%). According to this survey, somewhat less than one third of school children aged 15 made an attempt to smoke at least one cigarette per day.

European School Survey on Alcohol and Other Drugs (ESPAD) conducted in Montenegro in 2008 indicated that around 44% of school children experimented with smoking by the age of 15 years, out of which 51% boys.

More detailed information on smoking and tobacco control in Montenegro is given separately in the answer to question 48.

Alcoholism

Use of alcohol represents a risk factor for the onset of mental disorders, liver cirrhosis, hypertension, stroke, specific forms of carcinoma, as well as for all injuries, especially those that occur in traffic, while during pregnancy, it may lead to delivery of children with fetal alcohol syndrome.

With regard to drinking habit among the young (at the age of 15 years), according to the European School Survey on Alcohol and Other Drugs (ESPAD) conducted in 2008, there were around 74% of children in Montenegro who had an alcoholic beverage at least one time.

This issue is thoroughly addressed in the answer to question 58.

Drug Addiction

Even though Montenegro faced the problem of drug consumption considerably later than other countries in Europe, the current situation, according to the European School Survey on Alcohol and Other Drugs (ESPAD) conducted in 2008 indicates that 4% students who participated in the survey tried cannabis or hashis, out of which 63% boys and 37% girls. During the previous year, 2.4% students used cannabis or hashis. One percent of boys used exstasy in the course of the previous year (66% boys and 34% girls), and the equal percent of boys used amphetamines. The largest number of students started consuming the aforesaid drugs at the age of 15 years. According to their own statements, 6% students who participated in this study, aged 16, used some of the following types of drugs: cocaine, hallucinogens, crack, heroin, anabolic steroids or hallucinogenic drugs.

The data on drug abuse is separately addressed in the answer to the question number 54.

Nutrition and Nutritional Status

Nutrition is an important factor the influence of which is manifested during a lifetime. It influences growth and development of children, physical and working ability and defence mechanism, as well as cognitive functions of an organism.

The data on consumption of food and nutritional status indicates that there is not a significant presence of underweight in Montenegro, in terms of energetic deficit caused by insufficient quantities of food consumed. However, there are some specific qualitative nutritional deficits that affect, primarily, the economically weaker part of the population, but they also exist among the population in financially fortunate circumstances for adequate diet (an important role in the etiology of qualitative nutritional deficits is played by increased consumption of refined and industrially processed foodstuffs and dishes).

According to the data obtained in the survey of the Institute of Public Health conducted in 2008, there were around 10% of obese children up to five years of age in Montenegro, 3.3% children at a serious risk and 7.9% children at a moderate risk evaluated based on body weight, in comparison to the local reference values, while according to global reference standards, there are not any children at a serious risk of lagging behind in development. The number of children who are moderately underweight or underweight decreases with age, whereas boys are more commonly obese than girls.

Obesity is a disease featured by an increase in body fat mass to an extent that leads to deterioration of health status and development of a range of complications. The diseases develops due to:

- Consumption of food high in energy density,
- Significant share of fats in nutrition - especially of those with a high content of saturated fatty acids,
- Insufficient consumption of complex carbohydrates, insufficient dietary intake of fruit and vegetables,
- Insufficient physical activity, i.e. lower energy expenditure.

Inappropriate nutrition of our population and traditional national cuisine built on animal fat, fatty meat, starch and sugar, constitute a risk factor for the number one killer diseases (heart attack, hemorrhagic infarction, malignant diseases). Statistical data on the consumption of basic foodstaffs indicates that the dietary intake of the following food items is insufficient in Montenegro: whole grain cereals and dark types of bread, fish, fruit and some types of vegetables, due to which the intake of dietary fibres is very small, and therefore the diseases caused by such type of diet are common, according to the data of the Institute of Public Health. Qualitative deficits of vitamins and minerals in our population occur mainly in their chronic subclinical forms and do not represent by themselves a significant problem of our national pathology.

Population and Food Policy

Montenegro is one of the signatory countries to the Conclusions of the International Conference on Nutrition held in Rome in 1992, whereby it took on the commitment of developing its own national policy in this area.

The Ministry of Health and the Public Health Institute initiated the development of National Strategy for the Safety of Food and Law on Safety of Food. Based on an assessment of the nutrition of population, goals and priorities have been stated and measures proposed for the improvement of nutrition, which are set out in the Strategy for Safety of Food and Law on Safety of Food.

The objective of food policy is to improve the quality of nutrition and thereby the health of population. In the above mentioned document, the following priorities have been set out: modifications to eating habits of the population, education for the population and experts in the area of nutrition, elimination of public health problems relating to the influence of food on health, control of the quality of foodstuffs, introduction of consistent regulations that contribute to raising awareness of consumers, as well as collaboration with food industry in the implementation of

programmes for enriching foodstaffs with specific nutrients, or in the production of foodstaffs with the reduced quantity of salt, saturated fats, sugar and the like.

In respect of nutrition-related programmes and activities, the following is monitored in Montenegro:

- Nutritional status and quality of nutrition of the population,
- Prevention of sideropenic anaemia in vulnerable groups,
- Effect of iodine prophylaxis,
- Promotion of breastfeeding,
- Promoton of proper nutrition and physical activity,
- Harmonization of food standards, and
- Energetic value and food ingredient labels.

Physical Activity

Regular physical activity has a range of positive effects: it contributes to establishing a balance between the intake and consumption of energy, and thereby to maintaining desirable body weight, reduces the risk of coronary disease, decreases blood pressure and serum glucose level, reduces the loss of bone mass and enhances mental health.

Insufficient physical activity increases the risk of diseases of the heart and blood vessels, especially of coronary disease, for non-insulin dependent diabetes, colon and breast cancer, osteoporosis, etc.

According to surveys of the Institute of Public Health of Montenegro in 2008, only 11.5% adult population exercises more than three times a week. Exercising more than three times a week was significantly more frequent:

- In central Montenegro,
- Among men,
- Among younger persons,
- Among those with college or university education.

Children and adolescents spend their leisure time in a sedentary manner to a great extent, mainly by the computer or watching television (around 3 hours and 40 minutes during the school days, and 5 hours and 20 minutes on weekends). Regular attendance at physical education lessons in school is at a high level (97.2%), but somewhat less than one third of children and adolescents spend a minimum of two hours a week in vigorous activity outside school.

Sexual Behaviour

Sexual behaviour is a very significant determinant of health, especially among the young, because it increases the risk of unwanted pregnancy, onset of sexually transmitted diseases, sterility, etc. The risk of morbidity from sexually transmitted infections is the greatest among those young people who early become sexually active and are prone to changing partners. This population group is the group that is not inclined to use condom as the safest means of protection both from sexually transmitted infections and from unwanted pregnancy.

Sexually transmitted diseases display great changes over the past decade in agents, symptomatology, gravity and prognoses. "Classic" sexually transmitted diseases such as syphilis and gonorrhea become increasingly less common, while morbidity grows more dominated by diseases caused by the agents discovered not so long ago (chlamydia, ureaplasma, human papillomavirus, etc). The most significant sexually transmitted diseases nowadays are those caused by the following viruses:

- Human immunodeficiency virus (HIV) that causes AIDS,
- Genital herpes virus,

- Human papillomavirus, and
- Viruses causing hepatitis B and C.

The most spread bacterial sexually transmitted infection is caused by the bacteria chlamydia trachomatis.

According to the survey that the Institute of Public Health conducted in 2007 on the topic of „Knowledge, Attitudes and Sexual Behaviour of the Young Aged 18 - 24 in Montenegro", it has been indicated that respondents, generally, have a positive attitude towards the use of condom, since more than two thirds of them think that the use of condom is desirable. In spite of that, only somewhat more than a half of the respondents used condom during the first sexual intercourse. Only one third of respondents always uses condom during sexual intercourse, whereas almost every fifth respondent never uses condom during sexual intercourse. Even during the sexual intecourse with casual partners, two thirds of the respondents did not use condom.

Every sixth respondent was not acquainted with the methods of protection from sexually transmitted diseases, i.e. with the fact that condom constitutes safe protection from infection transmission. As many as one third of respondents do not believe that disease may be prevented by engaging in sexual intercourse with only one (healthy) partner. The results of the survey indicate that most sexuality-related information is obtained from friends, partners, TV, while the least information is received from teachers and doctors. More than two thirds of men and less than one third of women believe that it is good to have as much experience in sex as possible. Around one third of girls and two thirds of boys believe that it is normal to engage in sexual intercourse early. Nearly a half of the male respondents and only around 14% of female respondents believe that it is normal to engage in sexual intercourse on the first date. Twice as many girls do not approve of a one night stand. Nearly one half of the respondents believe not to mind much older sex partners.

During the last year, 3 young men have been diagnosed with genital herpes, two young men with candidiasis and one young man with hepatitis B, whereas morbidity from candidiasis is significantly higher among girls, two girls reported the presence of chlamydia and human papillomavirus, while one third of the female respondents visited gynaecologist within the last 12 months. A considerably larger number of respondents had severe symptoms of sexually transmitted diseases. Nearly every fourth female respondent has been pregnant minimum one time, while every fifth one has born children.

The survey confirmed that there is a low risk of HIV infection, according to the respondents' self-assessment. Only 2.7 respondents believe to be at a high risk of HIV or some other sexually transmitted disease.

HIV/AIDS

In the period from 1989 until the end of 2008, there were 89 persons in total registered as HIV infected. The ratio between all men and women with HIV/AIDS from the beginning of the epidemic in the Republic of Montenegro has been 4.7:1. This piece of data supports the fact that in Montenegro the level of promiscuity among men is higher, but it must not be overlooked that men are predominant in certain risk groups, e.g. men who have sex with men, sailors, etc. In the light of these facts, it may be concluded that the ratio between genders is somewhat more balanced in respect of the overall population. If the number of registered persons with HIV infection is viewed in relation to the years when the infection was first detected, a mild growth trend may be perceived.

In the period as of 1989, when first cases were diagnosed, through until the end of 2008, 47 cases of AIDS were reported in Montenegro, out of that 37 men and 10 women (gender ratio is 3.7:1).

From the beginning of the epidemic until the end of 2008, there were 29 registered cases of death from AIDS in Montenegro (23 men and 6 women), with the gender ratio of 4:1.

In 2008, there were six registered cases of asymptomatic HIV infection and three cases of AIDS. The incidence of the new cases of infection was 0.92/100,000, and of the cases of the disease 0.46/100,000 population. The total incidence of newly detected infections in 2008 was

1.38/100,000 population. In this year, there was one registered case of death from AIDS, mortality being 0.15/100,000 population.

According to age distribution, all newly registered persons with HIV infection and persons with AIDS are between 20 and 37 years of age, except for one person who is 5 years of age.

Transmission of virus from infected mother to her child has been reduced to the minimum. According to the data from the submitted reports of the cases, one person was infected by HIV through vertical transmission (from mother to child), while other persons with HIV/AIDS became infected through sexual contact, out of which in 50% of the cases it was bi/homosexual contact.

The analysis of the epidemiological data obtained from infected persons in 2008 indicates that there were five new registered cases of HIV in the population groups more exposed to HIV infection, four cases of men who had sex with men and one case of female sex worker.

Out of the persons with HIV/AIDS registered in 2008, three were female, or 33.3%.

In 2008, according to the data delivered by health institutions to the Public Health Institute, 18 221 persons in total were tested for HIV, which was by 7.7% more in relation to the year before. Out of the aforesaid number of the tested, 17 782 persons were tested in transfusion units. There were 13 553 of voluntary blood donors tested, out of which 3 365 were new donors. There were not any HIV positive persons among new blood donors, whereas among the old donors, one HIV positive person was found who had been HIV negative on previous tests. The number of population tested on other various grounds (voluntarily, anonymously, upon referral, etc.) was 4 229. Out of this number of the tested, there were 8 persons with HIV infection detected.

Since 2005, when the first Counselling Centre for Voluntary and Confidential Counselling and Testing for HIV was opened at the Institute of Public Health in Podgorica, until now, counselling centres have also been opened at primary health care centres in Bar, Kotor, Herceg Novi, Nikšić, Berane, Bijelo Polje and Pljevlja.

The Environment

Monitoring, evaluation and reporting on the harmful environmental effects on the health of the population are priority development goals in this area in Montenegro.

This area is governed by the Law on Assessment of Influence on the Environment (the Official Gazette of the Republic of Montenegro 80/05), Water Law (the Official Gazette of the Republic of Montenegro 27/07), as well as the following strategic documents: Strategy for Sustainable Development, National Strategy for Biodiversity, Energy Sector Development Strategy, Strategy for Development of Tourism and other documents.

Data indicates that in Montenegro:

- Above 75 % of households (somewhat less population) is connected to public waterworks (in urban areas above 95%),
- Water supply is mainly carried out by groundwater tapping (3.3 m3/s),
- At most water supply source areas, a narrow zone of sanitary protection is established in accordance with the Water Law,
- Water disinfection is carried out at ground water sources used for public water supply, while the water tapped from the reservoirs undergoes separate treatment at water treatment facilities,
- Measuring, collecting and processing of data on the quality of water for all public water supply systems is conducted by the Institute of Public Health of Montenegro, in collaboration with sanitary/epidemiological departments of primary health centres. In the course of a year, around 5000 samples are examined, while 7.2% have been found inadequate in terms of physical/chemical quality, and 13.6% in terms of microbial quality.

Epidemics caused by water-borne agents are rare and mainly occur in smaller water supply systems that are not under constant supervision of public health services.

Health safety of food is a fundamental prerequisite for ensuring health, ability to work and quality of life of the population. This area is governed by the Law on Health Safety of Food, whereby supervision of foodstuffs and objects of common use is conducted. The enforcement of this Law and subordinate regulations is ensured by sanitary inspection that conducts supervision of production, importation and trade. The control of health safety on the market is ensured by a sanitary inspector through collecting samples and analysis in public laboratories authorized by the Ministry of Health. In authorized laboratories of the Ministry of health, more than 12 000 samples of foodstuffs per year are tested against physical/chemical and microbiological parameters. On the average, it turns out that there are around 3.5% inadequate samples according to the standards for chemical quality, and 4% against the standards for microbiological quality.

The Institute of Public Health monitors communicable diseases in Montenegro on an ongoing basis, and thereby food-borne diseases.

Apart from that, the Law on Protection from Noise in the Environment provides for the protection of the health of the population from noise. Specific provisions of this Law are presented in the section addressing the protection of the environment.

f) What are the diseases that cause most premature deaths and disabilities?

Except for occasional calculations of premature death indicators, there is not an ongoing monitoring of these indicators in terms of lost years of life, i.e. the total number of years that an individual has not lived and died before reaching 75 years of age (approximate life expectancy). Based on a specific survey conducted by the Public Health Institute on potentially lost years of life in 2004, it may be observed that, on the average, every citizen of Montenegro lost ten potential years of life. In other words, the dead in Montenegro died, on the average, ten years earlier than life expectancy for the period of survey in Montenegro. The most significant causes of premature death in Montenegro, according to this survey, are the following: diseases of the circulatory system - around 30% of the lost years of life in total, tumours - around 20% of the lost years of life in total, injuries and poisoning - around 10% of the lost years of life in total, other causes - around 40% of the lost years of life in total.

The answer to question number 36 on leading causes of death comprises the data indicating the number of the cases of death against their age categories, i.e. the share of the persons who died from leading causes of death before reaching 75 years of age (which is the average life expectancy in Montenegro) and before reaching 65 years of age (for diseases of the heart and circulatory system, malignant neoplasms, injuries).

37. With reference to the institutional framework and administrative capacity, please answer to the following questions:

The answer to the question is contained in the answers to questions 37a) and 37b).

a) Who are the main actors involved with public health in your country? How many people are currently working in the Ministry of Health and Social Welfare and the other public health institutions?

The main actors involved with public health are the Ministry of Health, as the authority responsible for health policy, JZU (Public Health Institution) the Public Health Institute, a highly specialized health institution at tertiary level of health care, the activity of which aims at preservation and improvement of health of all citizens.

By virtue of the Conclusion of the Government No. 03-8968 of 31 July 2009, the Rulebook on Internal Organization and Job Systematization of the Ministry of Health was adopted. This Rulebook provided for the systematization of all jobs of civil servants and state employees in the Ministry of Health for 110 incumbents.

The total number of the employed at the Public Health Institute amounts to 198 in 2009. In the structure of the employed, the number of employees with university education is 66, or 33.3% (8

holders of PhD degree, 6 holders of MSc degree, 21 specialists, 10 undergoing specialization and 21 with only university education). The number of remaining employees is 132 (15 with college and 101 with secondary education, 3 highly-skilled workers and 13 with primary education).

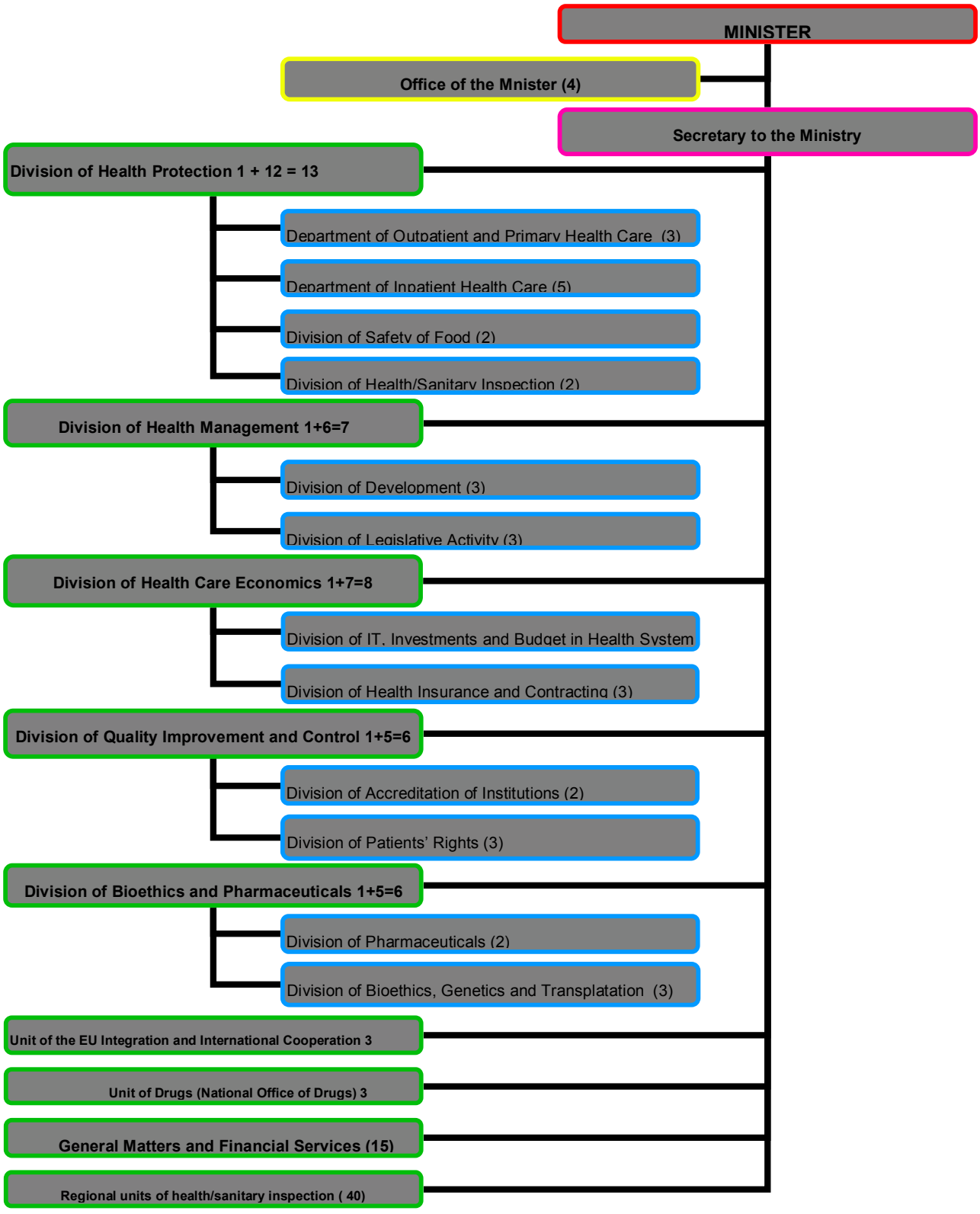
Human resources, as fundamental resources and agents of the process of work, are not quantitatively and qualitatively well-structured. In the following few years, through active work on upgrading the qualifications' structure of the employees, with ongoing education and professional development, a satisfactory level of education and experience of the human resources of the institution will be reached.

b) As candidate countries need to transpose all EU health acquis into their national legislation and enforce this legislation, adequate administrative and institutional capacity, and infrastructure is needed to apply the EU rules and standards at national, regional and local level. Please describe the current situation in your country. Are there any plans for changes?

The authority responsible for health policy in Montenegro is the Ministry of Health that performs the duties of administration relating to: making and pursuing health policy; health insurance and provision of health care from public revenues; foundation and organization of health institutions and determination of conditions relating to space, human resources and equipment of health institutions; professional development and specializations of health workers and health associates; health safety of food and objects of common use; protection of population from communicable diseases; national policy governing the production and sales of medications and medical devices; protection of population from tobacco products; granting consent for the carriage of toxic substances across the state border and in domestic transportation; production and sales of toxic substances; production and sales of narcotic drugs and precursors; coordination and monitoring of cross-sectoral activities and enforcement of policy governing drugs; management of medical waste and biohazard substances; proposal, negotiation, conclusion and implementation of agreements and other international treaties, affairs relating to international cooperation and the EU integration; cooperation with international and non-government organizations; administrative procedure; first-instance misdemenour procedure; administrative supervision of the areas for which the Ministry has been established, as well as other matters within the competence of the Ministry.

By virtue of the Conclusion of the Government No. 03-8968 of 31 July 2009, the Rulebook on Internal Organization and Job Systematization of the Ministry of Health was adopted (Annex 221), whereby all jobs of civil servants and state employees have been systematized for 110 incumbents.

The organizational chart of the Ministry of Health:



Institute of Public Health is a highly specialized health institution at tertiary level of health care, the activity of which aims at preservation and improvement of health of all citizens, and performs the following activities:

1. Monitors and assesses the health status of the population and creating databases for planning, monitoring and evaluation of all public health activities and health care activities in the Republic;

2. Identifies factors of health risk from communicable and chronic large-scale non-communicable diseases, including biological, environmental, socio-economic factors and life styles, and undertakes measures to reduce their effects or to neutralize them;
3. Conducts prevention and control of communicable diseases;
4. Proposes and implements measures for protection and promotion of health, especially with regard to the control of health safety of foodstuffs, objects of common use, drinking water, solid and other waste substances, noise and air pollution;
5. Analyzes the state of affairs and reports to the competent state authorities on the infrastructure, human resources, activities, utilization and quality of health care provided by all health institutions in the Republic;
6. Performs the functions of a reference laboratory for specific analyses the procedures for which are covered by its accreditation;
7. Researches and develops the public health activities and health policy and creates programmes for public health;
8. Organizes undergraduate and postgraduate education in public health disciplines, as well as the activities of continuing education in other fields of health care;
9. Participates in preventive supervision of designing projects for and construction of buildings and other facilities and in the development of spatial and urban development plans from the viewpoint of protection and improvement of the living and working environment and the health of the population;
10. Proposes the measures required in the events of extraordinary circumstances, extreme weather conditions and large-scale epidemics, and participates in their implementation;
11. Keeps records relating to health care and medical activity, pursuant to separate regulations.

The activity of the Institute is conducted in organizational units including: centres, services and departments.

The following centres are organized at the Institute:

- Centre of Development of Health Care System,
- Centre of Promotion of Health,
- Centre of Control and Prevention of Disease,
- Centre of Environmental Medicine,
- Centre of Microbiology.

The total number of the employed at the Institute of Public Health amounts to 198 in 2009. In the structure of the employed, the number of employees with university education is 66, or 33.3% (8 holders of PhD degree, 6 holders of MSc degree, 21 specialists, 10 undergoing specialization and 21 with only university education). The number of remaining employees is 132 (15 with college and 101 with secondary education, 3 highly-skilled workers and 13 with primary education).

Medical activity is organized at primary, secondary and tertiary levels of health care system.

The network of public health institutions consists of:

- Institute of Public Health,
- Clinical Centre of Montenegro,
- 7 general hospitals,
- 3 specialist hospitals,
- 18 primary health care centres,
- Emergency Care Service (recently founded),
- Blood Transfusion Service (recently founded),

- Public pharmaceutical institution of Montenegro - “Montefarm”.

With a view to creating a more efficient and sustainable system, the plan is to establish a partnership between public and private sectors. It is also necessary to raise awareness among citizens of the responsibility to preserve health, as well as of higher participation in the expenditure for excercising rights arising from compulsory health insurance.

The reformed health care system requires continuing human resource and infrastructure strengthening that has been provided for by the promulgation of a whole range of laws and strategies that are aligned with the EU rules and norms and require phased and organized implementation.

38. With reference to the health system reforms, please describe:

The answer has been provided under 38 a), b), c) and d).

a) Any on-going or planned reforms

The primary objective of the reform is to bring the health system to a state of optimum functionality in order to achieve, within the resources available, the maximum positive effect on the state of health of the population of Montenegro.

The health policy in Montenegro until 2020 represents a basis for legislative, planning and action programmes with a view to increasing the efficiency and quality of health care, and integrating the health system of Montenegro in European and global health development process, by setting the following goals:

- Extending life expectancy;
- Improvement of the Quality of Life in Relation to Health;
- Decreasing health inequities,
- Insurance from financial risk.

Health problems may have considerable negative financial effects on citizens and their families. Medical science and the expenditure for treatment and prevention concurrently grow faster than the economic basis of the society. It is, therefore, necessary to introduce adequate forms of health financing that will provide for an access to the health care required and distribute the financial risk, so that the citizens should not be exposed to considerable financial strain in the event of a disease.

Public health care institutions are organized through a network of primary, secondary and tertiary care consisting of: 18 primary health care centres, 7 general hospitals, 3 specialist hospitals, Clinical Centre of Montenegro, Institute of Public Health, Public Pharmaceutical Institution of Montenegro - "Montefarm”, and the newly founded Emergency Care Service and Blood Transfusion Service.

The reform provides for all citizens of Montenegro to have equal, available and quality health care at all levels.

The primary health care constitutes the basis for the health care system and the first level at which a citizen exercises his/her right to health care, or is referred to the provision of health care at other levels, except for cases of emergency.

The reform of the health care system that is based on the reform of the primary level of health care was launched within the Montenegro Health System Improvement Project.

What has been introduced includes the concept of a chosen doctor as an agent of the provision of health care at the primary level, support centres and units, while the primary health care centre as a reference primary health care (PHC) centre has been retained.

An integral part of the PHC reform is the development of a new method of funding PHC and of a new payment model - Methodology for Determining the Value of Capitation and Prices of Health Care Services in Primary Health Care System. Salaries of chosen doctors and nurses in chosen

doctors' teams depend on the number of insurees who have registered with respective doctors (capitation) and the number of services rendered, whereby the quality of their work is paid.

As of 1 July 2008, in all 18 primary health centres, conditions have been created for making electronic record of services rendered, monitoring all required parameters (number of registered insurees, number of coefficients, volume of services rendered, progress made against the plan for preventive check-ups, etc.) and making out electronic invoices by primary health centres.

Contingent on the extent of the performance and individual shares in the overall invoice, primary health centres calculate the salaries for the employees in accordance with the Methodology for Determining the Value of Capitation and Prices of Health Care Services in Primary Health Care System as of January 2009.

The PHC reform is addressed in more details within the answer to question 38.b).

Reform of Stomatological Health Care

As of 1 January 2008, stomatological health care has been reorganized through privatization at the primary level and contracts have been concluded between the Fund and private stomatological institutions.

In the course of 2008, contracts were concluded with 121 teams of stomatologists in 109 private stomatologists' offices, out of which 103 teams operated in 99 clinics that were rented within primary health care centres, while 18 teams worked in 10 clinics that had their own premises.

The new method of organizing the provision of stomatological care should satisfy the primary objective of the reform, i.e. the provision of available, efficient and quality stomatological services to insured persons.

Stomatological clinics operate under the new system in a considerably more organized and efficient manner, with higher satisfaction of insured persons with the volume and quality of services rendered.

Establishment of the Contracting System

Establishment of the contracting system in the health care sector of Montenegro has been supported by the World Bank. During 2008, work was done on the preparation of reports that comprised legal, methodological and organizational bases for the establishment of a system for contracting health services and development of operational and business procedures at the primary level, and subsequently at secondary and tertiary levels of health care.

The objective of establishing the contracting system is to set out clear obligations and responsibilities of contracting parties, transparent financing of health care services and improved availability of health care to insured persons.

By virtue of the new model of organizing and funding primary health care centres, conditions have been provided for contracts between the Fund and primary health centres to be concluded in 2009. The contracts will precisely stipulate mutual rights and liabilities, and provide for the implementation of the Health Care Programme. Conditions for control and monitoring of the legitimacy of spending according to the structure set will be created.

Voluntary Health Insurance

In accordance with the Strategic Development Plan of the Health Insurance Fund for the period until 2011, during 2007 and 2008, intensive work was done on creating conditions for the implementation of the project of introducing voluntary - supplementary health insurance, which is of paramount importance since additional funds for the health care sector will thereby be provided and, concurrently, the pressure on the public sector will be alleviated.

Development of Integrated Health Information System in Montenegro

Strategic commitment of Montenegro is to develop an integrated health information system. Within the past couple of years in Montenegro, integrated health information system has been implemented at a very high technological level, with a completely open platform for connecting key health care institutions with organizations dealing with insurance and with pharmaceutical sector.

The system has become operational in all 18 primary health care centres. As of July 2008, all primary health care centres have been sending to the Health Insurance Fund electronic invoices for the services provided.

Within the IT solution for stomatologists' performance, the IT support has also been provided to all stomatological clinics that signed contracts with the Fund on the provision of stomatological services. Conditions for the application and utilization of the advantages provided by ICT, which is the first and essential step to e-Health.

IT support, from the systems in which it has been implemented, also provides a range of benefits to other entities, such as providers of services (doctors and management) and the Institute of Public Health for the purpose of monitoring health status and keeping health statistics. Therefore, the data is provided for quality scientific and technical analyses that constitute the basis for pursuing health policy and passing strategic documents by the Ministry of Health in every country.

Additional Financing (DF)

Negotiations on Additional Financing of the Montenegro Health System Improvement Project (MHSIP) in the amount of EUR 5.100 million (US$6.765 million equivalent) between the Ministry of Health and the World Bank are currently in progress.

Montenegro Health System Improvement Project was originally financed by a credit in the amount of US$7.0 million[1]. The additional funds would support the expansion of activities started under the Montenegro Health System Improvement Project (MHSIP) to support health reform through the development of institutional capacity and policies in the areas of health finance, pharmaceutical policy, health policy and planning, as well as to provide further support for the phased implementation of the primary health care reform.

While MHSIP has been successful in establishing a legal and institutional base for the health sector and in starting to reform the primary health care system based on a model of a chosen primary physician, the reform of the health system still requires further institutional development and follow-up on the implementation.

The Project will support the health reform by including more focus on:

- Development of the information base,
- Strategy to reform the secondary and tertiary levels of health care,
- Establishment of a health quality assurance system,
- Further development of the capacity of the Montenegro Agency of Medicines and Medical Devices.

The Project will also scale-up and expand the implementation of the Primary Health Care sector development by supporting further investments in the human and capital resources of the PHC sector outside of Podgorica. Investing in the PHC system development outside of Podgorica is justified in order to bring the benefits of a strengthened PHC system to more of the citizens living outside of the capitol and to ensure that a strong national primary health system is established.

b) What was the scope of the previous reforms (since 1990)?

The health care system in Montenegro had, in the period preceding the reform, a range of weaknesses in its structure and the method of operation, which reflected in the health status of the population and, jointly with the economic factors that culminated in a long-term crisis, contributed to deterioration of health of the population and inefficiency of the health care system itself.

[1] At the time of Project Approval in 2004, the Project was agreed with the Republic of Montenegro within the union state of Serbia and Montenegro. Following its independence from Serbia in June 2006, the Republic of Montenegro became responsible for the Project and the Credit.

The health care system in Montenegro has been based so far on the principles of social justice, equality and availability, which provided the broadest scope of the rights to health care funded from public resources.

The critical reasons for the reform were the following:

- Increasing costs for health care resulting from aging of the population, increase in chronic diseases, increased requirements for more quality services, economic situation,
- Inability to provide for the needs for health care to the extent determined by the former Law on Health Care,
- Deterioration of indicators of the health status, primarily resulting from a decline in the quality of life, living standards and poverty,
- Underdevelopment of economic relations in health and financing of health activity featured by evidently low level of professional satisfaction and motivation of health workers for work,
- Excessive expenditure and liabilities of the Health Insurance Fund,
- Insufficiently regulated operation of the private health sector, without objective parameters relating to the effects of privatization,
- Underdeveloped information system to support health system management.

By adopting «**Health Policies in Montenegro Until 2020**» in 2000, Montenegro became a part of the integrated international process of following the documents of the World Health Organization “Health for All in the Twenty-First Century” and “21 Targets for the 21 Century”.

The health policy in the Republic of Montenegro until 2020 represents a basis for legislative, planning and action programmes with a view to increasing the efficiency and quality of health care, and integrating the health system of Montenegro in European and global health development process.

Strategy for Health Care Development (adopted in 2003) (Annex 218) set out in the said document is based on the increase in the quality of health of the population, jointly with the adjustment and improvement of the health system operation in accordance with financial capacity.

With a view to overcoming the above mentioned problems that existed in the health care system, a large-scale reform project titled "Montenegro Health System Improvement Project (MHSIP)" was launched, with the support of the World Bank through a credit package in the amount of US$7 million. MHSIP was approved by the Board of the Bank on 8 June 2004, and the credit became effective on 1 December 2004.

The contract that the Government of Montenegro signed with the World Bank stipulated that the project would be implemented in a four year period.

The Project comprised the following:

1. Support to improvement in financial sustainability of the health care system by strengthening institutional capacity and information systems for health policy, planning, regulation and management in the Ministry of Health, Health Insurance Fund, Institute pf Public Health;
2. Improvement in the quality, efficiency and access to primary health care services through investments in staff training, facilities and equipment, reform of the organization and financing of primary health care starting in Podgorica, and then scaling-up the reform outside of Podgorica country-wide;
3. Support to the Project Management Network under the Ministry of Health, and central Technical Support Unit responsible for carrying out procurement and financial management for this and other projects funded by the World Bank in Montenegro.

The Project defined the following key indicators to monitor the outcomes of the Project:

1. Prices of medicines reduced and common indicators for rational consumption of medicines improved;
2. Annual deficit of the Health Insurance Fund reduced until the end of the Project;
3. Reduced waiting time from arrival to consultaton in primary care;
4. Increased utilization rates and satisfaction for primary health care in Podgorica, for the Roma and internally displaced persons;
5. Reduced gap between primary health care utilization of the poor and non-poor;
6. Immunization rates for DPT and measles maintained or improved following reform;
7. Increased utilization of day care services by the elderly.

In order to achieve the health policy targets set, it was necessary to conduct a radical reform of the systems of health care and health insurance. For that purpose, important systemic laws have been enacted defining the general principles of health care, the system and organization of health care aiming at increase in efficiency and quality, compliant with the principles of democratic countries, and conditions have been created for health care improvement and stable functioning of the health system as a whole:

- Law on Health Care (Annex 208),
- Law on Health Insurance (Annex 207),
- Law on Medicines
- Law on Medical Devices,
- Law on Limiting the Use of Tobacco Products (Annex 214),
- Law on Protection of Population from Communicable Diseases,
- Law on Protection and Exercising of Rights of Mentally Ill Persons (Annex 213),
- Law on Health Inspection (Annex 209),
- Law on Health Data Collections (Annex 210),
- Law on Protection from Noise in the Environment (Annex 212),
- Law on Emergency Care (Annex 215),
- Law on Provision of Blood,
- Law on the Conditions and Procedure for Termination of Pregnancy.

The Law on Assisted Reproductive Technologies and Law on Taking and Transplantation of the Parts of Human Body for Treatment have been prepared and placed under the Parliament procedure for adoption.

With a view to providing conditions for efficient, rational and sustainable development of the health care system, the Ministry of Health, i.e. the Government of Montenegro adopted the Master Plan for Health System Development (for the period 2005-2010) (Annex 223) in 2004.

The plan is political in nature, since political consensus is necessary for the resources and methods for making decisions on the status of the health system. Namely, development of health care system may directly influence the decision to allocate a greater or smaller amount of resources for health from GDP, or to have different priority objectives and goals set, different time frames to achieve them, different definitions of solidarity and relations within the society, change in the method of organizing and financing health activity. Therefore, every plan for health care system also has certain political dimension. This stems from the fact that the health care system is an integral part of the society and may function only within the framework of the society, correlating with other economic, social and development trends. Health sector does not constitute expenditure, but an investment into enhancing social and economic development and overall development of the society.

General development objectives of the health care system in Montenegro are as follows:

- Development of health policy that should make citizens aware of health consequences of their own decisions and of their responsibility for health,
- Improvement to health care in the most acceptable and equality-based manner,
- Development of health system in line with the EU health development trends,
- Increase in the efficiency of the health system through rational and available resources,
- Improvement in the quality of services,
- Employment of modern health technologies,
- Financial stability of the system.

In the societies embracing social dimension, health care and health activity represent a public interest of the state. Therefore, pertaining development may not be abandoned to chance, ambition and deftness of certain clusters of service providers, or the rules of the market, but adjusted to the needs of the society. The supply and demand law characteristic for market relations and business activities is not fully acceptable and does not fully apply to the health care system. If the health care development were left only to service providers, i.e. the supply, that would lead to a imbalance, where the offer in some services would be excessive, whereas the offer in some other services would be scarce. It could occur that specific programmes of services are not found to be interesting (for financial or other reasons) by service providers (health institutions). It could also occur that preventive services, home visits, transfusiology, pathology, social medicine and some other activities may not be provided at all, while the offer in some services interesting to health professionals would be abundant. A large portion of the needs would never be fulfilled, or would be fulfilled under unacceptable conditions. The objectives of improvement of health, satisfaction of citizens and successful performance of the health system would not, therefore, be accomplished.

The basic concept of the health system reform builds on improvement of the primary health care that is rendered capable of providing health care services at the local level, that is family-oriented and the focus of the entire system of health care.

At the primary health care level, every citizen is enabled to register with a doctor of choice who monitors his/her state of health and refers him/her to higher levels of health care and who is motivated by the payment system to provide higher quality of performance.

Reform of the primary health care system is based on clear separation of the primary level from the secondary and tertiary levels of health care.

In accordance with the document of the Model for Primary Health Care System, chosen doctors are the agents of health care at the primary level and of the primary health system, since insured persons have the largest number of their needs fulfilled by their chosen doctors.

According to the model, there is a chosen doctor for adults (general practitioner, specialist in general practice, specialist in occupational medicine, specialist in emergency medicine and specialist in internal medicine), chosen doctor for children/pediatrician, chosen doctor for women/gynaecologist and chosen stomatologist.

The PHC system model provides for every insured person to choose one doctor through which he/she exercises rights arising from the basic package of health services. As a rule, one insured person may have only one medical record that is kept by the chosen doctor.

The chosen doctor for adults may be: general practitioner, specialist in general practice, specialist in occupational medicine, specialist in emergency medicine and specialist in internal medicine.

Chosen doctor provides services to insured persons who chose him/her 24 hours a day, 7 days a week and 365 days a year. If a chosen doctor is not able to provide services to his/her patients, being "outside" of the system of Primary Health Care Centre, he/she is obliged to provide replacement.

Pursuant to the Law on Health Insurance, the Government of Montenegro passed a Decree on the Scope of Rights and Standards for Health Care Arising from Compulsory Health Insurance.

This Decree outlines the scope of rights and standards for health care arising from compulsory health insurance that insured persons are entitled to under the Law. The scope of the rights and standards for health care comprises:

1. Medical measures and procedures for improvement of health, prevention, combating and early detection of diseases and other health disorders;
2. Medical check-ups and other types of medical assistance,
3. Treatment for the ill and injured and other types of medical assistance,
4. Treatment outside of Montenegro and abroad,
5. Prevention of and treatment for diseases of the mouth and teeth.

The reform project attached special importance to the functions of public health, with an emphasis on the prevention of chronic non-communicable diseases, such as cardiovascular diseases, smoking and consequences of smoking, protection and promotion of health of mothers, children, the young and the elderly. Many strategic documents have been adopted:

- Strategy for Improvement of Mental Health (Annex 217),
- Strategy for Preservation and Improvement of Reproductive Health (Annex 219),
- Strategy for Application of ICT in Health System,
- National Strategy for Tobacco Smoking Control (Annex 222),
- National Strategy for Drugs,
- National Strategy for HIV/AIDS,
- Strategy for Prevention and Control of Chronic Non-Communicable Diseases,
- National Strategy on Medical Waste Management,
- Strategy for Safe Blood (Annex 220),
- Strategy for Health Safety of Food (Annex 216).

Within the reform, it has been envisaged that the Health Insurance Fund provides financing of the basic package of health services, while all other services, as well as the price differences paid by insured persons through the participation fee system, will be covered by voluntary health insurance.

The planned changes in health care also include changes in the organization and operation of the Health Insurance Fund, as a part of the reform process. This particularly applies to health care planning and establishment of partnership relations with health institutions and workers. Experiences of countries indicate that reforms were successful only if accompanied by adequate financing and changes in this field. Having regard to the importance and responsibility of the Fund for the success of health care reforms and for the provision of financial sustainability of the health system, the Government of Montenegro adopted the Financial Plan for Sustainability for the period 2005-2010.

c) Are the reforms monitored and evaluated? If so, to which degree?

Primary health care reform is monitored through the indicators set.

Monitoring the results of the reform in 2004 and 2005 was partial, while in 2006, 2007, 2008 and 2009 it was performed in full due to introduction of the integrated information system in primary health care.

The Ministry of Health is responsible for monitoring and evaluation of the activities under the reform project (MHSIP).

Monitoring and evaluation activities have the following targets:

- Supervision and assessment of project outcomes and effects;

- Provision of a basis for making decisions on necessary amendments and improvements to the sectoral policy;
- Promotion of accountability for the use of resources, and
- Collection of feedback on the experience acquired in the process of monitoring and evaluation.

The project document defined key indicators (outcome indicators) for monitoring the project results as follows:

1. Prices of medicines reduced and common indicators for rational consumption of medicines improved;
2. Annual deficit of the Health Insurance Fund reduced until the end of the Project;
3. Reduced waiting time from arrival to consultaton in primary care;
4. Increased utilization rates and satisfaction for primary health care in Podgorica, for the Roma and internally displaced persons;
5. Reduced gap between primary health care utilization of the poor and non-poor;
6. Immunization rates for DPT and measles maintained or improved following reform;
7. Increased utilization of day care services by the elderly.

In November 2008, the *Project Appraisal Document* was developed, comprising an analysis of the above listed indicators. During the development of the report, the use was made of the results of public opinion polls that were conducted several times in different cities across Montenegro.

The reports showed positive results according to all indicators, as follows:

Indicator 1.

Prices of medicines decreased from EUR 2.28 per unit in 2004 to EUR 2.06 per unit in 2007 (fall by 10%), without adjustments for inflation. Following the adjustments for inflation made (realistic prices in 2004), the average price of the basket of high cost and high volume medicines decreased from EUR 2.28 per unit in 2004 to EUR 1.98 per unit in 2007 (fall by 13%). Resulting from the aforesaid, this project target has been achieved.

Indicator 2.

In the course of 2004, there was a suficit in the amount of 0.821,6 millon euro, while in 2005, the deficit increased to 2.444,7 million euro due to the large burden on the health system in the form of the costs resulting from the influx of refugees. Despite the fact that the Health Insurance Fund still suffers from the deficit in 2005 and 2007 in absolute value in euro, the deficit increase rate has significantly reduced. The trends indicate that it will take additional three to four years for the Health Insurance Fund to generate suficit. Resulting from the aforesaid, this project target has been partially achieved.

Indicator 3.

The share of respondents who reported „up to ten minutes of waiting“ considerably increased from 22% in 2004 to 39% in 2008 (rise by 77%), while the share of respondents who reported "more than 30 minutes of waiting" considerably decreased from 36% in 2004 to 22% in 2008 (fall by 39%). In addition, the category of "less than 30 minutes of waiting" increased from 64% in 2004 to 78% in 2008 (increase by 22%). This indicates an increase in the efficiency of appointments in Podgorica – PHC as a result of project actions. Resulting from the aforesaid, this project target has been achieved.

Indicator 4.

The utilization rate for PHC increased in Podgorica, in particular the utilization rate for the non-poor population and the Roma, compared to 2004 (baseline) and 2008. The utilization rate for the general population increased from 11.4% in 2004 to 34.7% in 2008 (increase by 204%), while for the poor population, the utlization rate increased from 11.9% in 2004 to 37.4% in 2008 (increase by

214%). Utilization rates for the Roma also indicate considerable increase from 15.7% in 2004 to 33.2% in 2008 (increase by 111%). This indicator was also calculated based on utilization rates for subcategories of population (the share of the poor who utilize PHC in the overall poor population, the share of the non-poor who utilize PHC in the overall non-poor population, and the share of the Roma who use PHC in the overall Roma population). Based on the aforesaid, we can see that, in respect of the share of the poor who utilize health care facilities in the overall poor population, the utilization rate increased from 24% in 2004 to 46% in 2008 (92%); with regard to the share of the non-poor who utilize health care facilities in the overall non-poor population, the utilization rate increased from 39% in 2004 to 49% in 2008 (26%), while in reference to the share of the Roma who utilize health care facilities in the overall Roma population, the utilization rate increased from 21% in 2004 to 39% in 2008 (86%). Resulting from the aforesaid, the utilization rates significantly increased for all subcategories of the population, particularlyb for the poor and for the Roma. This project target has been achieved.

Indicator 5.

Satisfaction of patients increased from 62% in 2004 to 66% in 2008, which represents an increase by only 6%. In mid-period (2006), there was even a decrease by 51%. The aforesaid year (2006) was also affected by a larger problem of refugees, which resulted in tremendous pressure on the health system of Montenegro in its entirety. The share of "partially satisfied" increased from 29% in 2004 to 31% in 2008, while the share of the "dissatisfied" decreased from 18% in 2004 to 3% in 2008 (fall by 83%). During 2006, it increased to 21%. Although it would be ideal to achieve a higher level of satisfaction, it is important to highlight that the category of the "dissatisfied" considerably decreased. Resulting from the aforesaid, the project target has been reached.

Indicator 6.

This indicator is a representative variable for measuring efficiency and quality of PHC. That is why the Project Appraisal Document (PAD) includes this indicator. From the above given table, we can see that the share of children who underwent immunization against DPT (initial and follow-up) increased from 86% in 2004 to 92% in 2007 (increase by 7%), while the share of children who received vaccines against MMR (initial and follow-up) increased from 82% in 2004 to 91% in 2007 (increase by 11%). Therefore, the project target relating to improvement of immunization rates has been achieved.

Indicator 7.

Palliative care has a broad meaning. Terminally ill patients, the ill with cancer, victims of stroke, patients with end-stage renal diseases, the ill with acute arthritis, etc. all fall under palliative care. The situation before 2007 was such that nurses went directly to the homes of patients (home care service) in order to provide palliative care. The current situation is such that the chosen doctor refers his/her patient in need of palliative care to the home care nurse. Based on such referral, the nurse will visit the patient at his/her home to provide the palliative care needed. Sometimes, catholic nuns are trained for this job. In Montenegro, as well as in most other countries in the Balkans, palliative care is not institutionalized and does not exist as a field of specialization in general practice. Patients in need of palliative care are treated by chosen doctors, or emergency care units of the Primary Health Centre. During 2007 (until March 2008), 1 272 old persons received palliative care. Until 31 December 2008, the share of old persons who were provided with palliative care increased by 12% (compared to 2007) to 1 425.

Project management, monitoring and evaluation are the responsibilities of the Project Management Network (PMN) that produces the Report on Monitoring the Progress on the Project and Action Plan for the following six months, on regular basis. Technical Services Unit (TSU) submits the Report on Financial Management produced within 15 days following the end of every quarter. The reports are produced in a timely fashion.

The PMN Coordinator had regular weekly meetings with working groups, with the coordinators for respective components of the project and with the relevant staff of the Ministry of Health. Meetings were also held with directors of the relevant agencies, if needed. In 2007 (mid-period), working groups were dissolved, and the PMN Coordinator and coordinators for respective project components currently have direct communication with directors of the relevant agencies.

The Minister of Health formed Project Steering Committee (PSC) with full participation of the representatives of the agencies (with minutes kept). The project document envisaged that the meetings would be held once a month. Subsequently, it was decided that the PSC would have two meetings a year. However, there have been more meetings held, the minutes of which were kept. There were eight meetings during 2007, and four meetings in the course of 2008.

d) What part of the health care system should be reformed?

In Montenegro, the health capacity at the secondary and tertiary levels is not divided in terms of organization. The existing network of health institutions at the secondary and tertiary levels needs reform and re-organization in order that the maximum efficiency, safety and quality of secondary health care may be achieved.

Secondary level activity comprises acute hospital processing and specialist-clinical activity. By international standards, the number of beds is not large and neither corresponding to demographic and epidemiological trends and changed needs of the population.

Analyses of possible solutions will determine the final decisions on the issues of regionalization, networking, establishment of day hospitals, non-acute wards, palliative care and other matters, which will be the subject of revision of the Master Plan for Health System Development that is in progress and expected to be finalized until the end of 2009.

With regard to specialist - clinical processing, referrals from the primary to the secondary level of health care depend on a number of factors such as: age structure of population, current guidelines for patient processing at the primary level, gravity of the state of a patient, public network or available resources (human, financial and material resources). Trends in intensive, integrated, safe, quality and efficient processing of patients urge the development of clinical and specialist activity as a priority.

In the following period, it will also be necessary to define re-deployment of doctors and nurses within the specialist activity. If it is assessed that the needs of citizens in the public health care system are not provided for in a satisfactory manner, as well as that waiting time is longer than professionally acceptable, private doctors will be approached to become integrated in the public network. This solution as to private-public partnership will be the subject of changes and amendments to the Law on Health Care.

With regard to hospital wards, it will be required to provide for rendering of services 24 hours a day without intermissions, in addition to all cases of emergency, and to meet the criteria for quality, safe and efficient processing. It will also be required in this respect to define the minimum number of patients per year for justifiable quality and efficiency of performance, the number of hospitalized and clinically processed patients (per 1,000 population), fields of respective specializations, the average number of patients to be processed by one medical team per year, the size of the catchment area of the hospital, the length of the waiting list for specific health care services, etc.

The original Montenegro Health System Improvement Project provided a strong institutional, legal and regulatory base for the health system including the basic laws of the health system, the institutional development of the health insurance system and the key components of defining, organizing and financing the primary health care system

However, as mentioned above, many important aspects of a well-functioning health system still need to be addressed. Towards this end, it is expected that the Additional Funding (AF) in the following two years will mainly support three current priority health policy reforms.

First, and most importantly, it will provide technical assistance and training to support the development of a secondary and tertiary care health sector reform strategy. The components of this reform will include:

- The plans and normative for the health network;
- Defining the package of services financed by the state (and those that are not financed);
- Defining an output-based (i.e. Diagnostic Related Groups, or DRGs) payment mechanism and contracts between the providers and insurer;

- Developing the priority clinical guidelines to ensure effective and efficient delivery of the state financed services;
- Determining models of public and private cooperation in the delivery of health services;
- Using communications and information to ensure stakeholder involvement and acceptance of the reform strategy.

However, the components will not necessarily be limited to the above listed.

The second reform area is to further develop the institutional capacity of the Montenegrin Drug Agency responsible for the oversight of the pharmaceutical sector. Specifically, the arrangement with the World Bank in the form of Additional Financing is expected to provide support through technical assistance, training, and information system support to enhance the Drugs Agency capacity. The third priority is to initiate the establishment of a quality assurance system. By virtue of amendments to the organization of work and systematization of jobs in the Ministry of Health, it has already been provided for the possibility of forming a separate sector and a department the primary duty of which will be to establish a health quality assurance system. With reference to the aforesaid, technical assistance and training would be provided in order to develop local capacity and for the Ministry of Health to determine the quality assurance strategy suitable for Montenegro

The activities under the Additional Financing aiming to develop the strategy and information base for the reform of the secondary and tertiary care sector build on the lessons learned during the original Project in terms of the how to develop the sector reform strategy, as well as on international (notably EU and regional) experience. Notably, this experience includes:

(i) Reforming the hospital sector based on a strong primary health care system;

(ii) Establishing the information and technology base for developing a payment reform, which will allow to measure, monitor and boost productivity (i.e. including incentives for outputs);

(iii) Developing the guidelines and quality assurance system necessary to counter-balance the productivity incentive.

e) In particular, what eHealth strategy exists in the country? How embedded is it with the overall health strategy and with the strategic orientation and investment plans in health? In particular, how does it (plan to) contribute to patient safety, healthcare quality (measurement and improvement), health professionals' efficient use of time and coordination of care?

The importance of the development of e-Society (e-Government), including e-Health in its framework, in Montenegro was recognized in 2004, when the Government of Montenegro adopted the Strategy for Development of Information Society – a Path to a Knowledge-Based Society. Today, one of the strategic priorities of Montenegro in particular reflects in the application of information and communication technologies in the implementation of all development strategies of Montenegro, since ICT provides great opportunities and has an overall impact on national economies and global competitiveness. Having regard to the importance of the use of information and communication technologies, the Government of Montenegro, i.e. the Ministry of Information Society, passed a Strategy for Development of Information Society in Montenegro from 2009 to 2013 (http://www.gov.me/files/1235731125.pdf).

As a part of the Strategy, there is a Chapter 9 - e-Health that is aligned with the strategic documents on health system development (Strategy for Development of Health Care in Montenegro http://www.gov.me/files/1170680229.doc and Strategic Development Plan for Health Insurance in Montenegro untill 2011

http://www.fzocg.me/docs/175/strateaki_razvojni_plan_zdravstvenog_osiguranja_crne_gore_do_2011.pdf).

The body responsible for the activities as to development and application of information and communication technologies (ICT) in the health system is the Health Insurance Fund, the development and investment plans of which comprise the development of an integrated health information system.

Strategic priorities in establishing e-Health are the following:

- Establishment of basic information infrastructure in the health system and creation of organizational, human resource and technological prerequisites for the development of information system, definition of basic collections of health and social data for establishing and keeping electronic documentation on the patient, which is a base for defining electronic medical record;
- Definition of safety and technological standards for safe communication, management and storage of data in the health system;
- Development of an integrated health information system;
- Integration of all health and social information systems into one common information system through the development of an electronic portal.

The application of ICT in the health care system (e-Health) improves efficiency, results and quality of medical and business procedures conducted by relevant institutions, professional staff, users, insurance companies and the state in the view of improving patients' state of health. The position and role of the user in this process have changed and now he/she has a central - active role, instead of the passive role he/she has had until now.

E-Health is of great importance to the development of a country. It has the capacity to improve access to health care and increase the quality and efficiency of services offered.

At the beginning of 2009, an integrated information system started being implemented in the health system of Montenegro, whereby all service providers at the primary level were connected. This provides for the application of electronic prescriptions, electronic referrals, electronic certificates for sick leave and electronic delivery of all invoices at the PHC level to the Fund.

In respect to the method of integration of business procedures, quality of technological solution and organization of health information system, according to the assessment of many relevant entities, this system is unique in the region, and probably even wider!

By recording services at the place of their being delivered (all organizational unit locations) and defined indicators for the assessment of quality of performance, all conditions have been created for in-depth analytical monitoring of operations of all teams and centres, i.e. of all organizational units.

Taking into consideration the fact that doctor's work and decisions he/she makes require a whole range of information on the state of health of a patient, from birth until the end of life of the patient, even on his/her social status, habits, risk factors, etc, such a system has been developed to collect the information on a patient and store it in one place, irrespective of when and in which part of the system the information was entered.

The data may be accessed at the locations of service delivery, up to a level within the authorization of the person who has access to the data.

Therefore, a common electronic medical record for every insured person in Montenegro has been provided at the primary level.

The access to the data is secured through several levels of protection and security policies, which provides for a high level of security of data. Through the implementation of the health insurance card project, which has been planned for 2011, an even higher level of security of access to data in the system will be provided, which will contribute to the compliance with the regulations on protection and privacy of data.

The application supports all business procedures that fall under the scope of work of a chosen doctor. For the first time, ICPC2 - International Classification of Primary Care, Second edition, which is recommended by WONCA (World Faily Doctors Association) and implemented in only few EU countries, is being introduced in the health care system in Montenegro. This provides for the possibility of reporting on and monitoring of the state under this classification as well, even though the official classification is ICD10 and therefore the two classifications are fully inter-related.

The data that a doctor enters into the system during the contact with a patient is reduced to a minimum. At the moment of the end of the contact, by confirming all the data entered, the doctor has fulfilled obligations towards all stakeholders in the system, which he/she is bound by the regulations governing health records.

This reduces to a large extent the time that the doctor used to spend on administrative procedures necessary for reporting.

The reform concept highlights the importance of preventive activities and urges planning based on quality data and evaluation of the results achieved. Information system provides all data necessary for planning, no matter if the data pertains to demographic situation, or to the patient's state of health, or even to the use of resources and equipment.

This contributes to the possibility of measuring performance of doctors and staff at the primary level against the indicators set, and having their time used in an efficient manner, with mutual coordination of activities in certain business procedures.

f) How is Health in All Policies being incorporated as a horizontal priority?

The Government of Montenegro defined its priorities within the development objectives of Montenegro, one of which is preservation and improvement of health of the population.

The Constitution of Montenegro guarantees to all citizens equal rights and enjoying ad exercising all human rights, as well as the right to health protection. Democracy and human rights stem from the principle that the right of every human being to life is inalienable and inviolable; that all human beings are born equal and have inviolable rights such as the right to life, freedom and the right to happiness. Formulation of the principles of development of all segments of the community requires respect for the rights of the population to life and health.

In accordance with these strategic commitments, the health policy and documents of the Government of Montenegro, such as Master Plan for Development of Health System in Montenegro 2004-2009, a stand has been taken that better health of the population will not be achieved if it is a concern of the health service only. It is therefore necessary to plan the required measures outside of the health care system as well. Hospitals, primary health care centres and pharmacies do not build health, but prevent and treat for diseases that develop in social and natural environments in which a person lives and works. Environmental health determinants are not subject to any influence of the health service and produce both positive and negative effects on the population. Health service activity may not settle the issues of the preservation of the environment and environmental pollution, safety in traffic, safety at work, provision of housing conditions, employment, education of people, solving social problems and poverty, alcoholism and other diseases of addiction.

All the aforesaid factors have significant roles and impact on health. Therefore, better health and quality of life do not fall only under the competence of the Ministry of Health, but are also the responsibility of other sectors, i.e. the Government and the Parliament. Accomplishment of tasks and responsibility as to the state of health of the population depend on the approach to solving the above mentioned problems. These principles were followed during the development of the Master Plan that comprises specific commitments and orientations towards the development of those areas that influence more considerably the changes in the state of health of the population:

- Planned commitments towards the improvement of health are acknowledged in the enactment of laws and other regulations, and it is provided for them to be put into practice;
- Activities aiming at the promotion of better health, whereby the society as a whole will come to realize the background and purpose of such legal and planning measures;
- Government activities for the creation of a positive environment and conditions for achieving better health of the population and ensuring equity in all areas of social and health protection for all population.

The documents of the World Health Organization and of the European Union serve as a guide for the changes and activities necessary to achieve better health in Montenegro.

A range of issues arising from different areas of non-health activities, where changes should occur, are related to investments, i.e. economic capacity that direct effects on health will depend on. For this reason, the required changes planned are not acceptable and feasible in the short term. It is the fact that better health is always and everywhere in the world associated with material resources. Still, there is a range of the activities that could produce a more significant impact on the improvement of health, without requiring new or larger financial investments. In some other areas, where larger investments are still required, they should not be seen as expenditure, but as an investment into human resources that will return with enhanced productivity and higher generated income, which already constitutes a contribution to better health, economic development and better opportunities for development of other sectors.

In accordance with the development policy adopted and being aware of the influence of environmental determinants on health and of the responsibility for the health of the population, the Government pursues an active policy aiming at better health, which is carried out through the implementation of laws and different measures in all spheres of life.

Within these lines, the Ministry of Health has initiated, and in collaboration with other responsible authorities, prepares and implements adequate regulations in the areas of:

- Education, for the introduction of health education in primary and secondary schools, as a separate subject or/and incorporated in another teaching programme. Children and youth (and especially their parents) should develop basic knowledge and habits relating to a healthy life style, personal hygiene, proper diet, physical activity required, prevention of diseases and injuries, sexual behaviour, diseases of addiction (alcohol, drugs, smoking) and harmful effects thereof, etc. Another task of the education sector is to increase the level of general education, to provide acquisition of broad knowledge to the greatest possible number of population and to eradicate illiteracy, since it is a common fact that the state of health is poorest among the illiterate and persons with low level of education. It is very important to underline that the Ministry of Health liaise with the Ministry of Education on almost all of its projects, in order that the activities of providing information and education are as successful as possible;
- Traffic safety, for further implementation of the regulations passed governing the obligations of cyclists and motorcyclists (and their passengers, especially children) in respect of wearing helmets, compulsory use of separate seats for small children in cars, compulsory use of safety belts by all passengers in cars and on line buses, limiting carbon monoxide in car exhaust gases, limiting alcohol in blood of the participants in traffic, prohibition of driving under the influence of drugs, etc. In addition, the Ministry of Health advocates a more consistent control of and sanctions for the lack of compliance with traffic regulations, which may per se reduce the number of accidents and health insurance costs, and contribute to the improvement of health;
- Ecology, to encourage promulgation of and consistent compliance with the regulations on preservation of natural environment from pollution, and prevention of interventions that are most harmful to the health of the population. The Ministry of Health, jointly with other competent authorities responsible for ecology, public utilities and agricultural activity, advocates safe disposal of waste substances, especially of municipal waste and wastewater, prevention of pollution of drinking water sources and stricter supervision of the use of pesticides and herbicides in agriculture, stricter supervision of the quality and safety of foodstuffs and of exhaust gases from all sources. The Ministry of Health will particularly insist on consistent compliance with the Law on Limiting the Use of Tobacco Products in public places: at kindergartens, schools, hospitals, in-door sports centres and other large gathering places, public services and offices, public transport and all places where a larger number of people gather;
- Social policy, which implies creation of an adequate social network and support for the provision of optimum conditions for the development of the community. In addition, it involves provision and implementation of conditions for an environment committed to pursuing active employment policy, exploring possibilities for the creation of new jobs and boosting development of small enterprises, special care for the »marginal groups« of

population, for elderly and disabled persons, those who are lonely, feeble, unable to move and in need of other people's assistance in performing everyday activities, for the socially handicapped, for retired persons with lowest pensions and for the implementation of the Strategy for Poverty Reduction. All the aforesaid for the reason that weak economic position and poverty of the individual and the family are the largest cause of disease and poor state of health. The measures will be implemented to the extent of economic development;

- Tax policy that will, through lower tax rates and other facilities, encourage enterprises, employers and citizens to engage in the activities (services), production, manufacture and consumption of commodities that are useful for the improvement of health, or at least are not harmful, and exempt from taxation some business activities, services and products that are necessary for preservation of health. Tax rates will continue to increase for the products that are harmful to health, such as tobacco products, alcohol, foodstuffs with a high share of animal fats and sugar, production and commodities that pollute the environment. Through adequate tax policy instruments, the Government will support social policy and give a contribution to the reduction of poverty and resolution of the gravest social problems that result in to poor health;
- Life styles and living habits, with the activities aiming at better provision of information to citizens and their engagement in the efforts to abandon bad habits that represent external factors of risk and are associated with the »epidemic« of chronic degenerative diseases. With reference to the aforesaid, measures are being taken to increase individual responsibility of citizens for their own health and health of other persons. A special stress is placed on the need to reduce the level of smoking among the population, to decrease, i.e. limit the consumption of alcoholic beverages, to prevent drug addiction, to increase the level of physical activity and recreation, to modify nutrition, to control body weight, etc. Montenegro became the second country in Europe that passed a regulation to limit smoking in public places through the adoption of the Law on Limiting the Use of Tobacco Products. The Ministry of Health will propose actions to limit the use of alcohol by younger persons, in the vicinity of schools and in other locations. Apart from the aforesaid, an effort will be made to start the activities and introduce the programme for "Healthy Cities" in Podgorica and other cities of Montenegro. All health strengthening programme activities, which for the most part relate to changes in the living habits of the population, will be coordinated by the Institute of Health in terms of their content, whereas participation in the implementation of the programme will also be taken by primary health care centres' units for improvement of health, non-government organizations, humanitarian and variuos other associations of the ill, the disabled and other citizens and local community. In schools, preventive check-ups of students are performed on a regular basis and measures for specific prevention are conducted, as well as the supervision of the space where children spend their time and of the food that they receive while staying at those institutions (kindergartens, schools).

In addition to the above mentioned, it is important to emphasize that a range of strategies have been developed at a inter-sectoral level, which outline the principles of health care for the population from the perspective of overall development of the country. Namely, health must be an integral part of the objectives of other segments of the society. Such strategies include the Strategy for Sustainable Development, Strategy for Poverty Reduction, Strategy for Tobacco Control, Strategy for the Prevention and Control of Chronic Non-Communicable Diseases, Strategy for Medical Waste Management, Strategy for Safe Blood, Strategy for Health Safety of Food, Strategy for Improvement of Mental Health, Strategy for the Preservation and Improvement of Reproductive Health, Strategy for Application of ICT in Health System, National Strategic Response to Drugs, National Strategy for HIV/AIDS and other strategies.

g) How is Health being considered for the future drafting of a national strategic reference framework for the use of structural funds?

National strategic reference framework for the use of structural funds has not been prepared yet. The role of Health will be subsequently defined in accordance with the recognized priorities defined

in strategic documents of the Ministry of Health and in the Master Plan for Health System Development.

h) What kind of healthcare quality indicators are used in your country?

The issue of quality in the health system is differently addressed by professionals and users of their services. For doctors, the quality implies quality diagnostics, therapeutic and technological capacity for their performance, results of treatment, i.e. accuracy of diagnoses. By quality, patients refer to the attitude of health workers towards patients, conditions of hospital accomodation, time of waiting for check-ups or interventions, respect for their rights, etc.

One of the objectives of health system reform in Montenegro is to increase the quality of performance in the health system, for which it is necessary to approach the development of quality indicators for all health care activities, in collaboration with health institutions, Institute of Public Health, Chamber of Medicine, etc.

Master Plan for Health System Development sets out the following indicators as general indicators for quality of health care activities:

- Ratio between initial and follow-up visits per respective health departments,
- The shares of undefined conditions at the point of discharging patients and of conditions with symptoms:
- The share of inaccurate diagnoses,
- The shares of antibiotics prescribed in respective health departments and for respective diagnoses,
- The share of preventive visits conducted and of preventive services delivered,
- Length of treatment and of medical condition,
- Numbers and shares of respective hospital infections,
- Number of relapses and re-operations,
- The share of persons covered by immunization.

The above listed quality indicators and the status thereof are monitored by the Institute of Public Health through annual analyses of performance of health service per health care level.

i) How are the different health stakeholders, in particular health professionals and patients, involved in the definition, validation, implementation and evaluation of healthcare strategies? What governance mechanisms are set in place for such purpose?

Ministry of Health formed working groups for respective areas of public health, which consist of, apart from the representatives of the Ministry, the representatives of other ministries and Government institutions, business organizations, as well as the representatives of the non-government sector and non-government organizations that are engaged in the activities relating to a specific area of public health. Working groups and committees of the Ministry of Health define strategic documents and monitor the implementation of the documents through programmes and action plans.

Each working group is chaired by the coordinator of the working group, and in most cases, coordinators are the focal points appointed for cooperation with the World Health Organization and other international organizations, who are experts in given fields.

Working groups and committees of the Ministry of Health define strategic documents and monitor the implementation of the documents through programmes and action plans. The public is also included in the process of adopting legal and strategic documents through public debates organized during the development of each of these documents. The programme of a public debate is announced in the media and this mechanism provides for the wider public to become informed and involved in the process of adopting documents.

39. What share of the mental health services is provided within institutions? Are there other ways to get treatment (community based care)? What are the selection criteria's for admission to and release from institutions? Who develops treatment plans? What are the patients' rights?

Basic documents relating to mental health are the Strategy for Improvement of Mental Health, adopted by the Government of Montenegro in May 2006, and the Law on Protection of the Rights of the Mentally Ill (the "Official Gazette of the Republic of Montenegro", No. 32/05). The Strategy outlined a vision of the development and improvement of mental health in accordance with the WHO recommendations for the development of community-based psychiatry.

Institutions provide the following services relating to mental health:

- Hospital – inpatient care, provided in Specialist Psychiatric Hospital in Kotor, the Psychiatric Clinic of the Clinical Centre of Montenegro in Podgorica and in the Psychiatric Ward of the General Hospital in Nikšić - with the total capacity of 311 beds. In accordance with the above mentioned Strategy, the number of beds in Specialist Psychiatric Hospital in Kotor has been reduced over the last couple of years from 303 to 241 beds;
- Non-hospital - outpatient care, provided in Centres for Mental Health, mental health units within primary health care centres and in private psychiatric practice.

Certain number of mental patients is still accomodated on a long-term basis in Specialist Psychiatric Hospital in Kotor, where some of them remain until the end of their lives. Such manner of providing care reflects the negative attitude of the immediate family environment that should constitute support in the process of treatment and rehabilitation.

With reference to the aforesaid, Specialist Psychiatric Hospital, as a largest psychiatric institution in the country, in collaboration with the NGO Global Initiative on Psychiatry, within MATRA programme, implements the project "Towards Inclusion of People with Mental Disability ", which comprises the following activities:

- Development of a psycho-social rehabilitation programme,
- Public awareness,
- The development of a patient council,
- Development of an implementation plan for the National Mental Health Strategy
- Setting up a non-governmental organization.

Mental health centres and units for mental health in primary health care centres mainly operate based on day care services, while they are still not rendered capable of providing home-based care and rehabilitation, i.e. assistance in cases of crises.

In respect of the diseases of addiction, in all major cities in Montenegro, there are offices for the prevention of diseases of addiction and other risky behaviours and non-government organizations that promote healthy life styles, while in 2008, in Podgorica, the Centre for Psychosocial Rehabilitation of the Addicted to Psychoactive Substances, Kakaricka gora, started to operate, and psychosocial rehabilitation lasts for one year.

In Montenegro, there are clubs of treated alcoholics in Herceg Novi and Nikšić, the regular activities of which include public discussions on alcoholism, establishment of contacts wih alcoholics' families, field visits and promotion of healthy life styles through media presentation.

The selection criteria for admission to and release from institutions primarily refer to current state of mental health of the person with a mental disorder (deterioration/improvement) and objective social and family circumstances (capacity/the lack of capacity) relating to re-integration in the community and further psychosocial rehabilitation.

Planning treatment and treatment are approached through teams, for each patient respectively and depending on manifested pathology. The team, apart from doctors (neuropsychiatrist/psychiatrist and, if neded, other medical specialists) consists of a psychologist, social worker, occupational therapist and nurse.

Patient rights are provided for under the *Law on Protection and Exercising Rights of the Mentally Ill (Art.18 - 28):*

Article 18

A mentally ill person who is placed in a psychiatric institution shall have the right to:

1. Become acquainted with his/her rights at the time of admission and later at his/her express request, and to be instructed on how to exercise his/her rights, in a manner and language he/she understands;
2. Become acquainted with the reasons and purpose of his/her placement, as well as with the purpose, nature, consequences, benefits and risks of the proposed type of treatment and other possible types of treatment;
3. Take an active part in planning and carrying out of his/her treatment, recovery and re-socialization;
4. Receive education and training for work according to the general and special programme for mentally ill persons with development and learning difficulties;
5. Submit an objection to the authorized person in the psychiatric institution, as well as to the independent multidisciplinary body, referring to the method of treatment, diagnostification, discharge from the institution, and violation of his/her rights and freedoms;
6. Without surveillance and constraints, submit requests and lodge objections, complaints and other legal remedies to the competent judicial and other state authorities;
7. Have consultations, at his/her own expense, in private with the doctor of medicine or a lawyer of his/her own choice;
8. Socialize with other persons, engage in recreational activities and participate in work therapy activities in accordance with his/her abilities, and receive visitors;
9. At his/her own expense, send and receive, with full respect for privacy, without surveillance and constraints, mail, parcels, newspapers, and make telephone calls;
10. Listen to radio and watch TV programmes;
11. Keep with himself/herself objects for personal use;
12. Be accommodated and sleep in a room separate from a person of the opposite sex;
13. Express his/her religious beliefs, within the possibilities provided by the psychiatric institution;
14. Ask for a transfer to another psychiatric institution;
15. Be discharged from a psychiatric institution with a safe support for acceptance in the community.

Information from paragraph 1, items 1 and 2 of this Article shall be entered into medical documentation of the metally ill person.

The rights from paragraph 1, items 1, 2, 3, 5, 6, 7 and 14 of this Article, may be exercised by the members of the family and by a representative of a mentally ill person, on behalf of the person.

The rights referred to in paragraph 1, items 8, 9, 10 and 11 of this Article, may be limited when there is a reasonable suspicion that the mentally ill person intends to obtain weapons, narcotics or psychoactive substances, colludes to escape, plans to commit a crime, or when so required by the health state of the mentally ill person.

Article 19

Treatment of a mentally ill person, when the need for such a treatment is determined in accordance with the law, shall be carried out in a psychiatric institution located in his/her place of permanent residence or, if the person does not have a place of permanent residence, in his/her place of temporary residence or, if the person does not have a place of temporary residence, in the place where he/she was found.

In the event that there is not any psychiatric institution in the place referred to in paragraph 1 of this Article, the treatment shall be carried out in the nearest psychiatric institution determined in accordance with the Law on Health Care.

Treatment of the mentally ill person may be carried out in another psychiatric institution, with a written consent of the person, i.e. of the legal guardian of the person who has been divested of his/her capacity to exercise rights or of juvenile mentally ill person, pursuant to the provisions of Article 14, paragraph 1 and Article 15, paragraphs 2 and 3 of this Law.

Article 20

Treatment of juvenile mentally ill persons in a psychiatric institution shall be carried out separately from the treatment of adult mentally ill persons.

Article 21

Electroconvulsive or hormonal therapy may be applied only under the following conditions:

1. Based on the written consent of a mentally ill person or, if the person is not able to give a consent, based on the written consent of his/her legal guardian;
2. With positive opinions of at least two psychiatrists on the necessity and consequences of the application of such medical procedure;
3. If all other treatment methods have been previously exhausted;
4. If the application of the above mentioned treatment method is necessary for the treatment of the mentally ill person, and
5. If it is not expected that the application of the above mentioned methods could have adverse side effects.

Electroconvulsive treatment may be applied to a person with a severe mental illness who was forcefully detained or forcefully placed in a psychiatric institution, even without a consent of the person or his/her legal guardian, only with the approval of the ethical committee of the psychiatric institution and under the conditions referred to in paragraph 1, items 2, 3, 4 and 5 of this Article.

Application of the treatment referred to in paragraphs 1 and 2 of this Article shall be entered in the medical documentation jointly with the written consent of the mentally ill person or his/her legal guardian, opinions of at least two psychiatrists and approval of the ethical committee of the psychiatric institution.

It shall be prohibited to apply electroconvulsive or hormonal treatment to juvenile mentally ill persons.

Article 22

It shall be prohibited to apply sterilization of mentally ill persons.

Article 23

Psychosurgery and other irreversible methods may be applied to mentally ill persons under the conditions referred to in Article 21, paragraph 1 of this Law.

Methods referred to in paragraph 1 of this Article may also be applied without a consent of the mentally ill person or his/her legal guardian, only with the approval of the ethical committee of the psychiatric institution.

Within the meaning of paragraph 2 of this Article, psychiatrist shall notify the independent multidisciplinary body on the application of the methods.

It shall be prohibited to apply psychosurgery and other irreversible methods to juvenile mentally ill persons.

Article 24

Biomedical research on mentally ill persons may be carried out if:

1. There is not any other appropriate method of research on people;

2. The risk of the research on mentally ill persons is not unproportionate to the benefits from the research;
3. The research project has been approved by the public administration body competent for health-related issues (hereinafter referred to as: the competent body of the public administration), following an independent review of scientific importance, significance of the purpose and ethics of the research itself;
4. The persons who participate in the research are informed of their rights and legal protection they enjoy;
5. The persons who participate in the research have given a written consent that they may withdraw at any moment.

Biomedical research on a mentally ill person who is not able to give a consent may be undertaken under the conditions referred to in paragraph 1, items 1 to 4 of this Article and Article 15, paragraph 2 of the Law, and provided that:

1. It is expected that the results of the research will be of real and direct benefit to the health of the person, and
2. Ethical committee of the psychiatric institution gives approval for each respective case if the purpose of the research is to contribute to better understanding of a particular illness or condition, to provide a benefit to the person who participates in the research or to the persons of the same age suffering from the same disorder, if the research represents the least possible danger and burden to that person.

The biomedical research referred to in paragraph 2 of this Article may be carried out only if it is not possible to carry out this research on mentally ill persons who are able to give their written consent by themselves.

It is prohibited to carry out biomedical research on juvenile mentally ill persons.

Article 25

Psychiatrists, mental health care workers, mental health associates and other persons who perform the activities relating to protection and treatment of mentally ill persons shall keep, as a professional secret, everything they learn or observe while performing those activities.

The persons referred to in paragraph 1 of this Article may disclose what they learnt or observed during the examination of a mentally ill person only with the approval of the person or his/her representative, in accordance with the provisions of Article 14 of this Law.

By way of exception, the persons referred to in paragraph 1 of this Article may, without the approval of the mentally ill person, but with the approval of his/her representative, also disclose what they learnt during the treatment and care provided to that person:

1. To another psychiatrist or doctor of medicine, if that is necessary for providing medical care to that person;
2. To the official staff at the centre for social work and within the state authorities, when necessary in order that they may conduct a procedure in relation to the mentally ill person arising from and within the limits of their power, only in the event that the mentally ill person is not able to give a written consent, and the persons referred to in paragraph 1 of this Article are convinced that the mentally ill person would not object to disclosing such information;
3. It is necessary to do that in public interest or in the interest of another person, pursuant to the Law on Health Care.

In the event referred to in paragraph 3 of this Article, only the information required for fulfillment of the purpose for which it has been admitted to disclose the information may be disclosed and shall not be used for other purposes.

Clinical and other materials used in lectures or in scientific publications must conceal the identity of a mentally ill person.

Article 26

Medical documentation shall be kept on all medical procedures undertaken in the treatment of a mentally ill person, pursuant to the law.

Article 27

Medical documentation on the treatment of a mentally ill person shall be available to the court for the purposes of a proceedings.

The medical documentation referred to in paragraph 1 of this Article may contain only the data necessary for fulfillment of the purpose for which the submission of the documentation has been requested.

Statements of a mentally ill person, which are contained in the medical documentation, may not be used as evidence in the court proceedings.

The data from the medical documentation which is necessary for exercising the rights of a mentally ill person, may be provided for official purposes on request of the competent bodies only with the approval of the person, and if the person is not capable of giving an approval, only if there is a reasonable assumption that the mentally ill person would not object to the provision of the data.

A mentally ill person shall be entitled to have an insight into his/her medical documentation, provided that it would not have a serious impact on deterioration of his/her state of health or on the protection of other persons.

Article 28

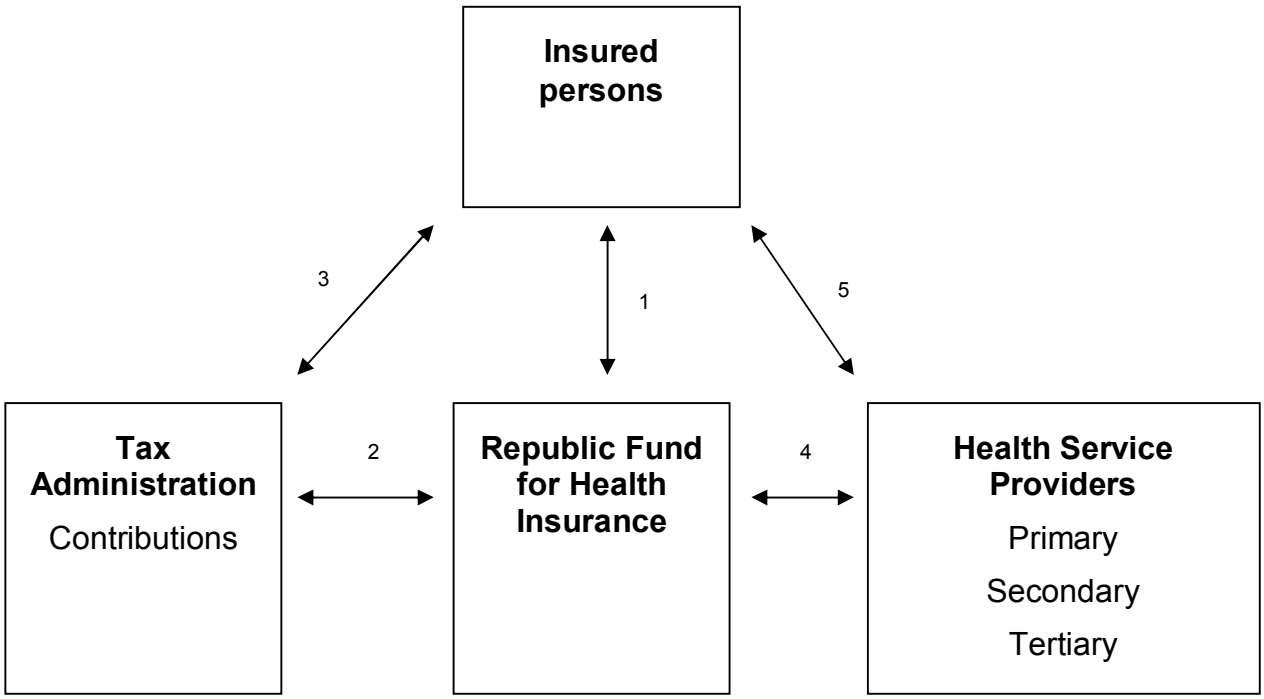
A psychiatrist may approve of the conversation between a mentally ill person placed in a psychiatric institution and the official staff of the administration body competent for internal affairs and professional workers in the centre for social work, only when the state of health of the mentally ill person provides for that.

A psychiatrist may not approve of the conversation between the persons referred to in paragraph 1 of this Article and the mentally ill person who is not capable of understanding his/her condition, or the consequences of such a conversation.

40. What are your current health expenditures, as a percentage of GDP, and in absolute terms (in Euro), and how are they structured, including the amount spent in the public sector and the private sector, the amount spent on prevention, and health promotion?

The concept of financing compulsory health insurance in Montenegro has been developed in such a manner to be available to all social strata.

The health insurance system builds on the principle of mutual adjustments to the interests of insured persons, payers of contributions and the rights provided for under the law. In exercising public authority, the Health Insurance Fund of Montenegro (RHIF) is the entity competent for compulsory and voluntary health insurance in Montenegro and it is obliged to provide for the rights of insured persons within financial possibilities. Insured persons exercise their right to health care in health institutions that RHIF has concluded contracts with. Legal liabilities of the payment of contributions are consolidated at the Tax Administration of Montenegro.



KEY:

1. Provision of health insurance, management, organization
2. Contribution payment methods
3. Collection of contributions
4. Contractual relations and payment mechanisms
5. Provision of health care services

The basis source of funding compulsory health insurance are contributions. Apart from contributions, RHIF generates resources from the general revenues of the national budget, resources arising from conventions, indemnities, interests and other sources in accordance with the law.

Payers of contributions, bases and rates of contributions, payment time limits and other matters relating to the payment of contributions for compulsory social insurance are set out in the Law on Contributions for Compulsory Social Insurance (the Official Gazette of Montenegro 13/07 and 79/08). Contributions for compulsory social insurance, for the purpose of the aforesaid law, include: contribution for compulsory health insurance, contribution for compulsory pension and disability insurance, and contribution for unemployment insurance.

Contributions for compulsory health insurance constitute the revenue of Montenegro Health Insurance Fund.

The Law on Contributions for Compulsory Social Insurance provides for the rates at which the contribution for compulsory health insurance is paid on the base prescribed, and the rates are as follows:

- The rate of contribution for compulsory insurance of the employed in 2009 is 10.5%, of which 5.5% to the debit of the employer and 5% to the debit of the insuree, while the law provides for further reduction to 9% in 2010, of which 5% charged to employer and 4% charged to employee.
- The base for the payment of contribution is salary, i.e. compensation of salary in accordance with the law, collective agreement and employment contract, where the base may not be lower than the lowest monthly contribution base. The lowest monthly contribution base is the basic salary on which contributions for one callendar month of

insurance are calculated and paid, prescribed by the general collective agreement for respective categories of qualifications, given in gross amount.

- Entrepreneurs who are self-employed pay contribution at the rate of 10.5%, while the base for the payment is taxable income from self-employment in accordance with the regulations on personal income tax, where the base may not be lower than the average monthly salary in Montenegro for the month for which the contribution is paid.
- For self-employed payers who pay the tax in an annual lump-sum amount, the base for contribution is 50% of the average monthly salary in Montenegro.
- The rate of contribution for compulsory health insurance of agricultural insurees is also 10.5% (as of 2010 - 9%), while the base is 12% of the average monthly gross salary in Montenegro earned in the previous year, per employee in Montenegro, according to the data of the state authority competent for statistics.
- The rate of contribution for health insurance of pension users is 19% according to the regulations on pension and disability insurance, nad the base is the amount of pension.
- Employment Agency pays contributions for health insurance of unemployed persons who receive unemployment benefit, at the rate of 5.0% of the amount of the benefit.

The largest portion of revenues from contributions RHIF generates from contributions for health insurance of the employees engaged in economic and non-economic activities (real and public sectors). Contributions for health insurance of employees are paid by employers on payment of salary, i.e. compensation.

In addition to the revenues from contributions, a significant source of revenues (cca 20%) are general revenues from the national budget, from which health care is provided to unemployed persons who do not receive unemployment benefits, as well as to refugees, and from which the lacking resources are provided for financing health care activity due to lower generation of revenues caused by the contribution rate reduction. (The Budget of Montenegro pays contributions for health insurance of unemployed persons who do not receive unemployment benefits, at the rate of 5.0% on the base consisting of the amount of the lowest cost of labour in Montenegro in the month for which the contribution is paid.)

The resources of RHIF are public resources from which only the rights arising from compulsory health insurance in Montenegro are financed, while amendments to the Law on Compulsory Health Insurance are being prepared, whereby the procedure for introduction of voluntary - supplementary health insurance will be defined in more detail.

Of private resources, the health system includes only the resources from the participation fee paid by insured persons as a share in the costs for the utilization of health care, which cover less than 1% of the total expenditure for health care.

Expenditure on health care comprises the resources spent for day care and clinical services, as well as for inpatient care services in health institutions inside and outside of the public health care system in Montenegro, resources spent for prescription medicines and medicines and medical material (medical devices) spent in primary health care centres and hospitals, as well as the expenditure on orthopaedic and technical appliances and aids.

Expenditure on other rights arising from health insurance, i.e. compensation of salary during the temporary inability to work - sick leaves, travel costs while being provided with health care services in the country and abroad, is also provided for by the resources of RHIF.

Expenditure for compulsory health insurance in relation to GDP

Year	Gross Domestic Product - GDP (million euro)	Expenditure of RHIF (million euro)	Share of RHIF in GDP	GDP per Capita
2001	1 295.1	76.0	5.9	2 113.0
2002	1 360.1	92.1	6.8	2 208.0
2003	1 510.1	96.6	6.4	2 435.0
2004	1 669.8	95.6	5.7	2 684.0
2005	1 815.0	108.9	6.0	2 912.0
2006	2 148.9	117.9	5.5	3 443.0
2007	2 807.9	138.5	4.9	4 484.0
2008	3 338.0*e*[2]	172.5	5.2	5 312.9*e*
2009	3 715.0*e*	160.0	4.3	5 893.4*e*

Source: MONSTAT, Economic Policy of Montenegro for 2009

EXPENDITURE OF MONTENEGRO HEALTH INSURANCE FUND

Level	DESCRIPTION	2004	%	2005	%	2006	%	2007	%	2008	%
I	**Primary care**	**37,221,272**	**38.9**	**41,545,448**	**38.2**	**44,837,761**	**38.0**	**51,812,855**	**37.4**	**58,042,107**	**33.7**
	Clinical services at PHC	19,860,701	20.8	23,524,832	21.6	25,600,503	21.7	31,445,220	22.7	35,795,499	20.8
	Stomatological services	3,208,559	3.4	3,216,192	3.0	2,619,786	2.2	2,545,786	1.8	3,840,881	2.2
	Medicines and medical material at PHC	3,973,962	4.2	3,883,634	3.6	3,528,340	3.0	4,249,991	3.1	4,244,062	2.5
	Prescription drugs	10,178,050	10.6	10,920,790	10.0	13,089,131	11.1	13,571,857	9.8	14,161,666	8.2
II	**Secondary care**	**32,352,914**	**33.8**	**39,026,234**	**35.8**	**39,773,340**	**33.7**	**48,983,449**	**35.4**	**62,612,929**	**36.3**
	Inpatient care services in hospitals	11,467,541	12.0	16,077,096	14.8	12,728,934	10.8	18,328,254	13.2	23,957,865	13.9
	Specialist, consultation and diagnostic services	10,497,337	11.0	10,751,434	9.9	12,950,710	11.0	14,705,976	10.6	20,285,827	11.8
	Medicines and medical material in hospitals	10,388,036	10.9	12,197,704	11.2	14,093,696	11.9	15,949,219	11.5	18,369,237	10.6
III	**Tertiary care**	**7,759,754**	**8.1**	**9,589,938**	**8.8**	**9,793,975**	**8.3**	**12,039,146**	**8.7**	**15,371,356**	**8.9**
	Inpatient care services in hospitals	2,866,885	3.0	4,019,274	3.7	3,182,234	2.7	4,582,063	3.3	5,989,466	3.5
	Specialist, consultation and diagnostic services	2,295,860	2.4	2,521,238	2.3	3,088,317	2.6	3,469,777	2.5	4,789,580	2.8
	Medicines and medical material in hospitals	2,597,009	2.7	3,049,426	2.8	3,523,424	3.0	3,987,305	2.9	4,592,309	2.7
IV	**Other rights arising from health care**	**7,997,398**	**8.4**	**8,528,319**	**7.8**	**10,581,355**	**9.0**	**12,398,890**	**9.0**	**14,952,115**	**8.7**

[2] For 2008 and 2009, there are only GDP estimates (*e*).

	Clinical treatment abroad and outside of the health system of Montenegro	542,911	0.6	668,229	0.6	632,874	0.5	645,522	0.5	765,428	0.4
	Inpatient treatment abroad and outside of the health system of Montenegro	6,821,476	7.1	7,285,323	6.7	9,240,383	7.8	11,035,055	8.0	12,395,192	7.2
	Other expenditure on health care	633,011	0.7	574,767	0.5	708,097	0.6	718,313	0.5	1,791,495	1.0
V	**Other rights arising from health insurance**	**4,293,208**	**4.5**	**4,421,072**	**4.1**	**5,009,446**	**4.2**	**5,566,412**	**4.0**	**7,316,490**	**4.2**
	Orthopaedic appliances and aids	1,019,278	1.1	920,637	0.8	825,741	0.7	585,939	0.4	826,996	0.5
	Compensation for sick leaves over 60 days	1,085,850	1.1	1,210,388	1.1	1,606,791	1.4	2,269,607	1.6	3,325,172	1.9
	Compensation for travel costs	2,188,081	2.3	2,290,047	2.1	2,576,913	2.2	2,710,866	2.0	3,164,323	1.8
VI	**Other expenditure and funds for the operation of the Fund**	**5,956,319**	**6.2**	**5,781,107**	**5.3**	**7,943,306**	**6.7**	**7,720,040**	**5.6**	**14,189,684**	**8.2**
TOTAL		**95,580,866**	**100.0**	**108,892,118**	**100.0**	**117,939,181**	**100.0**	**138,520,792**	**100.0**	**172,484,682**	**100.0**

SHARE OF THE HEALTH INSURANCE FUND EXPENDITURE IN GDP

Level	DESCRIPTION	2004	2005	2006	2007	2008
I	Primary care	2.23	2.29	2.09	1.85	1.74
II	Secondary care	1.94	2.15	1.85	1.74	1.88
III	Tertiary care	0.46	0.53	0.46	0.44	0.45
IV	Other rights arising from health care	0.48	0.47	0.49	0.44	0.45
Total for health care		**5.11**	**5.44**	**4.89**	**4.46**	**4.52**
V	Other rights arising from health insurance	0.26	0.24	0.23	0.20	0.22
VI	Other expenditure and funds for the operation of the Fund	0.36	0.32	0.37	0.27	0.43
TOTAL		**5.72**	**6.00**	**5.49**	**4.93**	**5.17**

For the time being, official records on health expenditure in private sector are not kept in Montenegro. However, in recent years, activities have been carried out to establish National Health Accounts (NHA), which will enable us in the following period to establish the above mentioned records as well.

For promotion and prevention of health in Montenegro, we estimate that cca 10.0 million euro, or 0.30% of GDP is allocated per year (resources for the Institute of Public Health, operation of guidance centres, all preventive check-ups in PHC and the like).

41. With specific reference to health promotion and disease prevention, please answer to the following questions:

The basic goal of health policy in Montenegro, providing efficient and high-quality health care and health system in accordance with the European and world standards included in the processes of modern health care development, has been set out by the document Health Policy in Montenegro till 2020 (2001). Notably, some of the general goals of health policy till 2020 are extending life duration by undertaking measures of disease prevention and treating the sick, as well as improving the life quality and preventing decrease in life quality due to health problems, whereas some of the specific goals of the health policy till 2020 are healthy beginning of a life, the health of the young, healthy aging, promoting mental health, preventing and fighting contagious and non-contagious diseases, preventing and fighting injuries and reducing harmful effects of alcohol, drugs and smoking.

Reform of primary health care has provided for conditions for implementing program of measures for improvement and preservation of the health of population of Montenegro by measures of health care which will be implemented by teams of selected physicians, centres and support units for public health centres. Namely, developers of prioritised prevention programmes with will be public health centres at the territory of the municipality. A part of preventive activities, public health centres will conduct in accordance with the package of services and provisions of the Rulebook on Detailed Conditions Regarding Standards, Norms and Manner of Realization of Primary Health Care Through a Selected Team of Physicians or a Selected Physician and the Decree on Scope of Rights and Standards of Health Care from Obligatory Health Insurance.

A part of preventive activities of the service package defines a great number of preventive examinations within the scope of work of the selected physician of the most vulnerable population – i.e. selected physician for children – a paediatrician, preventive examinations of pregnant women, parturient women, and other members of female population that ought to be performed by the selected physician for women and no less important examinations by selected physicians for the adult, such as preventive examination of men older than 40 and women older than 45 years which is conducted with the aim of prevention and early detection of a disease.

Another part of preventive measures is conducted through programmes defined by Population Health Care Programme for 2009 and will be carried out in the Support Centres for public health centres, such as Parenthood School in the Reproductive Health Counselling Centre. Adoption of the Strategy on Prevention and Control of Chronic and Non-contagious Diseases with the measures and dynamics of their realization is of a great significance to the whole population.

The aim of the Strategy is avoiding “early” mortality and reducing incidence of main chronic non-contagious diseases such as ischemic heart conditions, cerebrovascular diseases, malignant diseases, diabetes mellitus and COPB. This includes multi-sector programmes for health improvement and prevention which add up to preventive measures from service package and hereby complement them. The same applies to the third part of activities in the support centres to public health care centres which will be carried out through programmes of state importance and they are financed from the budget, e.g. fighting TB.

All activities of the health strengthening programme, which for the most part refer to changing life habits of the population, in terms of content will be coordinated by the Health Institute and in the realization of the programme units for health improvement of public health centres, non-governmental organizations, humanitarian and other associations of the sick, disabled persons and other citizens and local communities will be included.

Within public health centres the following Support Centres will be formed: Centre for Pulmonary Diseases and TB, Diagnostics Centre (lab, microbiology, x-ray and ultrasound), Centre for Mental Health, Centre for Children with Special Needs, Prevention Centre with population counselling, counselling for children, counselling for the young, counselling for reproductive health and hygiene – epidemiological service.

In order for a high-quality health care to be equally accessible to all citizens, Support Centres have been regionalized in accordance with the gravitation area covered by a particular public health

centre and therefore: the Centre for Pulmonary Diseases and TB will be organized in Bar with a unit in Ulcinj; in Kotor with units in Tivat; Herceg Novi; in Podgorica for Podgorica, Danilovgrad and Kolašin; in Cetinje for Cetinje and Budva; Nikšić; Pljevlja with a unit in Žabljak; Bijelo Polje with a unit in Mojkovac and in Berane with units in Andrijevica, Rožaje and Plav. The Centre for Mental Health will be organized in Bar with a unit in Ulcinj; Kotor with units in Herceg Novi and Budva; Podgorica with units in Danilovgrad and Cetinje; in Nikšić; Pljevlja; Bijelo Polje with a unit in Mojkovac and in Berane with units in Rožaje and Plav. The Centre for Children with Special Needs will be organized in Bar, Herceg Novi, Podgorica, Nikšić, Bijelo Polje with a unit in Pljevlja and in Berane with a unit in Rožaje. The Prevention Centre: population counselling, the counselling for children and for the young will be organized in each public health centre, whereas the counselling for reproductive health will be organized in each public health centre with regional centres in Berane, Nikšić and Bar. HES (Hygiene – Epidemiological Service) will be organized in Pljevlja, Bijelo Polje, Berane, Rožaje, Nikšić, Podgorica, Budva, Tivat, Herceg Novi, Kotor, Bar and Ulcinj.

In the Centre for Pulmonary Diseases and TB a pneumo-phtysiological health care at the primary level is conducted and a specialist doctor is obliged to provide, in addition to curative services for the whole population, a series of preventive examinations within the scope of his work in accordance with the Decree on Scope of Rights and Standards of Health Care from Obligatory Health Insurance. Just alike, activities provided for by programmes for primary and secondary protection of the diseased from TB and other pulmonary diseases are conducted in the Centre. Basic goals of the prevention of the diseased from TB and other pulmonary diseases are health enlightenment with the aim to change habits and motivation related to risk factors for causing lung diseases (smoking, alcoholism, exposedness to allergens, living and working environment factors etc), health enlightenment of the TB diseased, their families and other citizens, active screening for tuberculosis among various groups,…

In the Centre for Mental Health, mental health care is conducted and it includes preservation and improvement of mental health, early detection, treatment and rehabilitation from mental disorders and diseases at the primary level and a specialist doctor is obliged to, alongside curative service conduct a series of preventive examinations within the scope of his work in accordance with the Decree on the Scope of Rights and Standards of Health Care from Obligatory Health Insurance. Just alike, activities provided for by programmes paying special attention to prevention of mental diseases, with coordination and expertise of psychiatric services at the secondary level of health care, as well as establishing cooperation with educational institutions and social work centres are also conducted in the Centre.

Basic goals of prevention are primary prevention of mental disorders and early detection of mental disorders. Identification of risk factors, examining the degree of spread of abuse of narcotics and other opiates, correlation between sectors (education of school children and teenagers with gradual introduction of health education) with a special emphasis to addiction disease aiming at better monitoring of development of addiction disease in the community. Reduction of morbidity (number of the diseased) from mental disorders and behavioural disorders. Reduction of the mortality rate (the number of deaths) caused by psychiatric illnesses (suicide, poisoning, injuries and similar). In all activities of health care, vulnerable groups (children, adolescents, the elderly, the handicapped, persons exposed to violence etc) are the priority.

Centre for Children with Special Needs

Preventive services in the Centre for Children with Special Needs are conducted through a series of preventive examinations of a neonatus and nursling at risk, preventive examinations of children at risk, preventive examinations of children with developmental difficulties, as well as through parent training.

Prevention Centre

Chronic non-contagious diseases will be treated in the population counselling centre in each public health centre, with the view to promote healthy life styles and prevent diseases of special socio-medical significance. During 2009 the following programs will be conducted in all public health centres:

1. Counselling centre for diabetes, whose primary goal is prevention of diabetes and prevention of chronic diabetes complications

Counselling tasks are the following: individual detection of high diabetes risk; setting diagnosis of pre-diabetes; diabetes prevention directed toward the whole population; diabetes prevention directed at an individual; prevention by a special approach to persons with a high risk of diabetes and prevention of complications with diabetes diseased.

A nurse educates newly detected diabetics concerning therapy implementation and surpassing therapy related problems, surpassing sugar self-control and conducts minimal sugar control and high blood pressure control at the counselling. The doctor employed by the counselling centre conducts analysis of nutrition of diabetics and advises in therapy implementation, analysis on implementation of physical activities, analysis of individual habits (smoking, alcohol,…).

Group work will also be conducted in the counselling centre by a team consisting of a selected physician, nurse, nutritionist or hygiene specialist in the field of health promotion through a series of workshops and counselling.

2. HIV Counselling Centre

Counselling centres operate in 7 public health centres (Bar, Kotor, Herceg Novi, Nikšić, Berane, Bijelo Polje and Pljevlja) and at the Public Health Institute.

3. Counselling centre for the young conducts activities with the population of adolescents, teenagers and the young according to the program. The following programs will be conducted in the counselling centre for the young during 2009:

- Prevention of Addiction Diseases

This year the Smoking Cessation Program will be conducted

4. Counselling centres for reproductive health are being developed with the aim to promote reproductive and sexual health at the regional level. Activities are carried out by the team of a selected gynaecologist supported by necessary doctors and medical associates (psychologists, pedagogues, social workers).

In the counselling centre for reproductive health the following program will be realized during 2009

- School for Pregnant Women – Healthy Parenthood Programme

Pregnant women are prepared for giving birth to a child upon completion of the seventh month of pregnancy. Fathers can also be included in the activities. Mothers to be obtain information about pregnancy and childbirth, psycho-physical preparation for childbirth, fitness in the last trimester of the pregnancy, breathing exercises for a safe childbirth, breast feeding and preparation for breast feeding, instructions for care and hygiene of a mother and newborn as well as advice for a successful parenthood.

Counselling centre is lead by an educated nurse with a long experience and a selected gynaecologist. There are also consultations with a psychologist once in three months, as well as with a dentist in agreed terms.

Hygiene – epidemiological service will be organized at the regional level.

Within HES, during 2009 the following programs will be financed:

- programme for control and prevention of contagious diseases (intestinal contagious diseases and parasitic diseases, respiratory contagious diseases, zoonoses and vector-borne contagious diseases, sexually transmitted contagious diseases, control of intrahospital infections, immunoprophylaxes according to epidemiologic indications, control of quarantine diseases with monitoring travellers in the international transport),
- programme for preventive medical protection in extraordinary conditions
- programme for control and prevention of non-contagious diseases (malignant neoplasm, sugar disease, cerebrovascular disease, ischemic heart disease, hypertension with complications, chronic renal insufficiency, neuromuscular diseases and multiple sclerosis,

mental illnesses, addiction diseases, chronic obstructive diseases of the respiratory system – lungs, control of traffic traumatism and control of injuries at work and at home).

In addition to the above stated activities regarding health promotion and disease prevention within specified actions, the following preventive measures have been defined:

a) What measures are you taking to improve health promotion and disease prevention e.g. 3 types of cancer screenings (colorectal, breast and cervical)?

Health promotion and disease prevention measures

- preventive examination of students in the first grade of secondary school
- preventive examination of students in the third grade of secondary school
- preventive examination of the first-year university students
- preventive examination of the third year university students
- preventive examination of more than 65 years old
- other preventive examinations.

Targeted examinations:

a) Examination before immunisation for the purpose of detecting contraindications among students whose terms for immunization do not match preventive examination

b) Examination for the purpose of detecting abilities and contraindications regarding accommodation into certain facilities of family accommodation, travel, doing sports and recreation.

- Screening, which represents preliminary detection of persons with unknown forms of health disorders, by the means of easily and quickly applied procedures, at the initiative of a doctor, related to the diseases being tested for

Screening for early detection of elevated blood pressure, cholesterol and triglycerides and risk factors for incidence of hearth and blood vessel diseases.

These are conducted among all men older than 40 and all women older than 45, once in every 5 years. Detection is conducted by regular curative examination. (Exceptionally as a special service if a person did not have a checkup or treatment for more than 5 years.) These examinations include elevated blood pressure detection and lab detection of high cholesterol, triglycerides, blood sugar etc.

Screenings for early detection of breast cancer among women

These are performed among all women, once in three years, by a clinical breast examination and, if needed, by mammography. Screenings are conducted every year among women from risky groups (with breast cancer diagnosed to their mother, sister, daughter, aunt).

Conducted by: selected physician with their team.

- Vaccination and revaccination of school children and teenagers over 15 years old

It is conducted in compliance with the law and programme for obligatory immunization at the territory of Montenegro, which is developed every year by the centre for disease control of the Public Health Institute.

- Anti-flu vaccination of person over 65 years old with chronic diseases

Anti-flu vaccination is conducted by dead vaccine among persons older than 65 who have chronic respiratory diseases, circulatory system diseases, kidney diseases, chronic metabolism disorders and those who are in collective accommodation institutions.

- Other preventive measures

Chemoprophylaxis and seroprophylaxis by implementation of certain appliances (among persons who are exposed to certain infections – in accordance with the existing regulations). Special measures related to risk of an epidemics, outbreak of a contagious disease in a family, carrier state

and undertaking measures of health enlightenment, appropriate anti-epidemic measures and similar.

- Protection of persons with increased health risk

It includes overall care of persons with increased health risk, such as: the elderly, smokers, alcoholics, psycho-active drugs abusers, overweight persons, persons with professional hazards etc. Keeping records, monitoring and implementation of healthcare-preventive measures (health monitoring, counselling, health enlightenment as to acquiring habits beneficial to health and changing harmful habits, monitoring social, family, professional and other health habits).

- Protection of persons with chronic health disorders

Examinations, counselling and control of undertaken measures, control of treatment and rehab successfulness, introducing certain records of persons with chronic diseases, and planned and organized implementation of health care (house calls, scheduling examinations, organizing and implementing house treatment).

- Sanitary-hygienic monitoring over secondary schools

Supervision implementation for the purpose of estimating hygiene-sanitary conditions in premises for holding classes, stay and diet of students. Control of conditions of work and stay in schools, at least once a month. Due attention has to be paid to communal-hygienic conditions: lighting, heating system, cleaning, airing, condition of sanitary blocks, waste disposal, class regime, water supply system etc. In schools with kitchens, surveillance over diet and monitoring regime and hygienic safety of the food and promotion of healthy hygiene habits of students.

- Sanitary- hygienic supervision over and in facilities for accommodation of students (pupils' hostel)

Conducting supervision for the purpose of an estimate of hygienic-sanitary conditions in living premises, at least once a month. Inspection and control of hygiene conditions in premises for daily and night rest, reading rooms etc. Special attention is paid to communal-hygienic conditions and cleanness, lighting, sanitary blocks and devices, heating system, waste material disposal, water supply system etc. Then, diet control – control of food preparation process, preparation of a menu and meal distribution (serving), control of supply hygiene conditions, transport and storage of foodstuffs.

- Sanitary-hygiene supervision in facilities for accommodation of students (students' hostel)

Supervision implementation for the purpose of estimating hygiene-sanitary conditions in the premises for living and diet of students, carried out at least once a month. Inspection and control of hygiene conditions in premises for accommodation, living and in premises for daily and night rest, and waiting rooms is also conducted. Special attention is paid to cleanness, lighting, condition of sanitary blocks, heating system, waste disposal, control of kitchen and premises for foodstuff storing. Control of food preparation, preparation of a menu, meal distribution, control of supply and storage, foodstuffs and diet.

- Counselling

Individual counselling is conducted in accordance with psycho-social indications and the agenda. It is implemented within hours assigned for counselling and it involves teenagers, the young, their parents, professors and teachers. It is focused on the issues of adaptation to secondary school education and studies, school, failure and learning difficulties, behavioural disorders, problems in development and growing up, chronic health disorders, family planning, sexually transmitted HIV infections, abuse of psycho-active substances and other forms of addiction, problems with mental health etc. Counselling also includes the following examinations: clinical examination with consultations with various specialist physicians, as needed, implementation of appropriate diagnostic procedures and treating the young.

- Health promotion

Health educational activities with secondary school students. The aim of activities is stimulating students to develop and adopt healthy life styles, change habits harmful to health and take responsibility for their own health.

Health educational activities with the students

Activities with the view to take responsibility for one's own health. Modification in behaviour with the aim to adopt behavioural patterns acceptable in terms of health. Education.

Health education and population enlightenment

Stimulating population to develop and adopt healthy styles, i.e. lifestyles beneficial to health, adopt habits beneficial to health and change those harmful to health (smoking cessation, regular and healthy diet, regular physical activity, healthy environment, promotion of mental health including activity prevention, non-violent conflict resolving, avoiding stress, responsible sexual behaviour and similar) through educative activities, using methods and means of health education.

Prevention of chronic non-contagious diseases

Implementation of measures in accordance with the plan of activities from the Strategy for Prevention of Chronic Non-Contagious Diseases.

Prevention of malignant diseases

Implementation of measures in accordance with the plan of activities from the Strategy for Prevention of Chronic Non-Contagious Diseases.

Prevention of injuries

Implementation of measures in accordance with the plan of activities from the Strategy for Prevention of Chronic Non-Contagious Diseases.

Family planning

It will be implemented in accordance with the plan of activities from the Strategy on Reproductive Health.

b) Could you provide us information on the pilot project in Podgorica (2004-2009) on prevention, immunization, health promotion and screening?

Mid 2005 Primary Health Care Centre Podgorica began the primary health care reform process. During 2007 the reform extended to public health centres in Danilovgrad, Tivat, and Rožaje and in 2008 to all public health care centres in Montenegro.

In accordance with the adopted law and by-law regulations, Public Health Centre during the pilot project changed its organization scheme and work content, systematisation, the insured were registered, financing model was defined etc.

In terms of organization, Public Health Centre consists of three basic units: selected physician's surgery or teams of selected physicians (selected physician paediatrician, selected physician for adults, and selected physician gynaecologist), support centres for selected physicians who are organized at local and regional level for the following: pulmonary diseases and TB, diagnostic, mental health, children with special needs, prevention and similar and units for: house calls, physical therapy at the primary level and medical transport.

Capitation is defined as health care financing model. Payment to selected physicians (selected physicians for children up to 15 years old, selected physicians for persons more than 15 years old and selected physicians gynaecologists) is defined as a combination of capitation payment and a service fee (in the proportion 50% : 50%); payment to dentists by service fees, except for Prevention Centre, which is financed by the programme.

All public health centres, including Primary Health Care Centre Podgorica make work plans based on methodology which puts the insured in the centre of the health care system, relying on standards and norms ("The Rulebook on Detailed Conditions Regarding Standards, Norms and Manner of Implementation of Primary Health Care through Selected Team of Physicians or a

Selected Physician", Official Gazette of Montenegro 10/2008) which were developed at the national level and have IT support.

Determination to create an insured-oriented health care is achieved through calculation of number of examinations (overall and per patient), with specifically underlined number of screening; i.e. for 2008 it was planned to have screenings participate in Montenegro with 30.3% or for selected MDs with 22.1% (www.fzocg.me, Program for Population Health Care for 2009, March 2008).

Selected MDs perform preventive services in Support Centres as well.

The Decree on Scope of Rights and Health Care Standards from Obligatory Health Insurance (Official Gazette of Montenegro 79/2005) determined medical measures and procedures for heath improvement, prevention, eradication and early detection of diseases. Plan and Programme for Preventive Heath Care Measures was not adopted in Montenegro. Programme of heath care of population in Montenegro (it is adopted and evaluated yearly) has quantified the scope of specific preventive activities, immunization, health promotion activities and screening for each institution at the primary level, thus including Primary Health Care Centre Podgorica.

As regards health promotion and disease prevention in the Primary Health Care Centre Podgorica Prevention Centre is formed, and it is financed by the program.

Primary Health Care Centre Podgorica does not have HES service nor HIV and proper diet counselling centres as the Public Health Institute (institution which, within its scope of work deals with public health activities at the primary, secondary and tertiary level) is situated in Podgorica.

Prevention Centre organizes screenings, individual and group counselling and other activities related to health promotion, disease prevention and control. In accordance with the Priorities and Directions for Health Care Improvement in Primary Health Care Centre Podgorica in 2009, on the basis of the Programme, the following counselling centres are planned:

- Diabetes Counselling Centre (for all the insured)

Counselling Centre activities are realized through methods of individual and group work, in compliance with the Public Health Institute Programme. The Counselling Centre has a permanently employed nurse.

Counselling Centre for Children operates within the surgery of a selected physician and here are the programmes for children not older than 15 carried out. The work is registered as a service of selected physician (vaccination and preventive examinations).

In counselling centres for the young, activities with the population of adolescents, teenagers and the young are conducted in accordance with the programme. In counselling centres for the young in 2009 the program Addiction Prevention will be conducted and with a view to this, the following centres will be formed:

- Smoking Cessation Counselling Centre

Programme activities will be carried out in accordance with the Public Health Institute Programme. The Counselling Centre has a permanently employed nurse.

Reproductive Health Counselling Centre is formed with the aim to promote reproductive and sexual health. Activities in the counselling centre are carried out by a team of selected gynaecologist with the support of other necessary physicians and medical associates (psychologists, pedagogues, social workers).

In accordance with the Healthy Parenthood Programme, within reproductive health centre the following will be realized in 2009:

- School for pregnant women

Program activities are carried through in accordance with the Public Health Institute Programme. The Counselling Centre has a permanently employed nurse.

Activities of Hygiene-Epidemiological Service are organized within Public Health Institute.

According to IT supported report of Primary Health Care Centre Podgorica, during 2008 in Primary Health Care Centre Podgorica selected physicians for children up to 15 years old and selected physicians for adults conducted the following: 14,300 preventive examinations of children in their first year; 1,982 preventive examinations in their second year; 977 preventive examinations in their fourth year; 2,255 preventive examinations just before going to school; 7,654 preventive examination in primary school in the 2nd, 4th, 6th and last grade of primary school; 2,748 general medical examinations of students in 1st and 3rd grade of secondary school; 293 general medical examinations of students at their 1st and 3rd year of studies; 1,892 preventive examinations of persons more than 65 years old; 6,530 control examinations after preventive examination; 531 preventive examinations of children up to 15 years old in cases of some contagious disease epidemics; 50,868 vaccinations and revaccination of children and teenagers according to vaccination calendar; 5219 anti-flu vaccination for those more than 65 years old; 1,504 immunoprophylaxis, immunoprophylaxis with serum and chemoprophylaxis for prevention of contagious diseases in accordance with the law; 2,690 preventive examination of men exceeding 40 years and women exceeding 45 due to early detection of increased blood pressure, cholesterol and triglycerides and risk factors for heart diseases and blood vessels diseases once in 5 years and 2,170 examinations for early detection of breast cancer with women, once in 3 years, and among those at risk, yearly.

During 2008 in Primary Health Care Centre Podgorica, selected physicians for women conducted 7,407 preventive examinations during pregnancy (examination of a pregnant women in her I trimester of pregnancy and four control examinations; 5,107 ultrasound examinations during pregnancy; 3,865 preventive examinations with counselling for women in the reproductive age, women's reproductive organs cancer screening, etc.

Information on immunization in Primary Health Care Centre Podgorica is provided within the answer to the question about immunization in answer number 50 d).

The service of screening all children for inborn metabolism disorder (phenylketonuria and hypothyroidism) are not performed by selected physicians and during the pilot project it was not performed in Public Health Care Centre Podgorica. As newborns are most often released from maternity ward the third day upon their birth, and the service is conducted the fourth or the fifth day upon birth, it is planned to have the realization of the service defined by a programme. This service is performed at the Institute for Children's Diseases at the Clinical Centre of Montenegro.

In Public Health Care Centre Podgorica during 2008 there was only one screening for developmental hip anomalies at the Centre for Radiological Diagnostics. Due to lack of staff, the service of ultrasound screening for developmental hip anomalies is performed at the Institute for Children's Diseases at the Clinical Centre of Montenegro.

42. Are you implementing the OECD manual "A system of health accounts"? If no, when are you planning to do so?

The answer is provided by the answers to question 43a), 43b), 43c) and 43d)

Activities of designing and developing National Health Accounts in Montenegro were a part of a bigger project for promoting health care system in Montenegro financed by the International Development Association (IDA) and co-financed by the Canadian International Development Association (CIDA).

Within the project of Technical Assistance with creating and developing national health care accounts, one international consultant and four local experts were hired in 2007 at developing national health care accounts in Montenegro for period 2004-2006. Final workshop was organized in January 2009, where final reports and results of NHA were shown and the manner of further work organization at the development of NHA was proposed.

Development of national health accounts will provide conditions for improving health care system in Montenegro.

Introduction of national health accounts will result in reliable information on sources and usage of health care funds which will lead to improvement of the following: health care system functioning,

keeping records on spending in the health care area according to health care services and service providers, the data on share in public spending and GDP, as well as in encompassing portrayal of efficiency of all health care sectors.

As a basis for development of national health accounts in Montenegro, OECD methodology "A System of Health Accounts - Version 1.0" of 2000 was used, as well as additional methodology to this manual which was developed 2005-2006 and explained in Joint Questionnaire in 2007. Also, the instructions from World Health Organization for developing national health accounts with special emphasis to countries with small and medium revenues from 2003 and directions from the System of Health Accounts provided by national statistics service in Great Britain (2003 were used).

NHA were developed following the methodology concept of System of National Accounts (SNA 93), European System of Accounts (ESA 95) and International Classification for Health Accounts (ICHA).

In addition to official data on public health spending, this project includes estimates on private sector but these data still can not be considered reliable and in future special attention should be paid to keeping record of them and determining them.

Preparations for work organization and continuation of development of national health accounts are in progress.

43. With reference to cross-border healthcare, please specify the following:

The answer is provided within answers to question 43a), 43b), 43c) and 43d)

a) Do you have cross-border arrangements for treating patients with any EU Member State or candidate countries?

By the proclamation of independence, Montenegro acquired fool international legal subjectivity within the existing state borders.

In accordance with the Decision on Proclamation of Independence, adopted by the Parliament of Montenegro at the session held on June 03, 2006, Montenegro assumed and continued to implement all international treaties and agreements which were concluded and implemented by former state union of Serbia and Montenegro, which refer to Montenegro and are in compliance with its legal system.

With a view to provide heath care to our citizens abroad and vice versa, the following international treaties on social insurance are being implemented:

a) With European Union member states:

- Austria, Belgium, Germany, the Netherlands, Luxembourg, France, Romania, the Czech Republic, Italy and Hungary following the insurance principle which implies that every country bears the costs of health care of its insurants, where foreigners who use health care based on the treaty do not pay the health service fee directly, as the costs are calculated and compensated between competent insurers of the two countries.
- Great Britain, Bulgaria, Slovakia and Poland following the reciprocity principle, which means that foreigners who use health care based on the treaty do not pay health service fees, as the costs of health care are borne by the country which is the health care service provider.
- Sweden and Denmark in the same way and under the same conditions as our insurants, where nationals of these countries pay for costs of health care services directly.

  Health institutions are obliged to issue them receipts, based on which they claim the right to a refund in their country in accordance with national regulation.

b) With European Union Candidate Countries:

- Macedonia and Croatia following the principle of insurance, which means that each country bears costs of health care for those they insure, where foreigners who use health care based on the treaty do not pay the health service fee directly, as the costs are calculated and compensated between competent insurers of the two countries.

Basic principles of concluded international treaties in the area of health care are:

- ensuring health care for foreign nationals in the same manner and under the same conditions as for domestic insurants;
- determining conditions for acquiring the rights, content and scope of the rights (emergency, essential health care and fool scope of health care), duration of the rights and family members who are entitled to health care in accordance with the legal regulations of the country which ensures them;
- providing health care in accordance with the regulations of the country where the health care is being provided;
- providing necessary administrative assistance in exercising rights of health care to foreign nationals by competent institutions.

b) What is the annual flow of patients into and from your country by sending/receiving country?

Concerning the annual flow of persons into and from our country, data can be provided only for persons who were, in accordance with the concluded treaties on social insurance, issued certificates i.e. appropriate document by the competent insurer for using health care in another country, on the basis of which they had health care costs.

Annual flow of persons into and from Montenegro in 2008

Country	Persons from our country	Persons into our country
AUSTRIA	11	140
BELGIUM	1	35
GERMANY	82	1,867
NETHERLANDS	/	57
LUXEMBOURG	1	743
FRANCE	14	17
ROMANIA	/	3
CZECH REPUBLIC	33	8
ITALY	13	29
HUNGARY	/	9
GREAT BRITAIN	/	8
BULGARIA	/	3
SLOVAKIA	/	2
POLAND	/	2
SWEDEN	/	/

Country	Persons from our country	Persons into our country
DENMARK	/	/
MACEDONIA	67	73
CROATIA	254	240

c) What is the annual expenditure (percentage of GDP and total amount in Euro) for treatments of patients from your country abroad?

On the basis of concluded international treaties, for the purpose of treating our insurants in European Union Member States, in 2008 expenses amounted to 137,078.00 € and this amount was distributed as follows:

(for Austria – 70.79 €; Germany – 184.34 €; Luxembourg – 17,223.33 €; for EU Candidate Countries– Macedonia – 3,586.45 €; Croatia – 116,013.09 €).

In addition to health care provided in accordance with the above stated international treaties, citizens of Montenegro are also being provided with treatments abroad on the basis of referral, for diseases and conditions which can not be treated in the country.

The right to the above stated treatment is stipulated by Article 52 of the Law on Health Insurance, and detailed procedure and manner of exercising this right is regulated by the Rulebook on the Manner and Procedure of Referring Insured Persons Abroad for Treatment.

On the basis of referral abroad for treatment insured persons have right to surgery and hospital treatment, right to an attendant during treatment, right to have a refund of travel costs and accommodation and living costs.

Most persons were referred to Serbia through implementation of commercial agreements with biggest health care institutions in Serbia, as well as, to a lesser degree, to other countries abroad, as illustrated by the following overview:

No	COUNTRY	Number of those referred abroad for treatment			Amount in €		
		2006	2007	2008	2006	2007	2008
1	Germany	9	18	16	175,195.6	220,440.4	252,222.4
2	France	2	6	5	127,675.1	72,257.1	68,501.8
3	Switzerland	5	6	1	116,596.6	283,886.9	1,551.0
4	Italy	7	18	11	99,631.1	48,445.1	149,949.1
5	Great Britain	2	6	14	52,326.5	21,192.5	130,668.6
6	Monaco	2	3	2	46,748.3	87,500.0	37,821.7
7	Slovenia	6	5	7	16,165.0	19,934.4	44,000.7
8	Austria	2	1	0	9,124.8	1,328.5	
9	Croatia	2	12	7	7,552.2	48,493.2	24,139.0
10	Belgium	2	4	3	2,571.0	11,692.6	13,768.5
11	Russia	0	2	2		31,332.7	81,959.5

No	COUNTRY	Number of those referred abroad for treatment			Amount in €		
		2006	2007	2008	2006	2007	2008
12	Ukraine	0	2	0		20,000.0	
13	Hungary	0	1	1		1,000.0	10,000.0
14	USA	0	1	1		8,901.10	
15	Sweden	0	1	1		11,939.62	14,536.00
16	Macedonia	0	0	1			283.42
TOTAL		39	86	72	653,586.27	888,344.18	829,401.71
17	Serbia	6,785	6,331	6,525	4,546,687.29	5,775 876.92	6,996,991.25
TOTAL		6,824	6,417	6,597	5,200,273.56	6,664 221.10	7,826,392.96

Total annual costs for treating our insurants abroad, at the yearly level, is approximately € 8.0 m, which accounts for 0.24% in GDP.

d) Irrespective of arrangements, what information on cross-border is gathered at the moment?

Since gaining the independence, competent institutions are conducting many activities directed at gathering data with the aim to conclude new international treaties i.e. to revise treaties that are being implemented. To this effect, the data on tourist movements, travels for the purpose of a private matter, conducting individual activity and similar are being gathered. Company activities on foreign markets are also being monitored, activities at opening new diplomatic missions and consular representations of our country abroad and of foreign countries here.

Based on these indicators, procedures for concluding new insurance treaties are initiated through line ministries. To this effect, Montenegro concluded new treaties with Grand Duchy of Luxembourg, the Republic of Hungary and the Republic of Serbia. Negotiations for concluding a new treaty with Kingdom of Belgium, Former Yugoslav Republic of Macedonia, Slovenia, Turkey and Greece are in progress. Principles, i.e. the rules of European Union are used as guidelines when concluding new treaties.

44. Are your health institutions members of any European or WHO networks? If so, which ones?

Montenegro is a member of a number of international organizations dealing with health care aspect and those are the following:

- World Health Organization (WHO)
- South-Eastern Europe Health Network (SEEHN)
- United Nations Development Program (UNDP)
- United Nations Children's Fund (UNICEF)
- World Bank (WB)

Although SFRY was one of the founders of WHO in 1948, disintegration of the country put en end to its membership of UNO and WHO. From 1992 to November 28, 2000 FRY was the only European country which was not a WHO member state. During this period WHO had an office for humanitarian aid in Belgrade.

In November 2000 FRY became a full member of UNO and its specialised agencies, thus including WHO. The first two-year agreement on cooperation was signed on February 18, 2002, the next one in 2004, and then followed the agreement for 2006/2007.

After gaining independence on May 21, 2006, in February 2007 Montenegro became a member of WHO and signed is first individual two-year agreement in 2008/2009 at the 57th session of the Regional Committee for Europe.

At 58th session of Regional Committee for Europe in September 2009 Montenegro signed a new two-year agreement on cooperation with WHO.

WHO office for Montenegro was opened in November 2008, and it is the only specialized office for health care field in Montenegro.

Montenegro has been a member of South Eastern Europe Health Network ever since it was formed by signing the Dubrovnik Pledge in 2001. Within this Network, Montenegro is the leading country for the project “Environment Impact on People’s Health”.

Concerning UNDP and UNICEF, the Ministry of Health has a good cooperation with theses two organizations, but they are not specialized in the health care field.

Early in 2002 there was a UNDP communications office in Montenegro within the FRY, but Montenegro became a UNDP member in September 2006 by signing the State Programme which defined objectives for the period 2007-2011. One of the most significant issues UNDP is dealing with in Montenegro is HIV/AIDS.

UNICEF office was first opened in Podgorica, Montenegro in 1993 in order to help the Government of Montenegro during the inflow of a great number of refugees from former Yugoslav countries, as well as from Kosovo 1998-1999. After the independence of Montenegro, UNICEF opened the first independent office and the First State Program for 2007-2011 was created.

Montenegro has been a World Bank member since January 18, 2007. The project “Promotion of Heath Care System in Montenegro” was realized by WB credit.

Montenegro cooperates with the Global Fund for Prevention of HIV/AIDS, Malaria and Tuberculosis.

Also, Montenegro cooperates with the European Centre for Disease Prevention and Control and preparations for signing Cooperation Memorandum are in progress.

45. With reference to health information and knowledge, are your health statistical institutions members of any Eurostat networks? If so, which ones?

According to information at our disposal, health statistics, which is conducted in the Public Health Institute is not a member of EUROSTAT networks.

Cooperation at the international level with WHO in the field of health statistics is realized through the Centre for Disease Prevention and Control (contagious diseases monitoring) and Centre for Development of Health Care System (health monitoring of certain HFA-DB database indicators) within the Public Health Institute.

46. The EU has established a network of competent authorities in health information and knowledge. Does your country have the administrative capacity, including human and material resources, to participate in the work of such a network? Please describe the system used to collect, analyse and report health data and information in your country.

The Public Health institute, as the competent institution, is monitoring health-related statistics data for all three levels of health care at the national level, through reports of non-hospital and hospital health care.

According to the Law on Data Collections in the Field of Health Care (Official Gazette of Montenegro 80/2008) and the Program of Statistical Research of Montenegro for 2009, the Public Health Institute manages health-related statistics data in the public health field by gathering them, processing, keeping, analyzing, and publishing proscribed reports. Until the development and

adoption of new regulations, methodology of filling report forms is conducted in accordance with the existing regulations. Non-hospital health care includes reports on organization, work, staff and recognised diseases, conditions and injuries for children up to 15, adults, women, medicine of work, dental health care, ambulance. At the level of hospital health care, the data contained in reports on organization and work of hospitals, staff, and patients treated in hospital-stationed treatment service are monitored.

All health institutions are obliged to submit data in proscribed forms to the Public Health Institute within the proscribed deadlines. In the Institute, data are processed, analysed and published regularly once a year according to health care activities. In addition to regular report submitting and publishing stipulated by law, other researches in the public health area are conducted depending on needs and demands.

In accordance with the new legal regulations in the area of obligatory health records (December 2008), by-law acts which will regulate methodology of establishing a record of diseases of greater socio-medical significance and other system records in the area of health resources are being prepared.

The development of an integral health information system, first at the level of the primary health care with a view to further improvement and expanding to the entire health care system.

It is difficult to estimate, notwithstanding the interest and significance for participation in EU network in the information area and findings in the health area, whether, having in mind lack of sufficiently trained staff, needs for further development and improvement of health-related statistic and information centre, Montenegro currently has all necessary capacities to participate in the work of network, but it will be improving its capacities with the aim to take participation in the network.

47. With reference to health workforce, please specify the following:

The answers are provided within answers to sub-questions 47a), 47b), 47c), 47d) 47e), 47f), 47g), 47i), 47j) and 47K)

a) is there mobility of clinical staff (nurses/doctors) to/from your country to EU Member States, candidate and potential candidate countries, or others? If so, in which numbers and to which countries?

Mobility of clinical staff (nurses, physicians) from Montenegro into EU member state is present but to a barely evident degree. We do not have precise data or researches on the number and countries. As regards membership candidate countries and potential candidates, staff mobility is most evident towards Serbia, due to territorial closeness and Universities where a great number of Montenegrin staff is being educated, whether it is graduate or post-graduate education.

b) How is healthcare staff appointed, and what is the distribution of health personnel across the country?

Employing healthcare staff in Montenegro is conducted in accordance with the regulations from the field of work, health care and other general acts of health institutions.

The Ministry of Health conducts employment policy in the health area and at the same time takes account of distribution of medical staff at the territory of the whole country.

Each health institution, based on the Rule Book on Internal Organization and Systematization, which is approved by the Ministry of Health, employs necessary healthcare staff through a public vacancy announcement.

Healthcare staff distribution is such that it ensures equality and accessibility of health care on the whole territory of the country, although there is deficiency in healthcare staff, especially at the primary level of the health care, in the northern region of Montenegro, as physicians are poorly motivated to work in less developed environments.

By revision of Master Plan for Health Care Development, which is being developed, the issue of distribution of healthcare staff at the territory of Montenegro is being discussed, in order to meet

the need of patients at the whole territory for high-quality, efficient and accessible health care in the best possible way.

If it is estimated that the needs of citizens in the health care system are not satisfactorily met, as well as that the waiting period is longer that professionally acceptable, physicians from private sector will join public network.

c) How many move across borders?

In 2008, in total 148 physicians and 57 nurses and medical technicians were abroad for some kind of professional and scientific capacity building.

d) Education and training

Health workers acquire high education at medical schools in the country and abroad.

The precondition for practicing health care activities independently is having passed licensing exam in addition to appropriate level of education. Medical, i.e. Pharmaceutical Chamber issues general work licence to healthcare workers who have served internship and passed licensing exam. Medical Chamber also issues practice licence, in compliance with the provisions of the Law on Health Care.

In accordance with the Law on Health Care of Montenegro, professional capacity building of health workers is conducted with the aim to improve health care quality.

By specialisation, i.e. sub-specialisation, as a specific kind of professional capacity building, knowledge and expertise for specialist and sub-specialist practice in a specific area of health care is being acquired.

The Ministry of Health adopts annual Plan of Needs for Specialisations and Sub-specialisations, in accordance with the standards of staff sufficiency for certain fields and levels of health care activities and the Plan of the Human Resources Development in the Area of Health Care, in accordance with the developmental needs and priorities of health care institutions.

Professional qualification and capacity building is realized through:

- postgraduate professional capacity building (specialisation and sub-specialisations)
- postgraduate scientific capacity building (doctor's/PhD studies)
- post PhD capacity building
- short-term professional capacity building in the country and abroad (courses, seminars, congresses, symposia etc)
- scientific project research
- continuous medical education
- continuous scientific researches within the line of profession
- capacity building through study programmes in the country and abroad
- capacity building and education of health workers with secondary school, higher medical school and medical school (tertiary education).

e) Where is the healthcare staff trained?

Education of nurses is conducted through four-year long secondary school, and Higher Medical School in Berane, upon conclusion of which Bachelor degree is obtained.

Also, education of a number of nurses is conducted at Medical Schools in the region (most often in Belgrade and Ćuprija), as well as the Nursing School in Maribor (Slovenia), up to specialisation degree and master's degree in nursing management.

f) To what educational level are nurses trained (e.g. degree level)?

Education of nurses is conducted through four-year long secondary school, and Higher Medical School in Berane, upon conclusion of which Bachelor degree is obtained.

Also, education of a number of nurses is conducted at Medical Schools in the region (most often in Belgrade and Ćuprija), as well as the Nursing School in Maribor (Slovenia) up to specialisation degree and master's degree in nursing management.

g) What are the mechanisms for planning the number of health medical doctors and nurses trained? E.g. is a numerus clausus in operation?

The Ministry of Health adopts the Annual Plan on Needs for Specialisations and Sub-Specialisations, in accordance with the standards of staff sufficiency for certain fields and levels of health care activities and the Plan of the Human Resources Development in the Area of Health Care, matching developmental needs and priorities of health institutions.

h) Does the number of staff correspond to the needs of the population?

The reform process of the primary level of health care is legislatively and institutionally concluded, and the reform of the secondary and tertiary level of the health care is on the way.

By adopting standards and norms for the secondary and tertiary level of the health care, the conditions for the optimal development of health care service will be provided for and thereby necessary staff will be provided in accordance with the needs of citizens.

Evaluation of the Health Care Programme for 2008 (www.fzocg.me) states that one of the basic parameters for monitoring the work of health care service and the precondition for improving the health care situation is ensuring enough medical staff for the population. Number of physicians per 1000 persons in 2008 was 2,045.

i) Is training paid for out of the public purse or does the student pay full cost?

Training of employees according to the developmental needs of the health institutions is financed entirely from public purse.

j) Are there any policies to try and retain doctors and nurses in the health system?

Health workers and health associates are obliged to, upon completion of their education, serve internship in health institutions and pass licensing exam.

Health institutions are obliged to allow health workers and associates to serve internship.

Health workers with a tertiary education, upon the completion of their specialisation for the needs of a certain health institution, are obliged to stay working in that health institution for at least as long as the specialisation appointed to them (rights and obligations are defined by the Contract).

Trial period of three months represents one of the mechanisms used to check abilities during employment procedure both for health workers and health associates, which is stated in public vacancy announcements when announcing the need for filling a vacancy in a health institution.

k) Is there any estimate of numbers of trained health professionals not currently working in healthcare?

Estimates on the number of trained experts in the area of health care who currently do not work in this field have not been done and do not exist. However, there are data from the Employment Agency of Montenegro on the number of unemployed persons, health workers with a tertiary education.

According to the latest data (September 1, 2009) there are 66 health workers, 50 of whom are dentists with a tertriary education and passed licensing exam in the unemployed record of the Employment Agency of Montenegro.

B. Tobacco

48. With reference to tobacco control, what are the gender specific and combined smoking rates in your country by age groups (in percentages)?

Smoking is the most present addiction in the world and is considered one of the major preventable causes of illnesses and death. World Health Organisation estimated that, during 2002, 4.9 million people died due to smoking (Economic, Social and Health Issues in Tobacco Control, 2001, WHO), and it is expected that by the year of 2030, mortality will increase onto 10 millions, out of which 70% will be from the developing world (www.cdc.gov/tobacco/global/overview.htm). Due to very strong anti-smoking campaigns, that have already started in the developed world, the number of tobacco product users in these countries has been reduced. Today, it is estimated that 80% of all smokers live in the developing and transition countries, where the tobacco industry has found its market. The biggest problem is youth smoking and there is a tendency of young people to start smoking earlier in their life.

The use of tobacco products in Montenegro represents both health and economic problem. It is estimated that smoking is very present in Montenegro, so health problems occurring as a result of smoking complications are very frequent among the population as well. Data show that circulatory system disorders are the main cause of mortality in Montenegro, since more than a half of the deceased are registered with these disorders. Cancer is on the second place.

In our country, we have not had a survey regarding a number of smokers in the total population. In 2003, we conducted the Global survey on the number of smokers in elementary schools and the survey showed that in this population we have about 4% of permanent smokers, and that every third pupil had already experimented with smoking. Apart from that, we conducted the Global survey on the presence of smoking in high schools. School response rate was 100%, and 82.5% of pupils in the high schools and 90% in the elementary schools answered to the questions. The research encompassed 1937 pupils in total.

Analysis of the results regarding the use of tobacco products showed that more than a half of the high school pupils had already tried smoking and one quarter had done that before the age of ten. There are 18.6% of permanent smokers in the high schools and almost 95% of them use factory cigarettes. The data show that male pupils are more frequent permanent smokers than the female ones, but there is no statistically significant difference between the genders. It is interesting to note that the girls experimented with smoking more than the boys were.

Out of the total number of non-smokers, 17.3% of the boys and 15.4% of the girls feel the need to light up a cigarette after they wake up.

About one out of six of the permanent smokers, in the high schools, stated they feel strong need to light up a cigarette in the morning. More than one fifth of the non-smokers think they will start smoking during the next year. In both cases there is no significant difference between the genders.

The number of youth smokers, according to the Global survey on tobacco consumption, decreased in 2008 when compared to the previous survey conducted in 2003 (in 2003 there were 5.6% of permanent youth smokers (5.6% boys and 6% girls) and then we can register the reduction of the number of the permanent youth smokers to 5.1% out of which 5.7% are the boys and 4.4% are the girls. According to the survey a fraction less than one third of the pupils, aged 15, had already tried smoking at least one cigarette a day.

European School Survey on Alcohol and Other Drugs (ESPAD) conducted in 2008 in Montenegro showed that, by the age of 15, 44% of pupils, out of which 51% are the boys, had already tried smoking.

In order to deal with the problem of smoking in Montenegro, the Ministry of Health and the Health Insurance Fund of Montenegro will, during 2009, conduct the Smoking Cessation Programme in the youth counselling offices. The aim of this Programme is to reduce the number of the smokers in the population and to reduce the number of population morbidity and mortality in Montenegro.

49. With reference to the following list of acquis, please answer to the questions below a) to d):

Answered under a), b), c), d).

Questions:

a) Are there legislative, regulatory or administrative provisions in force in your country covering these areas? If yes, please send summaries and, if possible, full texts in one of the official EU languages.

In 2004 Montenegro adopted the Law on Limiting the Use of Tobacco Products (the Law was published in the Official Gazette of Montenegro 52/2004 of 2 August 2004), which deals with the tobacco products and their production, advertising and putting into circulation. In the first part of the Law the purpose and the basic definitions are described. The second part addresses the control of harmful cigarette substances and compulsory labelling on tobacco products where we can find the following entries:

Article 7

Manufacture and trade of cigarettes that contain more than 10 mg tar, 1 mg nicotine and 10 mg of carbon monoxide per cigarette is prohibited.

The prohibition of cigarettes manufacturing referred to in paragraph 1 of this Article does not refer to cigarettes manufacturing intended for export to countries in which this ban does not apply.

Content of tar, nicotine and carbon monoxide in cigarettes shall be determined based on the stipulated standards:

ISO 4387 for tar;

ISO 10315 for nicotine;

ISO 8454 for carbon monoxide.

Article 8

It is prohibited to trade in cigarettes that are not imprinted with information regarding the amount of tar, nicotine and carbon monoxide.

Information referred to in paragraph 1 of this Article, must be printed on the side of the packaging and cover at least 10% of the side it is printed on.

Correctness of the information referred to in paragraph 1 of this Article, concerning tar and nicotine, shall be determined according to the method ISO 8243.

Article 9

Tobacco products may not be traded, except for snuff and chewing tobacco, which do not have one of the following warnings printed, such as:

1. on the front

“Smoking kills’

“Smoking harms you and the people around you”

2. on the rear

“Smokers die younger”

“Smoking causes heart diseases and heart attack”

"Smoking causes lung cancer"

"Smoking during pregnancy harms your baby"

"Protect children, don't let them breathe your smoke in"

"Your doctor can help you give up smoking"

"Smoking is addictive"

"Quitting smoking reduces the risk of serious diseases"

"Smoking may cause slow and painful death"

"Ask for help to give up smoking"

"Smoking may reduce blood circulation and cause impotence"

"Smoking causes skin aging"

"Smoking may reduce fertility"

"Cigarette smoke contains benzene, nitrosamine, formaldehyde and hydrogen cyanide"

The warnings referred to in paragraph 1 item 1 of this Article, must cover at least 30%, and the warning referred to in paragraph 1, item 2 of this Article, at least 40% of the space on which it is printed.

The warnings referred to in paragraph 1 of this Article, must be altered one after the other, so that every warning appears on an equal quantity of manufactured, or sold tobacco products, during the year.

Article 10

Snuff and chewing tobacco may not be sold without a warning labelled on the best visible surface of the packaging: "This product may harm your health and cause addiction"

The warning referred to in paragraph 1 of this Article, must cover at least 30% of the surface on the side it is printed on.

Article 11

Packaging of tobacco products, except cigarettes, snuff and chewing tobacco, whose best visible surface exceeds 75cm^2 must contain the warning referred to in Article 9, paragraph 1 of this Law, which cover at least 22.5 cm^2 of the front and 22.5 cm^2 of the rear side of the packaging.

Article 12

The information referred to in Article 8, paragraph 1 of this Law and warnings from Article 9, paragraph 1 and Article 10, paragraph 1 of this Law, must be printed:

1. in the official language of Montenegro;
2. in bold, lower case letters (apart from the first letter), black letters on white background, in Helvetica font, in the size that takes up the most possible surface intended for warnings and information;
3. On the area of packaging that is not intended for opening or discarding during packaging;
4. In a manner so that it is possible to neither discard nor destroy them, or hide by darkening or covering with other writings or symbols.

Information referred to in Article 8, paragraph 1 of this Law and warnings from Article 9, paragraph 1 of this Law, must contain a border, whose width may be neither less than 3mm, nor more than 4mm.

Information referred to in Article 8, paragraph 1 of this Law and warnings from Article 9, paragraph 1 and Article 10, paragraph 1 of this Law, may not be on the brand of tobacco product that is labelled on the packaging.

Warnings referred to in Article 9, paragraph 1 and Article 10, paragraph 1 of this Law, may be printed on stickers, under the condition that the sticker cannot be removed.

The provision of paragraph 4 of this Article, does not concern cigarette packaging.

Article 13

It is prohibited to print labels on tobacco products that smoking of that particular type or class is less harmful than any other, that the filter or other substances of the tobacco product make it less harmful than products, which do not contain similar substances.

Article 14

For cigarettes that are available in Montenegro, the manufacturer or the importer of cigarettes must measure the substances referred to in Article 7 of this Law, at least once a year.

Measuring of the substances referred to in Article 7 of this Law may be carried out upon the request of the authorised inspector.

The Institute carries out measuring referred to in paragraph 1 and 2 of this Article.

Expenses for measuring referred to in paragraph 1 of this Article, as well as expenses for measuring referred to in paragraph 2 of this Article, are covered by the manufacturer or the importer, if as an outcome of measuring it is proven that cigarettes contain substances referred to in Article 7 of this Law in quantities higher than permitted.

Article 15

Manufacturers or importers of tobacco products shall deliver to the Institute once a year the following documents:

- the list of harmful substances and quantities that were used to manufacture tobacco products, according to mark and type;
- the statement regarding the reasons for including harmful substances thus citing facts regarding the effects of these substances;
- toxicology data that the manufacturer or importer of tobacco products possesses, concerning the substances of the tobacco product in burnt and non burnt form, its influence on health, especially how it affects addiction.

Article 16

At least once per year the Institute informs the Ministry and public about:

1. The results of the measures taken for the cigarettes that are manufactured and sold in Montenegro;
2. The determined results of measures that are above the limit referred to in Article 7 of this Law;
3. The content of harmful substances of tobacco products with toxicological details referred to in Article 15 of this Law, while obeying protection of information with regard to specific formulae that represent a business secret;
4. Other information with regard to tobacco products that is significant for the protection of health.

Data concerning specific formulae referred to in paragraph 1, item 3 of this Article are not related to the data regarding tar, nicotine and carbon monoxide content.

The Ministry shall define the methods and terms for informing the public referred to in paragraph 1 of this Article.

The third part addresses the measures to decrease and limit use of tobacco products and the articles are:

Article 17

It is prohibited to sell tobacco products to persons less than 18 years of age.

The persons referred to in paragraph 1 of this Article, are prohibited to sell tobacco products.

Persons referred to in paragraph 1 of this Article, may not use tobacco products in public areas.

Article 18

A sign must be displayed in locations where the retail sale of tobacco products is carried out concerning prohibition of sale of tobacco products to persons less than 18 years of age.

The sign referred to in paragraph 1 of this Article, must be displayed in a visible area.

The Ministry shall determine the sign form referred to in paragraph 1 of this Article.

Article 19

The sale of tobacco products is prohibited:

1. In educational and health institutions, and in the vicinity of less than 150 meters of these institutions,
2. In pharmacies and specialised shops for medicinal products;
3. In sports-recreational facilities;
4. Through vending machines
5. directly or indirectly as specials to buyers or any third party, such as gifts, awards, reduced trade discount or the right to participate in prize games, lotteries or competitions;
6. when they contain signs, words or phrases that refer the brand is less harmful than others (e.g. “low tar”, “light”, “mild”, “ultra mild”, “ultra light”, or “low tar” and other similar phrases);
7. in a manner that allows self-service to consumers.

It is prohibited to sell tobacco for oral use.

Article 20

It is prohibited to sell:

1. sweets, toys and other products intended for children that are in the form of any type of tobacco product;
2. non tobacco product, but has the name of a manufacturer of tobacco product or name of any other type of tobacco product, or signs, logotypes and similar marks, that refer to a tobacco product.

Article 21

It is prohibited to advertise tobacco products: in media; via cinema slides, films, billboards, notice boards, stickers, and other forms of advertising in public areas, in facilities and public transport; via neon adds, through books, magazines, calendars, items of clothing and stickers, posters and flyers, if these stickers, posters and flyers are separated from the original packaging of tobacco products.

Products, which according to this Law are not tobacco products, but their appearance, name and intended use indirectly encourage the consumption of tobacco products, may not be advertised.

It is prohibited to give free tobacco products and every direct and indirect promoting is prohibited.

Article 22

In the sense of Article 21 of this Law, announcements are not considered as advertising:

1. manufacturer and importer of tobacco products through media: about medals and other public recognitions received for the quality of particular products, as well as working, manufacturing and other achievements accomplished in tobacco product manufacturing, but without individual naming the products;

2. manufacturer and importer of tobacco products regarding the quality and other characteristics of their products during the specialised fairs and exhibitions within the exhibition space, during new products' sampling, which are organised in closed areas, during the celebrations they organise and for the duration of consumers' visits;
3. announcements about quality and other characteristics of the tobacco product published in expert books, magazines and other expert publications, which are only intended for manufacturers and traders of those products;
4. announcements about other characteristics of tobacco products that may be obtained by consumers in facilities in which tobacco products are sold, in accordance with the Law.

Article 23

It is prohibited to smoke tobacco products during public media appearances.

It is prohibited to publish in print photographs or illustrations of persons smoking.

Article 24

It is prohibited to smoke in a public area referred to in Article 4, paragraph 1, item 1 and paragraph 2, item 1, 2 and 5 of this Law.

By way of exception to paragraph 1 of this Article is a health institution in which mentally disadvantaged persons are accommodated that may determine a space for smokers.

Article 25

In public areas according to Article 4 paragraph 1 item 2 and paragraph 2, item 4 of this Law, smoking is admissible only in areas allocated to smokers, which are specially marked and separated from areas intended for non smokers.

The area allocated for smokers may not be larger than 50% of the entire public space referred to in paragraph 1 of this Article.

The area referred to in paragraph 2 of this Article, must be equipped with ventilation equipment, ashtrays and prescribed fire prevention equipment.

Article 26

In public areas referred to in Article 4, paragraph 2, item 3 of this Law, in which smoking is admissible, the owner or beneficiary must allocate a separate space for smokers.

In public areas referred to in paragraph 1 of this Article, the owner or beneficiary of the area shall determine the size of the area for smokers.

For determination of the size of an area referred to in paragraph 1 of this Article, the limitation referred to in Article 25, paragraph 2 of this Law does not apply.

The area allocated for smokers referred to in paragraph 1 of this Article, must be designated and separated from the area for non-smokers so that ventilation or a room divider prevents the air from mixing.

Article 27

The owner or beneficiary of the area referred to in Article 4 paragraph 2 item 3 of this Law, as well as the employee and owner and beneficiary of another hospitality facility, may completely prohibit smoking in the entire public or working area.

In the case referred to in paragraph 1 of this Article, a sign at the entry of this facility must indicate prohibition.

Article 28

In public areas in which smoking is prohibited in accordance with this Law, the owner, that is, beneficiary of the area must in a visible manner display smoking is prohibited signs.

Article 29

It is admissible to smoke in working areas only in spaces allowed by the employer, which are physically separated from the remaining working area.

If an employer can not provide for a necessary separate space, within the meaning of paragraph 1 of this Article, he/she may ban smoking in the entire workplace.

Article 30

Educational institutions shall inform children and youth, through suitable educational programmes, about the harmful health effects of tobacco products.

Sports organizations, within their competences, shall inform sport active persons on harmful effects caused by the use of tobacco and tobacco products.

The Ministry responsible for education in cooperation with the Ministry establishes the education program referred to in paragraph 1 of this Article.

Supervision of carrying out the program referred to in Paragraph 2 of this Article is carried out in accordance with the Law.

The fourth part addresses the supervision over the implementation of the Law, i.e. inspection supervision through the following articles:

Article 31

Supervision over the implementation of the Law is performed by the state administration bodies, competent for the tobacco product use limitation measures, through inspection supervision, in accordance with the law.

Inspection supervision referred to in paragraph 1 of this Article is performed by:

1. Sanitary Inspector, with regard to contents of tar, nicotine and carbon monoxide and prohibition of smoking in public and working places, with the exception of item 4 of this Paragraph;
2. Health Inspector with regard to prohibition of advertising tobacco products, prohibition of smoking tobacco products during media appearances and prohibition of printing photographs or illustrations of persons smoking and the obligation to display signs with regard to prohibition of smoking in public areas.
3. Market Inspector with regard to the obligation of displaying information about the contents of tar, nicotine and carbon monoxide on packaging of tobacco products, as well as prescribed warnings about the harmful effects of smoking;
4. Tourist Inspectors with regard to prohibition of smoking in discotheques, patisseries, bistros, pizza places, fast food facilities and hospitality facilities in which food is served.

Apart from this Law, the Law on Tobacco (adopted by the Parliament in 2003, amended in 2008) also regulates production and processing of tobacco and tobacco products, methods of meeting the requirements for putting tobacco products into circulation, inspection supervision.

The field of tobacco smoking control in Montenegro is defined by the strategic document the Strategy on Tobacco Control as well.

The Strategy is based on the basic principles of Warsaw declaration, in accordance with the principles of the European Strategy for Tobacco Control (ECTC), and the abovementioned principles are, among others:

Getting the population to get used to non-smoking as a norm (socially acceptable behaviour).

Natural right of every citizen to clean air, since all people, and especially children and youth have the right to protect themselves from the influence of the environmental tobacco smoke..

Protection of environment and the right of the citizen to healthy environment.

The need to create conditions for steady reduction of the number of the smokers in the population and smoking as a risky manner of behaviour.

The smokers have the right to the adequate treatment in the smoking cessation process through the health protection system.

Activities set in the Action plan for the implementation of the Strategy are specially targeted towards the groups that are especially sensitive to the detrimental influence of tobacco smoke, to the population groups that have an emphasised tendency of the growth of smoking prevalence and the number of illnesses which are caused by smoking complications, the groups that are in a problematic economic and social situation, marginalised population groups, socially isolate groups etc.

The Strategy implementation activities are:

Defining measures and activities on the promotion of healthy lifestyles;

Defining measures and activities leading to the reduced smoking incidence and prevalence in the population, especially when it comes to children and youth, women, and other vulnerable categories as well;

Defining efficient children-targeted programmes for the prevention of smoking in elementary schools, in order to stop them from starting smoking;

Defining measures and activities which would cause the reduction of the environmental tobacco smoke influence on all population groups, especially on children, pregnant women and sick people;

Defining measures and activities in order to decrease the morbidity and mortality rate when it comes to tobacco-related diseases, which would, in turn, lead to the better health of the population;

Coordination and cooperation of experts in institutions and NGOs regarding the control on smoking;

Surveys on the presence of smoking and the negative effects of the smoking in the population groups lacking the data on smoking prevalence (prevention of smoking with health workers and others) and regular dissemination of information about the smoking tendency and the tobacco-caused diseases. The cooperation with the media is of vital importance;

Providing the availability of information regarding all relevant aspects for the protection from smoking and tobacco smoke.

b) In case there are no legislative, regulatory or administrative provisions in force, are there any drafts or proposals for these in the pipeline? If so, give details of these and of the timeline for their adoption.

The laws regulating this field in Montenegro are adopted, and that can be seen from the answers to the other sub-questions from the field, but we plan to introduce some new amendments to the Law on Limiting the Use of Tobacco Products.

c) In cases where neither of the above exist, are there any plans to start preparing proposals? Please explain, also indicating the envisaged timetable.

Both the Law on Limiting the use of Tobacco Products, and the Law on Tobacco (with amendments) are adopted. Regarding the deadlines for amendments to the Law on Limiting the Use of Tobacco Products, these activities will be implemented by the Ministry of Health by the first half of 2010.

d) Does your country have the necessary administrative capacity, including human and material resources, to fulfil the requirements laid down in the Community legislation listed above?

Montenegro has all necessary capacities for the implementation of obligations which are taken through the ratification of the Framework Convention on Tobacco Control. However, we lack human resources to implement all the proposed measures. We take all necessary actions in order to resolve the problem in order to be able to fulfil all the requirements prescribed by the Law.

Human resources is necessary in the part of monitoring of implementation, evaluation, and regular reporting on the implemented measures, and especially in the part of monitoring of the implementation of the Law on Limiting the Use of Tobacco Products.

The Ministry of Health appointed the Tobacco Control Committee, which is composed of the competent members, who are responsible for monitoring of the aforementioned obligations of all competent factors, and for the creation of plan and programme in the tobacco control field. The work of the Committee is headed by the National Coordinator for the tobacco control.

C. Communicable diseases

50. With reference to communicable diseases:

The answer to the question is under 50a), 50b), 50c), 50d), 50e)

a) Please describe your epidemiological surveillance (diseases monitoring) system, in particular the reporting mechanism, involved parties and their respective roles, as well as the list of communicable diseases notified to the national competent public health authority.

This Law on the Protection of Population against Communicable Diseases (Official Gazette of Montenegro 32/05) shall determine communicable diseases endangering the health of the population of Montenegro (hereinafter referred to as “communicable disease”), as well as the infections arising as a result of performing of health care activities (hereinafter referred to as “hospital infections”); measures for their prevention and fight; competent authorities for the implementation of measures; the method of securing the funds for the implementation of the measures, as well as performing the supervision over the implementation.

Epidemiological supervision and communicable diseases control are conducted through the following measures and activities:

1. Immunoprophylaxis and chemoprophylaxis;
2. Medical checkups of certain population categories with counselling;
3. Health care supervision and quarantine;
4. Laboratory testing in order to identify communicable disease agents and epidemic agents;
5. Early detection and reporting of communicable diseases and epidemiological supervision;
6. Epidemiological testing;
7. Health care education of the infected, members of their families and other persons who are at a risk to get a disease, and
8. Disinfection, disinfestations and deratisation according to epidemiological indications.

Epidemiological supervision is organised through the network of sanitary-epidemiology departments in health-care units and the Public Health Institute. Physicians, who diagnose the communicable diseases that are compulsory to report, are obliged to report such diseases through the appropriate report form and submit it to the epidemiological authority with territorial jurisdiction and the Institute for Public Health.

In Montenegro, according to the Law on the Protection of Population against Communicable Diseases (Official Gazette of Montenegro 32, 2005) and the Rulebook on reporting communicable diseases and hospital infections (Official Gazette of Montenegro 45, 2007), it is mandatory to report:

1. Disease or death caused by the following communicable diseases:

A 00.0 Cholera, caused by Vibrio cholerae 01, biotype cholerae (Cholera classica)

A 00.1 Cholera, caused by Vibrio cholerae 01, biotype El Tor (Cholera El Tor)

A 00.9 Cholera, unspecified (Cholera, non specificata)

A 01.0 Abdominal typhus (Typhus abdominalis)

A 01.1 Paratyphus A (Paratyphus A)

A 01.2 Paratyphus B (Paratyphus B)

A 01.3 Paratyphus C (Paratyphus C)

A 01.4 Paratyphus, unspecified (Paratyphus, non specificatus)

A 02.0 Small intestine inflammation caused by salmonellas (Enteritis salmonellosa)

A 02.1 Sepsis caused by salmonellas (Salmonellosis septica)

A 02.2 Localised infection caused by salmonellas (Infectio per salmonellam localisata)

A 02.9 Salmonella infection, not specified (Infectio per salmonellam, non specificata)

A 03.0 Dysentery, caused by Shigella dysenteriae (Dysenteria bacillaris per Sh. dysenteriae)

A 03.1 Dysentery, caused by Shigella flexneri (Dysenteria bacillaris per Sh. flexneri)

A 03.2 Dysentery, caused by Shigella boydi (Dysenteria bacillaris per Sh. boydi)

A 03.3 Dysentery, caused by Shigella sonnei (Dysenteria bacillaris per Sh. sonnei)

A 03.9 Dysentery, unspecified (Shigellosis, non specificata)

A 04.0 Intestine infection, caused by EPEC (Infection intestinalis per E. coli enteropathogenem)

A 04.1 Intestine infection, caused by ETEC (Infection intestinalis per E. coli enterotoxigenem)

A 04.2 Intestine infection, caused by EIEC (Infection intestinalis per E. coli enteroinvasivam)

A04.3 Intestine infection, caused by EHEC (Infection intestinalis per E. coli enterohaemorrhagicam)

A 04.4 Other intestine infection, caused by Escherichia coli (Infection intestinalis per E. coli)

A 04.5 Intestine inflammation, caused by Campylobacter (Enteritis campylobacterialis)

A 04.6 Small intestine inflammation caused by Yersinia enterocolitica (Enteritis yersiniosa enterocolitica)

A 04.7 Intestine inflammation caused by Clostridium difficile (Enterocolitis per Clostridium difficile)

A 04.9 Intestine infection, caused by bacteria, unspecified (Infectio intestinalis bacterialis, non specificata)

A 05.0 Food poisoning caused by staphylococci (Intoxication alimentaria staphylococcica)

A 05.1 Food poisoning caused by Clostridium botulinum (Botulismus)

A 05.2 Food poisoning caused by Clostridium perfringens (Intoxicatio alimentaria per Clostridium perfringentem)

A 05.3 Food poisoning caused by Vibrio parahaemolytica (Intoxicatio per Vibrionem parahaemolyticam)

A 05.4 Food poisoning caused by Bacillus cereus (Intoxicatio alimentaria per Bacillum cereum)

A 05.8 Other specified food poisoning caused by bacteria (Intoxicationes alimentariae bacteriales aliae, specificatae)

A 05.9 Food poisoning caused by bacteria, unspecified (Intoxicatio alimentaria bacterialis, non specificata)

A 06.9 Amoebiasis, unspecified (Amoebiasis, non specificata)

A 07.1 Lambliasis, caused by Lamblia intestinalis (Lambliasis)

A 07.2. Cryptosporidiosis, caused by Cryptosporidium (Cryptosporidiasis)

A 08.0 Rotavirus Enteritis

A 09 Diarrhoea and gastroenteritis, probably of communicable origin (Diarrhoea et gastroenteritis, causa infectionis suspecta)

A 15.0-A 15.9 Tuberculosis of respiratory organs, bacteriologically and histologically confirmed (Tuberculosis organorum respiratoriorum, per bacteriologiam et histologiam confirmata)

A 16.0-A 16.9 Tuberculosis of respiratory organs, bacteriologically and histologically unconfirmed (Tuberculosis organorum respiratoriorum, per bacteriologiam et histologiam non confirmata)

A 17.0-A 17.9 Tuberculosis nervous system (Tuberculosis systematis nervosi)

A 18.0-A 18.9 Tuberculosis of other organs (Tuberculosis organorum aliorum)

A 19.0-A 19.9 Disseminated Tuberculosis (Tuberculosis miliaris)

A 20.9 Plague, unspecified (Pestis, non specificata)

A 21.9 Tularaemia, unspecified (Tularaemia, non specificata)

A 22.0 Skin Anthrax (Anthrax cutaneus)

A 22.1 Lung Anthrax (Anthrax pulmonalis)

A 22.2 Gastrointestinal Anthrax (Anthrax gastrointestinalis)

A 22.9 Anthrax, unspecified (Anthrax non specificatus)

A 23.9 Brucellosis, unspecified (Brucellosis, non specificata)

A 27.9 Leptospirosis, unspecified (leptospirosis, non specificata)

A 32.9 Listeriosis, unspecified (Listeriosis, non specificata)

A 33 Neonatal Tetanus (Tetanus neonati)

A 34 Puerperal tetanus (Tetanus puerperalis)

A 35 Other tetanises (Tetanus alius)

A 36 Whooping cough (Diphtheria)

A 37.9 Whooping cough, unspecified (Pertussis, non specificata)

A 38 Scarlet fever (Scarlatina)

A 39.0 Meningococcal infection (Meningitis meningococcica)

A 39.1 Waterhouse-Friderichsen syndrome (Syndroma Waterhouse-Friderichsen)

A 39.2 Acute Septicaemia (Sepsis meningococcica acuta)

A 39.9 Meningococcal infection, unspecified (Infectio meningococcica, non specificata)

A 40.9 Septicaemia caused by streptococcus (Septicaemia streptococcica)

A 41.8 Other Septicaemias, specified (Septicaemia alia, specificata)

A 48.1 Legionnaires' disease (Legionellosis)

A 50.9 Congenital Syphilis, unspecified (Syphillis congenita, non specificata)

A 51.9 Fresh Syphilis, unspecified (Syphillis recens, non specificata)

A 52.9 Late Syphilis, unspecified (Syphillis tarda, non specificata)

A 53.9 Other Syphilis, unspecified (Syphilis alia et non specificata)

A 54.9 Gonorrhoea, unspecified (Infectio gonococcica, non specificata)

A 56.8 Sexually-transmitted Chlamydialis (Infection chlamydialis modo sexuali transmissa)

A 69.2 Lyme disease (Morbus Lyme)

A 70 Ornithosis, psittacosis (Ornithosis, psittacosis)

A 75 Spotted typhus (Typhus exanthematosus per Rickettsiam prowazeki)

A 75.1 Brill disease (Morbus Brill)

A 78 Q fever (Ferbis Q)

A 80.0 Acute infantile paralysis, post vaccination (Poliomyelitis paralitica acuta, postvaccinalis)

A 80.1 Acute infantile paralysis, wild imported virus (Poliomyelitis paralitica acuta, virus importatum)

A 80.2 Acute infantile paralysis, autochthonous virus (Poliomyelitis paralitica acuta, virus autochtonum)

A 80.9 Acute infantile paralysis, unspecified (Poliomyelitis acuta, non specificata)

A 81.0 Creutzfeldt- Jakob disease (Morbus Creutzfeldt – Jakob)

A 82.9 Rabies, unspecified (Rabies, non specificata)

A 84.9 Viral encephalitis caused by tick, unspecified (Encephalitis viralis ixodibus transmissa, non specificata)

A 85 Other viral encephalitis (Encephalitis viralis aliae)

A 87.0 Enteroviral meningitis (Meningitis enteroviralis)

A 93.1 Sandfly fever (Febris sandfly)

A 95.9 Yellow fever, unspecified (Febris flava, non specificata)

A 96.2 Lassa haemorrhagic fever (Febris lassa)

A 98.0 Crimean-Congo Hemorrhagic Fever (Febris haemorrhagica Crim-Congo)

A 98.3 Marburg viral disease (Marbus viralis Marburg)

A 98.4 Ebola disease (Morbus viralis Ebola)

A 98.5 Haemorrhagic fever with renal syndrome (Febris haemorrhagica cum syndroma renali)

B 01.8 Chickenpox with other complications (Varicella cum complicationibus aliis)

B 01.9 Chickenpox without complications (Varicella sine complicationibus)

B 05.8 Measles with other complications (Morbilli cum complicationibus alii)

B 05.9 Measles without complications (Morbilli sine complicationibus)

B 06.8 Rubella with other complications (Rubella cum complicationibus)

B 06.9 Rubella without complications (Rubella sine complicationibus)

P 35.0 Congenital rubella (Syndroma rubellae congenitae)

B 15.9 Acute viral hepatitis A without hepatic coma (Hepatitis A sine comate hepatico)

B 16.1 Acute viral hepatitis B with delta agent (Hepatitis acuta B cum delta agente)

B 16.9 Acute viral hepatitis B without delta agent (Hepatitis acuta B sine delta agente)

B 17.1 Acute viral hepatitis C (Hepatitis acuta C)

B 17.2 Acute viral hepatitis E (Hepatitis acuta E)

B 18.0 Chronic viral hepatitis B with delta agents (Hepatitis viralis chronica B cum delta agente)

B 18.1 Chronic viral hepatitis B without delta agents (Hepatitis viralis chronica B sine delta agente)

B 18.2 Chronic viral hepatitis C (Hepatitis viralis chronica C)

B 19.9 Viral hepatitis, unspecified (Hepatitis viralis, non specificata)

B 20 HIV disease, acquired immunodeficiency with communicable diseases and parasitary diseases (Morbus HIV-morbus deficientiae immunitatis aquisitae cum morbis infectivis et parasitariis adjunctis)

B 21 HIV disease with malignancy (Morbus HIV cum neoplasmatis malignis adjunctis)

B 22 HIV disease with other specified diseases (Morbus HIV cum morbis alis specificatis adjunctis)

B 23 HIV disease with other conditions (Morbus HIV cum statibus adjunctis aliis)

B 24 HIV disease, unspecified (Morbus HIV, non specificatus)

B 26.0 Inflammation of the testis caused by mumps virus (Orchitis parotitica)

B 26.1 Meningitis caused by mumps virus (Meningitis parotitica)

B 26.2 Encephalitis caused by mumps virus (Encephalitis parotitica)

B 26.3 Pancreatitis caused by mumps virus (Pancreatitis parotitica)

B 26.9 Epidemiological mumps without complications (Parotitis epidemica sine complicatione)

B 27.9 Communicable mononucleosis, unspecified (Mononucleosis infectiva, non specificata)

B 50.9 Tropical malaria, caused by Plasmodium falciparum (Malaria tropica)

B 51.9 Tertian malaria, caused by Plasmodium vivax (Malaria tertiana)

B 52.9 Quartan malaria, caused by Plasmodium malariae (Malaria quartana)

B 53.0 Ovale malaria, caused by Plasmodium ovale (Malaria ovale)

B 54 Malaria, unspecified (Malaria, non specificata)

B 55.0 Visceral Leishmaniasis (Leishmaniasis visceralis)

B 55.1 Cutaneous Leishmaniasis (Leishmaniasis cutanea)

B 55.9 Leishmaniasis, unspecified (Leishmaniasis, non specificata)

B 58.9 Toxoplasmosis, unspecified (Toxoplasmosis, non specificata)

B 67.0 Hepatic Echinococcosis (Echinococcosis hepatis)

B 67.1 Pulmonary Echinococcosis (Echinococcosis pulmonis)

B 67.9 Other Echinococcosis, unspecified (Echinococcosis alia non specificata)

B 75 Trichinellosis (Trichinellosis)

B 77 Ascariasis (Ascariasis)

B 80 Enterobiasis (Enterobiasis)

B 86 Scabies (Scabies)

B 96.3 Disease caused by haemophilus influenzae – Epiglottitis (Haemophilus influenzae ut causa morborum)

B 97.7 Papilloma virus as a disease cause

G 00.0 Meningitis, caused by Haemophilus influenzae (Meningitis haemophilosa)

G 00.1 Meningitis, caused by pneumococcus (Meningitis penumococcica)

G 00.2 Meningitis, caused by staphylococcus (Meningitis staphylococcisa)

G 00.3 Meningitis, caused by staphylococcus (Meningitis staphylococcisa)

G 00.9 Meningitis, caused by bacteria, unspecified (Meningitis bacterialis, non specificata)

G 83.9 Paralytic syndrome, unspecified (AFP)

J 02.0, J 03.0 Streptococcal pharyngitis and tonsillitis (Pharyngitis et tonsillitis streptococcica)

J 02.0 Streptococcal pharyngitis (Pharyngitis et tonsillitis streptococcica)

J 03.0 Streptococcal tonsillitis (Tonsillitis streptococcica)

J 10 Influenza, identified virus (Influenza, virus identificatum)

J 11 Influenza, unidentified virus (Influenza, virus non identificatum)

J 12 Viral pneumonia (Pneumonia viralis)

J 13 Pneumonia, caused by Streptococcus pneumoniae (Pneumonia pneumococcica)

J 14 Pneumonia, caused by Haemophilum influenzae (Pneumonia per Haemophilum influenzae)

J 15 Pneumonia, caused by bacteria (Pneumonia bacterialis)

J 84 Other interstitial pneumonias (Pneumoniae interstitiales aliae)

2. Laboratory identified agent of an communicable disease;
3. Death by communicable disease which is not stated in Article 2 of this Law;
4. Existing doubt on cholera, quarantine disease, poliomyelitis, diphtheria, measles, botulism;
5. The epidemic of communicable disease of known or unknown communicable agent;
6. Hospital infection;
7. The secretion of agents of abdominal typhus, paratyphus, other salmonella infections, shigelloses, yersiniose and campylobacteriosis as well as carriers of antigens of viral hepatitis “B”, antibodies to viral hepatitis “C” and AIDS and carriers of parasites-malaria communicable agents;
8. Every bite i.e. contact with rabid or suspicious animal;
9. Acute flaccid paralysis;
10. Suspect of the use of biological agents;
11. Side effects after the vaccination, and,
12. Anti-microbe resistance.

Note: On the basis of WHO and the US Public Health Service documents and recommendations, we have developed the Standards in epidemiological supervision of communicable diseases where the definitions of most of the diseases that are compulsory to report can be found.

Compulsory reporting is performed by the health institutions and other entities that perform health care activities, on the basis of the medical doctor report:

- Zero reporting
- Collective reporting
- Urgent reporting
- Early warning and urgent response system (ALERT)
- Individual reporting

Zero reporting is used to report the absence of acute flaccid paralysis, measles, morbillivirus, congenital rubella, and other communicable diseases and other events and conditions in accordance to the international health regulations, WHO programmes and other international acts. The reporting procedure is conducted according to the technical-methodological instruction of the Institute for Public Health that is harmonised with the programmes for elimination and eradication of communicable diseases.

Acute flaccid paralysis, measles, morbillivirus and congenital rubella require weekly reports for the previous calendar year. The report is completed by the appointed coordinator in the health care institutions. The report is submitted once a week to the Public Health Institute not later than 48 hours after the end of previous week.

Collective reporting is used for an identified virus, unidentified virus (except for avian influenza) and acute respiratory infection. The report is completed by a doctor who diagnosed the disease. The

report is submitted once a week to the competent sanitary-epidemiological unit and the Institute for Public Health, not later than 48 hours after the end of previous week.

Note: from 1 January 2009 we introduced weekly reporting for the diseases that resemble flu (influenza like illness-ILI) and acute respiratory infections (ARI) during the whole of calendar year.

Individual reporting is used for:

Communicable disease disorder, identifies flu virus, unidentified flu virus, acute respiratory infections, HIV, malaria disorders and tuberculosis

Death caused by an communicable disease

Death caused by an communicable disease that is not on the list of diseases which are compulsory to report

Doubt that there is a disorder caused by an communicable disease which is compulsory to report

Excretion of abdominal typhus and paratyphus agent

Excretion of shigelloses, yersiniose and campylobacter

Presence of viral hepatitis B antigens in the blood (HBsAg)

Presence of an antibody to the hepatitis C virus in the blood (anti HCV)

Presence of parasite that causes malaria

Presence of an antibody to the HIV virus (anti HIV)

Reporting of an communicable disease is performed on the basis of clinical/laboratory diagnosis, and according to the vase definition and on the basis of technical-methodological instructions of the Public Health Institute and the Standards in epidemiological supervision over the communicable diseases.

Two copies of the report are submitted, one to the competent sanitary-epidemiological unit and the other to the Public Health Institute.

Sanitary-epidemiological departments submit their weekly and monthly reports regarding the situation of communicable diseases on the territory for which they have authority to the Institute and the state administration body that is competent for health affairs. On the basis of individual reports on communicable diseases, and weekly and monthly reports obtained from sanitary-epidemiological units, the Institute makes weekly, monthly and annual reports on the situation of communicable diseases, except for tuberculosis for which the competent body is the Special Hospital for Lung Diseases and Tuberculosis - Brezovik. The hospital prepares monthly and annual reports.

The report on the situation of communicable diseases contains data on disease distribution per municipalities, months, age and gender.

b) Please describe your alert and response system, in particular the communication mechanism, risk assessment and risk management of public health emergencies of international concern in the field of communicable diseases, involved parties and their respective roles; provide some examples which illustrate how this system operates.

Competent sanitary-epidemiological unit according to the Law on the Protection of Population against communicable diseases and the Rulebook on communicable diseases and hospital infections reporting submits reports to the Public Health Institute regarding the disruption of health that is of public-health importance, and at the same time, informs (via telephone, fax machine or electronically) the Ministry of Health i.e. Department of health-sanitary inspection affairs.

Competent sanitary-epidemiological unit together with the Public Health Institute assesses the risk (epidemiological research), on the basis of which the sanitary-epidemiological unit performs supervision inspection, and reacts in accordance to the findings and takes measures defined by the Law.

The rapid information exchange system functions through a) urgent reporting and b) alert

Urgent reporting – is used for every case of acute flaccid paralysis (AFP) for the age of up to 15, when there is a doubt of: cholera, plague, yellow fever, viral haemorrhagic fever except for the haemorrhagic fever with renal syndrome, poliomyelitis, diphtheria, measles, botulism, avian flu, danger from a biological agent (and suspicion it was used) and other diseases that are not included in the list of the diseases that are compulsory to report, and which can endanger health of the population of Montenegro (the Government of Montenegro can decide, on the recommendation of the state administration body that is competent for the health affairs, to introduce all necessary measures prescribed by the Law on the Protection of Population against Communicable Diseases, other measures for the population protection, and the measures that are stipulated by the international heath and sanitary conventions and other international acts, and epidemic of communicable diseases as well. Urgent reporting is performed by: telephone, telegram, telefax, email and by any other manner that is convenient for urgent reporting and individual reporting as well.

Alert – is conducted in the territory where the Institute assesses there is danger of:

1. Outbreak of communicable diseases epidemic, in the events of weather disasters, catastrophes, and organised mass gatherings
2. Spread of communicable diseases epidemic, after the anti-epidemic measures have been taken
3. Occurrence of a new or insufficiently understood communicable disease
4. Occurrence of insufficiently defined symptoms and conditions
5. Biological agent, in the case that the agent has been used.

Alert reporting starts immediately if there is a danger for the abovementioned situations to occur and lasts until there is a reason to do so.

An example illustrating the functioning of the system for rapid response and information exchange is given for the case of diagnosing AFP. All necessary actions are described in details in the Guide for the conduct of active supervision over AFP and poliovirus (for instance, what are the monitoring units for AFP; which equipment should every monitoring unit have; how, on what form and what is the time limit for the reporting and investigation after the AFP diagnosis has been made; how to collect and submit samples etc.).

c) Please indicate if you have adopted a national epidemic preparedness plan, including pandemic influenza preparedness plan. Moreover, since 5 February 2008 International Health Regulations (2005) entered into force in your country. Indicate your National IHR Focal Point and what is your timetable to develop national action plans to implement and meet IHR (2005) requirements in order to strengthen national capacity.

In accordance with the WHO recommendations, the Ministry of Health created National Plan for Avian Influenza and Pandemic Flu. The plan was adopted by the Government of Montenegro in 2005. In 2006, Commission for communicable diseases of the Ministry of Health, adopted Guideline for the application of the National Plan for Avian Influenza and Pandemic Flu. In April 2009, after the emergence of a new flu virus A (H1N1), within the Ministry of Health we established Task force for the prevention and containment of pandemic flu. The Task force, in accordance with the WHO recommendations and experiences of the countries that have already registered the first cases of the new flu, adopted Algorithm for actions in the case of an infection from the new pandemic flu A (H1N1), and recommendations for the nationals of Montenegro and passengers in international traffic. The abovementioned algorithms and recommendations are regularly updated in accordance with the recommendations of WHO, European Centre for Disease Prevention and Control and the US Centres for Disease Control and Prevention as well. Furthermore, electronic and printed media are used in order to inform and educate population about the pandemic flu.

IHR focal point in Montenegro is Dr. Božidarka Rakočević, epidemiologist from the Public Health Institute, Podgorica, appointed on 28 April 2009.

The Ministry of Health – the IHR team located in the country, with the aid of the WHO office in Montenegro, in the following period (by the end of 2009) shall conduct the following activities:

Defining institutional arrangement that implies the nomination of particular ministries and agencies responsible for the IHR implementation. This arrangement will be implemented through the establishment of the IHR task force and the IHR contact points network for the sectors that have to be engaged,

Assessment of the national capacities,

Creation of the National Action Plan for the IHR.

Planned dynamics for the finalisation of the aforementioned activities is the end of 2009.

Additionally, the Ministry of Health formed the Task force for the harmonisation of the Law on the Protection of Population against Communicable Diseases with the new EU and IHR directives and recommendations. The Task force will work on the creation of the Law on Sanitary Inspection which should be done by the end of 2009.

d) Indicate your immunisation programmes, and the level of coverage.

Annual Programme of Compulsory Immunisations in Montenegro is adopted by the Ministry of Health on the recommendation of the Public Health Institute after the consideration of the Commission for Communicable Diseases of the Ministry of Health. Valid 2009 Programme of compulsory immunisations for Montenegro can be found in the Official Gazette of Montenegro 25/2009.

Compulsory immunisation for the people of a particular age is conducted against the following communicable diseases:

- tuberculosis,
- infantile paralysis,
- diphtheria,
- tetanus,
- whooping cough,
- measles,
- epidemic mumps,
- rubella,
- viral hepatitis "B", and
- haemophilus influenzae type b

Current calendar of the compulsory immunisations for all individuals of a particular age is shown in Table 1.

Table: 2009 Calendar of the compulsory immunisations for all individuals of a particular age in Montenegro

AGE	VACCINES						
Birth	BCG						Hep. B* HBsAg+
1 month after the birth							Hep. B* HBsAg+
2 months after the birth		DTP	OPV			Hep. B	Hep. B* HBsAg+
3 months after the birth					Hib	Hep. B	
4 months after the birth		DTP	OPV		Hib		
5.5 months after the birth		DTP	OPV		Hib		
12 months after the birth				MMR_1		Hep. B	Hep. B* HBsAg+
18 months after the birth		$DTPR_1$	OPV R_1		$HibR_1$		
At the age of 2, until the age of 5**					Hib**		
At the age between 5 - 7 (during the elementary school enrolment of during the school year)		DT/dT	OPV R_2	MMR_2			
At the age of 12 (6th grade of elementary school)				MMR_2***			
At the age between 13 – 15 (8th grade of elementary school)		dT	OPV R_3				
At the age between 17 - 19 (high school final year)		TT					

* Hepatitis B vaccine for the newborns whose mothers are HBsAg positive.

** Only for the children who were not vaccinated until the age of 12 months

*** MMR_2 for the generations that did not receive MMR_2 during the enrolment into an elementary school

Apart from that, the objectives of the Programme are compulsory immunisations with epidemiological and clinical indications which are performed against:

- hepatitis virus "B",
- abdominal typhus,
- rabies,

- tetanus,
- flu
- yellow fever,
- cholera,
- diphtheria,
- diseases caused by haemophilus influence type b,
- meningococcal meningitis,
- diseases caused by pneumococci,
- viral hepatitis "A"

and other communicable diseases for which the Ministry of Health, on the recommendation of the Public Health Institute defines the need for immunisations.

The following table shows the scope of the compulsory vaccinations in percentages (%) in Montenegro during the period of 2003 - 2008.

The scope of the compulsory vaccinations in percentages in Montenegro during the period 2003 - 2008

Year	Scope of particular vaccines in percentages %					
	BCG	DTP_3	OPV_3	Hepatitis B_3	Hib_3	MMR
2004	97.6	95.1	95.0	91.3	-	91.7
2005	98.0	94.6	94.6	91.4	-	90.3
2006	98.4	92.8	92.9	92.5	-	91.8
2007	98.2	93.1	93.2	91.6	89.2	91.6
2008	98.1	96.1	96.1	94.8	95.1	89.5

Epidemiological situation regarding the communicable diseases against which the compulsory vaccination is performed is as follows:

Diphtheria in Montenegro is practically eliminated. The last registered case happened in 1977.

Poliomyelitis caused by the wild type poliovirus, has not been registered in Montenegro since 1973. From June 2002, WHO members from the European region are considered free from autochthonous infantile paralysis. In accordance with the WHO requests, we are currently conducting active monitoring of acute flaccid paralysis.

Thanks to a high number of the immunised population and a high number of deliveries, performed with the professional help, in Montenegro, neonatal tetanus for the last 13 years has been registered in only one child. As for adults, tetanus is registered rarely, in the form of individual cases. During 2008 there were not registered cases of tetanus.

Whooping cough, during the period of 1991-2008 was reported in the form of pertussis-like syndrome, and registered only through individual cases. In 2008, five cases of the pertussis-like syndrome were registered.

After the introduction of the second dose of the combined vaccine against measles, mumps and rubella, (MMR) into the calendar of compulsory immunisations, we register a decrease in the number of people with measles. Although, during the period between 2005 – 2008 we did not register a single case of morbillivirus, the experience from the developed and neighbouring countries show that the morbillivirus epidemics (due to a highly contagious virus) are still occurring, except for the cases where vaccinations cover 100% of a population, which is practically very difficult. Internally displaced persons of Roma nationality represent particularly risk, due to their low response rate to regular and extraordinary vaccination campaigns. Therefore, we organise additional vaccination campaigns, several times a year.

Immunisation against parotitis has been carried out for the last two decades (first as a part of morbilli-parotitis (MP), and then as an integral part of the combined MMR vaccine). Although infections are not reduced to individual cases, epidemic waves are less frequent with lower infection rate when compared to the period prior to the introduction of the vaccination. During the

period between 1991-2008, the highest infection rate was registered in 2000 (120 per 100.000 residents), and the lowest in 2008 (2.3 per 100.000 residents).

Rubella vaccine is in the programme of the compulsory systematic immunisations from 1994 (as a component of the MMR vaccine) and significant infection rate reduction was expected not before the middle of the next decade. The infection rate has already been significantly reduced when compared to the time prior to the introduction of the vaccine. The highest infection rate in the period between 1991-2008 was registered in 1995 (426 ‰), and the lowest during the last three years (2006 - 2008) when there was not a single registered case. Registered rubella incidence is probably lower than the real one, since, except for epidemic years, rubella is harder to clinically identify. Apart from that, the majority of the cases is not too serious and, therefore, patients do not go to a health-care unit, which in turn make it impossible to register rubella. Therefore, all suspicious cases are tested on the presence of Immunoglobulin M antibodies in order to confirm or reject rubella diagnosis.

Taking into consideration that the effect of the vaccination against tuberculosis (BCG) is limited by the inherent disadvantages of the vaccine itself (it is a fact it usually protects from tuberculosis meningitis and hematogenic forms of tuberculosis in the early age), the success rate of the vaccination against tuberculosis is best perceived through the number of children infected with tuberculosis meningitis in the preschool age. Taking into consideration the BCG vaccination rate is very high, the occurrence of tuberculosis meningitis is extremely rare (has not been registered in the last five years), and in the preschool age the pulmonary form of tuberculosis is registered rarely as well (in 2004 two cases, 2005 two cases and 2007 one case).

Vaccination against Haemophilus influenza type b was introduced in the middle of 2006, so the result evaluation will be done during 2011.

e) Please provide the following information regarding communicable diseases:

- Is there/Are there plan(s) of action for an outbreak at national level? If yes, please provide a translation of one.

In 2007 the Government of Montenegro adopted the National Strategy for Extraordinary Situations. According to the planned dynamics, by the end of 2009 the National Action Plan for the case of biological incident is expected to be adopted. For the time being, we have the National Plan for the Pandemic Flu with the Guideline and Algorithm, Operative plan for SARS and the Guideline for the implementation active supervision over acute flaccid paralysis and poliovirus.

- Is there a legal basis for monitoring anti-microbiological resistance? How is the system organised?

The Law on the Protection of Population from Communicable Diseases states the obligation to establish the antibiotics resistance monitoring system. Bylaw (Rulebook) that would regulate this field with more details will be done in the following period.

- Can you provide the Commission with the curriculum of training in epidemiological specialisation?

Since in Montenegro we do not have the Department for specialisation in epidemiology, the Rulebook on specialisations (Official Gazette 74/2006) defines the specialisation must be done according to the plan and programme of the Faculty of Medicine at which a specialist is enrolled. Mostly, specialists enrol at the School of Medicine in Belgrade (the Republic of Serbia), which Rulebook on Specialisations (Official Gazette of the Republic of Serbia 111/93...36/34) is attached to this document.

Specialisation in epidemiology (total duration: 36 months)

Theoretical and practical education at the faculty (9 months) and practical vocational work in health-care institutions which meet the requirements (27 months, out of which: general and special epidemiology 17 months, microbiology 2 months, hygiene 2 months, infectology 2 months, social medicine 1 month, medical statistics and computer science 1 month).

Half of the time dedicated to the practical vocational work from the abovementioned epidemiological fields is spent in the Public Health Institute of Serbia or the Public Health Institutes in Novi Sad, Belgrade and Niš, and the other half is spent in other institutes of public health which meet the requirements (the Public Health Institute - Podgorica).

List of skills

Doctor specialising epidemiology, during the specialisation period, are obliged to participate in the implementation of prevention and containment measures for the following diseases:

- Diseases for the group of intestine infections (enterocolitis, HVA, elementary toxic infections, intoxications, salmonellosis, shigellosis, serious meningitis),
- Diseases for the group of respiratory infections (streptococcosis, flu, acute respiratory diseases of viral aetiology, some of the diseases that require immunoprophylaxis).
- Diseases from the group of anthropozoonosis and vector-borne diseases (the particular type of a diseases depends on the epidemiological situation)
- Blood-borne and sexually transmitted diseases (HVB, AIDS).
- Diseases that are non-communicable and of unknown aetiology (cardiovascular, malignant, etc.)
- The aforementioned activities are directed towards mastering of the following skills:
- Epidemiological observations 30
- Health supervision 20
- Sanitary supervision 20
- Sanitary examination 30
- Vaccination 15
- Medical and educational work in a family and a group 10
- Medical preparation of passengers in international traffic 5
- Epidemiological protection of a group 10
- Intrahospital infection control 10
- Active epidemiological research in the case of a disease 50
- Creation of a survey questionnaire 5
- Epidemiological survey 50
- Taking samples of a biological material for the microbiological analysis 20
- Taking samples of a biological material for the microbiological analysis from the immediate surroundings of an infected person, or environment where he/she lives and works 20
- Processing of the data collected by the epidemiological survey 20
- Suggesting the measures for the disease containment 20
- Containment measures implementation control 20
- Reporting on epidemic 10
- Keeping the documentation on vaccinations, the infected persons and carriers 20
- Studying the basic morbidity and mortality indicators 20
- Overview and flow of communicable and other diseases that are significant for the population 5

- What is the number of hospital departments and the number of beds for the treatment of communicable diseases?

Communicable diseases treatments are performed in 6 general hospitals, where there are departments or sections for communicable diseases, in the Clinical Centre of Montenegro. the Centre includes the Clinic for communicable diseases and the Special Hospital for Lung Diseases and Tuberculosis - Brezovik.

According to the data officially submitted to the Public Health Institute the total number of beds in the infective departments and the Infective Clinic is 58, and their distribution is as follows:

Podgorica: the Clinical Centre of Montenegro - the Clinic for Communicable Diseases, 20 beds

Nikšić: Infective department within the Internist service, 15 beds

Kotor: Infective diseases section within the Internist service, 7 beds

Berane: Infective department, 8 beds

Bar: Infective diseases department, 8 beds

Additionally, in the General Hospital Bijelo Polje within the Internal department there is Section for communicable diseases with 12 beds, and in the General Hospital Pljevlja there is Section for communicable diseases with 4 beds. The data for these two hospitals are not independently shown in the reports that are submitted to the Institute for Public Health.

Furthermore, within the Special Hospital for Lung Diseases and Tuberculosis - Brezovik there is the Third pavilion for tuberculosis treatment and diagnosis with 35 beds.

On the basis of the presented data, it could be concluded that the total number of beds for the treatment of communicable disease In Montenegro is 109.

- Is there a quality assurance system implemented for laboratory performance? How many laboratories have an accreditation?

There is no quality safety system that is applied to the work of microbiological laboratories. None of the microbiological laboratories have accreditation. Only, to a certain extent, the microbiological laboratory of the Public Health Institute in Podgorica has started the accreditation process that will be intensifies after the Institute is moved to a new building of the Public Health Institute..

51. With reference to the following list of acquis, please answer to the below questions a) to d):

The answer is contained in the answers to the sub questions 51a), 51b), 51c) I 51d)

Questions:

a) Are there legislative, regulatory or administrative provisions in force in your country covering these areas? If yes, please send summaries and, if possible, full texts in one of the official EU languages.

In Montenegro the following documents have legal force and effect regarding the fields of epidemiological supervision and communicable diseases control:

Law on Health Protection (Official Gazette of Montenegro 39/ 2004)

Law on the Protection of Population from Communicable Diseases (Official Gazette of Montenegro 32/ 2005),

Rulebook on communicable disease and hospital infections reporting (Official Gazette of the Republic of Montenegro 45/ 2007),

Decision on the manner of performance of compulsory health examinations of certain employee categories, other persons and carriers (Official Gazette of the Federal Republic of Yugoslavia 27/ 1997),

Decision on the manner of performance of immunisations and medical protection against particular communicable diseases (Official Gazette of the Federal Republic of Yugoslavia 27/ 1997),

Decision on the conditions that have to be met by legal entities and entrepreneurs for the performance of disinfection, disinsectisation and deratisation (Official Gazette of the Federal Republic of Yugoslavia 27/ 1997),

Decision on the protection measures from spreading of communicable diseases within health-care institutions, other legal persons and entrepreneurs that perform health-care activities (Official Gazette of the Federal Republic of Yugoslavia 27/ 1997),

Rulebook on medical examinations for the individuals, who were cured from abdominal typhus, bacillary dysentery and salmonellosis (Official Gazette of the Socialist Federal Republic of Yugoslavia 42/ 1985),

Rulebook on protection measures against insertion and spreading of cholera, viral haemorrhagic fevers, yellow fever and malaria (Official Gazette of the Socialist Federal Republic of Yugoslavia 42/ 1985),

Rulebook on conditions and manner of data keeping regarding laboratory examinations and notifications on the causes of particular communicable diseases (Official Gazette of the Socialist Federal Republic of Yugoslavia 42/ 1985/ ; Official Gazette of the Socialist Federal Republic of Yugoslavia 7/ 1992),

Rulebook on conditions that have to be met by health-care institutions which perform laboratory examinations of the causes of communicable diseases and verification of laboratory examination of the causes of communicable diseases (Official Gazette of the Socialist Federal Republic of Yugoslavia 21/ 1992),

Rulebook on conditions and manners of exhumation and transfer of the deceased (Official Gazette of the Socialist Federal Republic of Yugoslavia 42/ 1985),

Order on measures for the prevention of cholera insertion and spreading (Official Gazette of the Federal Republic of Yugoslavia 71/ 1994),

Tuberculosis Control Programme in Montenegro (2007),

2009 Programme of compulsory immunisation of the population against particular communicable diseases in the territory of Montenegro (Official Gazette of Montenegro 25/2009),

National Strategy for the Fight against AIDS 2005-2009,

Food Safety Strategy (2006),

Legal regulations in Montenegro are mostly harmonised with the EU regulations. Current Law on the Protection of Population against Communicable Diseases and Rulebook on reporting communicable diseases and hospital infections do not stipulate reporting of West Nile Fever, SARS and smallpox, but Article 2 of the Law on the Protection of Population against Communicable Diseases states that, in a case of a danger from an communicable disease which is not in the list of communicable diseases that are compulsory to report, the Government of Montenegro can decide, on the recommendation of the state administration body competent for the health affairs, to introduce all necessary measures prescribed by the Law on Protection of Population against Communicable Diseases, other measures for the population protection, and the measures that are stipulated by the international heath and sanitary conventions and other international acts, and epidemic of communicable diseases as well. The recommendation of the competent state administration body is made on the basis of the opinion of the Public Health Institute and contains the name of communicable diseases, prevention and containment measures, manner and funds necessary for the measures. As for smallpox they are not put on the list for reporting since WHO in 1977 announced global eradication, which means the virus can be found only in a number of laboratories. WHO suggestion was that even these samples should be destroyed in order to avoid for the virus to “leak out” from the laboratories. Considering the fact, that some countries did not heed the advice of WHO, there is a possibility that smallpox virus can be used for bioterrorism and small range biological war. Current Law and the Rulebook on compulsory reporting of communicable diseases define that if there is a doubt a biological agent

has been used it should be reported. In this manner we have covered the area of supervision over the possible occurrence of smallpox.

The process of harmonisation (with the new WHO and EU directives) of particular rulebooks that are still in force, but are from the time of the SFRY and the FRY is ongoing. Additionaly we are in the process of creation a number of regulations that we need: (Harmonisation of the Law on Prevention of the Population against Communicable Diseases (Deadline: 2009), the Law on Sanitary Inspection (Deadline 2009), Rulebook on hygienic correctness of drinking water (Deadline: 2009), Rulebook on the scope, type and manner of drinking water quality examination (Deadline: 2009), Rulebook on detailed requirements regarding the safety that have to be met by drinking, table and natural mineral water (Deadline: 2009), Rulebook on detailed requirements that have to be met by the swimming pool water (Deadline 2009), Rulebook on microbiological criteria regarding the allowed types and amount of microorganisms, parasites, bacterial toxins and histamines dangerous to health through food (Deadline: 2009), Rulebook on detailed requirements regarding the organisation and implementation of health supervision for the individuals coming from countries with cholera, yellow fever, viral haemorrhagic fever (except for the haemorrhagic fever with the renal syndrome) and malaria (Deadline: 2009); Rulebook on detailed requirements regarding the manner and conditions for transport, interment and exhumation, transport and interment of the deceased (Deadline: 2010).

b) In case there are no legislative, regulatory or administrative provisions in force, are there any drafts or proposals for these in the pipeline? If so, give details of these and of the timeline for their adoption.

Answer to this question can be found under the answer to the question 51a

c) In cases where neither of the above exist, are there any plans to start preparing proposals? Please explain, also indicating the envisaged timetable.

Answer to this question can be found under the answer to the question 51a

d) Does your country have the necessary administrative capacity, including human and material resources, to fulfil the requirements laid down in the Community legislation listed above?

Currently, Montenegro does not possess fully-fledged administrative capacities, including human and material resources, for meeting the requirements prescribed by the abovementioned European Community regulations. Provision of human resources is in progress, and in accordance with the plan of epidemiological departments network and strengthening of the capacities of the Public Health Institute. Considering the fact that specialisation form epidemiology lasts for three years, it is expected this project will be done by the end of 2012.

D. Safety and quality of blood, human tissues and cells

52. With reference to the following list of acquis, please answer to the below questions a) to d):

The laws regulating this area are currently in the parliamentary procedure. The current legislation regulating medical treatment by transplantation of human body parts (Law on Removal of Human Body Parts, Organs and Tissues for Therapeutic Purposes, and also the Law on the Conditions for Removal and Transplantation of Human Body Parts dating from the former SFRY) will be suspended following the adoption of new legal regulations satisfying modern professional and scientific standards harmonized with the European regulations and the related directives.

The Ministry of Health, Labor and Social Welfare (currently the Ministry of Health) prepared a draft **Law on Removal and Transplantation of Human Body Parts for Therapeutic Purposes** whereby the process of implementation of the foregoing directives of the European Parliament and

of the Council was initiated. The Government adopted this legal regulation in the form of a proposal and it is currently in parliamentary procedure. Accordingly, no regulations implementing the mentioned directives regulating this area of activity are currently in force; nevertheless, since the process of their adoption is currently in force, it is necessary to present a brief overview, in accordance with the question, as provided below.

The Law on Removal and Transplantation of Human Body Parts for Therapeutic Purposes regulates the manner of and procedure for removal of organs, tissues and cells from a living or deceased person for transplantation into another person's body for therapeutic purposes, the conditions under which those procedures are executed in medical institutions, and also the conditions that must be met by medical institutions performing such procedures. Core blood stem cells are also regulated by this Law.

Removal and transplantation of human body parts for therapeutic purposes is carried out in accordance with the applicable professional standards of medical science and practice, by observing the principles of ethics, and only if medically justified.

Before this type of medical treatment is applied, medical tests and other methods of treatment are carried out in order to reconfirm indisputably that this action is beneficial for the recipient, and also, according to the medical criteria, that an acceptable level of risk for the donor is involved, and that it is likely to result in a successful operation. Before a human body part is removed, the applicable medical examinations and tests are undertaken for the purpose of making an assessment and in order to reduce both physical and psychological risks relating to the donor's health, while no human body part can be removed unless it is assessed that the level of risk that the donor's life and health are exposed to is, according to the medical criteria, within the acceptable limits, and also in proportion with the expected benefits for the recipient. A physician is obliged to inform the donor about all relevant details concerning his or her health that are obtained in the process of medical examinations and confirmation of his or her state of health. Accordingly, some comprehensive risk assessment procedures are undertaken relating to the life and health of the donor and recipient respectively.

Transplantation of human body parts is carried out only if this is the only manner to treat a person who suffered a permanent damage of one or more human body parts or facial parts and whose quality of life worsened due to the damage suffered by one or more transplantable parts of the body and who cannot be treated using another comparably efficient method, but only provided that all therapeutic procedures have been previously completed in accordance with medical standards and practice. Transplantation of human body parts is performed as approved by the health institution's Medical Board, an expert advisory body that follows both scientific and professional work and scientific projects relating to clinical medicine and has a cooperation relating to scientific, research and educational activities with medical faculties and other scientific institutions in the country and abroad. The provisions of Article 66 of the Law on Health Protection relating to Medical Board equally apply to this Law. Removal and transplantation of human body parts for therapeutic purposes is performed in public health institutions that meet the applicable space, equipment and staff requirements following a special decision issued by the Ministry of Health.

Each specific case of this kind of treatment is carried out on the basis of a waiting list established by the Ministry, according to the lists of persons composed by health institutions where the removal and transplantation of human body parts is performed, whereby it is confirmed that transplantation of human body part is the only manner of therapeutic treatment; this list is composed according to the types of required human body parts, while the removed human body parts are allocated to transplant recipients from the List according to transparent, just and generally accepted medical criteria.

Removal and transplantation of human body parts is performed on the basis of freely expressed will, where the patient is fully informed about the nature, purpose, procedure, probability of success and normal risks. However, where due to an emergency situation the life of a transplant recipient is threatened and in case a compatible human body part exists, a doctor may carry out the transplantation even without the transplant recipient's consent in order to save his or her life.

According to this Law, the state of health of the transplant donor and recipient respectively is monitored also after the surgery has been carried out.

This Law is intended to promote and popularize voluntary giving and bequeathing of donor organs during the donor's life, i.e. consent for the donor's organs and tissues to be removed after his or her death. These activities are carried out by the Ministry, health institutions and health workers who take part in the process of removal, transplantation, keeping and exchange of human body parts, and also other health institutions.

A human body part may be removed from a living donor, following a decision issued by the health institution's Committee for Ethical Issues, exclusively to treat the transplant recipient, where no compatible human body part of a deceased donor exists or any other form of medical intervention. The donor must be of full age, able to work and reason, and must issue a written consent statement declaring such an act as an expression of his or her free will. The consent statement may be revoked until the beginning of a surgery.

The health institution's Committee for Ethical Issues may allow removal of regenerative tissue of an underage person or of an adult who is not capable of reasoning provided that the following cumulative requirements have been met: no available donor who is able to give a consent exists; the transplant recipient is the transplant donor's brother or sister; the purpose of organ donation is to save the recipient's life; a valid written approval was obtained from the legal representative, i.e. custodian of the donor, or if not applicable, then an opinion of the competent Center for Social Work, and where the potential donor and recipient have not opposed it. The same Article stipulates that human cells may be removed as donor material for the purpose of saving the recipient's life and following a valid approval of the legal representative, i.e. custodian of the donor, and if not applicable, then an opinion of the competent Center for Social Work, where confirmed that such a removal shall not include other than a minimum risk for and minimum burden on the donor.

Core blood stem cells may also be removed and stored, where removed from a detached naval cord of a live born baby, to be transplanted to relatives or other persons.

Voluntary donation means that no compensation is received either for giving or receiving human body parts, and no advertising of such offers or demand or mediation in such activities shall be allowed. However, compensation does not include salaries, travel costs, hospitalization costs, costs of medical examinations, laboratory tests, therapeutic treatments during and following the removal of human body parts, and also damage compensation originating from an inexpert and neglectful therapeutic treatment, against generally accepted medical criteria. According to the law, human body parts of live donors may be removed only at the health institution where the related transplantation will be performed.

Removal of human body parts from a deceased donor shall be carried out according to her or his written consent that was given when he or she was of full age, able to work and reason and deposited with the chosen doctor. Removal of human body parts from a deceased donor shall be carried out by respecting his or her dignity, by respecting the feelings of his or her family, and also by undertaking all necessary measures to have his or her outer appearance restored.

The Law provides for removal of human body parts from an underage donor, in order to be transplanted into another person for therapeutic purposes, only following a written approval of both of his or her parents, i.e. one parent in case the other parent died or was proclaimed dead.

Human body parts of a deceased donor may be taken when his or her death has been properly and with certainty confirmed by the health institution's commission, according to the medical criteria.

It is strictly stipulated by the law that the procedure of removal and transplantation of human body parts may be carried out exclusively at the health institutions that meet the necessary requirements for such surgeries. Such procedures include necessary undertaking of standard measures and activities in order to avoid the risk of transmission of contagious or any other diseases to the transplant recipient, or having an impact on the state of preservation of the human body parts intended for transplantation.

Before the transplantation, human body parts need to be tested at a laboratory that meets the requirements relating to optimal application of valid medical standards, area size, professional staff, technical and other specifications. A decision confirming that these conditions have been met is issued by the Ministry.

Removal, transplantation, confirmation of compatibility, preservation and exchange of human body parts is carried out by health institutions or parts of health institutions meeting the applicable standards relating to area size, equipment and professional staff. In such health institutions a coordinator shall be appointed, as a person responsible for the implementation of the procedure of removal and transplantation of human body parts. The coordinator organizes the cooperation with health institutions carrying out the procedure of removal, transplantation, confirmation of compatibility, preservation and exchange of human body parts. In case the transplantation is not carried out at the same health institution where the body parts were removed, the manner of preservation and transport of human body parts intended for transplantation shall be carried out according to the regulations issued by the Ministry.

It is stipulated by the law that in the procedure of removal and transplantation of human body parts the protection of identity, personal dignity and other personal rights and freedoms are guaranteed both to the donor and the recipient, so that the data concerning the transplant donor and recipient shall represent a professional secret, while no personal information about the deceased donor shall be provided to the recipient, and no personal information about the recipient shall be provided to the family of a deceased donor. Personal details of the donor may be available to the recipient's physician only where justified by medical reasons.

Health institutions performing the removal, transplantation, confirmation of compatibility, preservation and exchange of human body parts keep the records on personal details of donors and recipients, each removal and transplantation of human body parts, exchange of body parts, success of the procedure, possible complications, state of health of the donor and recipient after the procedure has been completed and undertaken measures, so that the quality of a medical intervention is ensured. The coordinator submits this information to the Ministry in an annual report, while the reporting period may also be shorter, if so requested by the Ministry.

The Ministry keeps a register of persons who agreed to have their respective body parts removed in case of their death, to be transplanted into the body of another person who cannot be treated in any other manner.

The adoption of this Law will represent the beginning of implementation of the directives from the foregoing question, as already stated before.

Further concrete actions and implementation of specific activities for the removal, transplantation, confirmation of compatibility, preservation and exchange of body parts shall be identified by secondary legislation to be adopted in order to implement this Law, in addition to the application of guides on good medical practices specifically addressing each organ, tissue and cell, to be applied as recommended by the most eminent experts in this field of activity, so that the procedures are carried out in accordance with the professional standards of medical science, standardized operating procedures and in compliance with ethical principles.

As a part of these activities, by adopting the regulations implementing this Law, the Ministry shall regulate the following segments: standard measures and activities that shall be undertaken by the health workers participating in the procedure of removal and transplantation of human body parts in order to avoid the risk of having a contagious or another disease transmitted to the recipient and prevent any impact on the state of preservation of human body parts intended for transplantation; manner and procedure of composing a waiting list, delivery of information by health institutions, waiting time criteria, conditions for the selection of the most adequate recipient and allocation of removed human body parts for therapeutic purposes; the procedure of issuance of an approval, contents of an approval and the statement whereby an approval for the removal of body parts from a live donor is revoked or modified; the procedure of collection, preservation and utilization of core blood stem cells; the procedure of issuance of an approval to remove body parts from a deceased donor, contents of the approval, manner of identification of the giver of an approval and declaration on its revocation; the procedure of issuance and the contents of the parents' approval to have the body parts removed from a decreased underage person; the manner, procedure and medical criteria for the confirmation of death of a persons whose body parts can be used as transplants for therapeutic purposes, in addition to a more detailed composition of the Commission to confirm the occurrence of death of a person whose body parts may be removed for the purpose of transplantation; form, contents and manner of issuance of an approval for the transplantation of

body parts for therapeutic purposes; the requirements relating to area size, equipment and necessary professional staff that must be met by the institutions performing the removal, transplantation, confirmation of compatibility, preservation and exchange of body parts, and also the manner of supervising the quality of work of such health institutions; the manner of perseverance and transport of body parts intended for transplantation, where the transplantation is carried out in a health institution other than the one where the removal of body parts was executed; the conditions relating to an optimum-level application of the applicable medical standards, area size requirements, professional staff, technical and other specifications that must be met by each laboratory performing the analysis of human body parts before their utilization; the activities performed by the coordinator in health institutions carrying out the removal, transplantation, confirmation of compatibility, preservation and exchange of human body parts; and also the manner and procedure of maintenance and registration of persons who agreed to have their respective body parts removed in case of death; data maintenance, preservation and protection; manner of and the procedure to access the data; and also the manner of issuing of an approval for the removal of body parts.

The foregoing regulations will be adopted within nine months from the date of entry into force of this Law.**a)** The response is contained in items a) and b).

b) The Law on Removal and Transplantation of Human Body Parts for Therapeutic Purposes stipulates, under the chapter with transitional and final provisions, that this Law will be applied following the expiration of the year of its adoption. It is also stipulated that secondary legislation will be adopted within nine months as of the day of its entrance into force, while the procedures of removal, transplantation, confirmation of compatibility, preservation and exchange of body parts shall be carried out by health institutions that meet the requirements relating to area size, equipment and professional staff, to be specified by the Ministry's decision.

In the process of preparation of the Law, it was assessed that the funds required for its implementation, to equip the health institutions, amounted to EUR 500,000 in 2010 and EUR 500,000 in 2011.

Regarding the Law on Assisted Reproductive Technology, it applies from the eight day following that of its publication in the Official Gazette of Montenegro. The regulations for its implementation will be adopted within 90 days following that of its entry into force, while the health institutions that, as a part of their respective activities, apply the procedures of assisted reproductive technology, shall harmonize their activities with this Law within six months as of its entry into force. A decision on the compliance of health institutions with the conditions for execution of such procedures, in terms of area size, equipment and staff, will be issued by the Ministry of Health.

Questions:

a) Are there legislative, regulatory or administrative provisions in force in your country covering these areas? If yes, please send summaries and, if possible, full texts in one of the official EU languages.

BLOOD SAFETY AND QUALITY

- Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood components and amending Directive 2001/83/EC , HAS BEEN IMPLEMENTED INTO THE LAW ON BLOOD PROCUREMENT SETTING CONDITIONS AND STANDARDS OF QUALITY, SAFETY AND SUPERVISION FOR THE COLLECTION, TESTING, PROCESSING, STORAGE, DISTRIBUTION, ALLOCATON AND UTILIZATION OF HUMAN BLOOD AND BLOOD COMPONENTS.

- DIRECTIVES 2004/33/EC, 2005/61/EC AND 2005/62/EC WILL BE IMPLEMENTED THROUGH PLANNED PREPARATION OF SECONDARY LEGISLATION IN 2009 AND 2010.

Organization and operation of Blood Transfusion Service in Montenegro relating to blood safety and quality is regulated by the following laws and secondary legislation:

1. LAW ON BLOOD PROCUREMENT (Official Gazette of Montenegro 11/07 of 13 December 2007).

This Law sets standards relating to the procedure of collection, testing, processing, storage, distribution and allocation of human blood and components aiming at ensuring sufficient volumes of safe blood, and also health protection standards relating to blood transfusion activities in accordance with the highest European standards.

A high-degree application of human blood for therapeutic purposes understands compliance with particular principles (guidelines) formalized by EU expert bodies and commissions for blood transfusion medicine in the form of directives of the European Union.

Adoption of the Law on Blood Procurement on the basis of Directive 2002/98/EC represents a step towards regional harmonization in this area.

2. THE LAW ON HEALTHCARE (Official Gazette of the Republic of Montenegro 39/04)

This Law stipulates that procurement of blood to meet the needs of the population will be one of the priority healthcare measures available to all citizens (Article 10 (1) item 13), and also the possibility of establishment of a healthcare Institution for a particular area of health protection (Article 44 of the same Law).

3. THE LAW ON THE PROTECTION OF POPULATION AGAINST COMMUNICABLE DISEASES (Official Gazette of the Republic of Montenegro 32/2005 of 27 May 2005).

This Law identifies infective diseases endangering the health of the population and infections resulting from the provision of healthcare services, specifies the measures for their repression and clearly defines the manner of their implementation, identifies competent authorities for their implementation, the manner of fund rising for their implementation and supervision over the execution of this Law. (Chapter 2 Article 19 item 2)

4. THE RULEBOOK ON THE MANNER OF REPORTING COMMUNICABLE DISEASES, HOSPITAL INFECTIONS, CONDITIONS AND DEATH CAUSED BY COMMUNICABLE DISEASE (Official Gazette of the Republic of Montenegro 45/07).

This Rulebook regulates in more detail the manner and deadlines for reporting communicable diseases, hospital infections, conditions and death of persons who caught such a disease, including the reporting forms.

5. THE LAW ON HEALTHCARE RECORDS (Official Gazette of Montenegro 80/08).

This Law, inter alia, stipulates obligatory maintenance of records of infective diseases and HIV/AIDS, and also of transfusiology (Chapter II Articles 8 and 9 of the Law)

6. THE LAW ON HEALTH INSPECTION (Official Gazette of Montenegro 79/08).

This Law regulates inspection control relating to implementation of healthcare protection laws and regulations, and also implementation of valid measures for health protection.

Until the secondary legislation implementing the Law on Blood Procurement is adopted, the Collection of Regulations on Blood Transfusion Service shall apply, published by the Institute for Blood Transfusion of Serbia in 1995, which had been in force until the mentioned Law was adopted.

Legal regulations on therapeutic treatment by removal and transplantation of human body parts are in the process of adoption by the National Parliament. The current laws on therapeutic treatment by removal and transplantation of human body parts (Law on Removal of Human Body Parts, Organs and Tissues for Transplantation for Therapeutically Purposes and the Law on Conditions for Removal and Transplantation of Human Body Parts dating from the period of former SFRY) will come out of force when the new regulations satisfying modern professional and scientific standards and harmonized with the European legislation and foregoing directives are adopted.

b) In case there are no legislative, regulatory or administrative provisions in force, are there any drafts or proposals for these in the pipeline? If so, give details of these and of the timeline for their adoption.

The first part of a response to this question is included into the response under 52 a).

The Ministry of Health, Labor and Social Welfare (now the Ministry of Health) prepared a proposal of the **Law on Removal and Transplantation of Human Body Parts for Therapeutic Purposes** whereby the process of implementation of foregoing directives of the European Parliament and of the Council has been initiated. The Government of Montenegro adopted this law in the form of a proposal and it was referred to the National Parliament for adoption. Accordingly, no regulations implementing the mentioned directives are currently in effect, and still, since those are in the process of being adopted, a brief overview needs to be presented, in accordance with the question.

The Law on Removal and Transplantation of Human Body Parts for Therapeutic Purposes regulates the manner of and procedure for removal of organs, tissues and cells from a living or deceased person for transplantation into another person's body for therapeutic purposes, the conditions under which those procedures are executed in medical institutions, and also the conditions that must be met by medical institutions performing such procedures. Core blood stem cells are also regulated by this Law.

Removal and transplantation of human body parts for therapeutic purposes is carried out in accordance with the applicable professional standards of medical science and practice, by observing the principles of ethics, and only if medically justified.

Before this type of medical treatment is applied, medical tests and other methods of treatment are carried out in order to reconfirm indisputably that this action is beneficial for the recipient, and also, according to the medical criteria, that an acceptable level of risk for the donor is involved, and that it is likely to result in a successful operation. Before a human body part is removed, the applicable medical examinations and tests are undertaken for the purpose of making an assessment and in order to reduce both physical and psychological risks relating to the donor's health, while no human body part can be removed unless it is assessed that the level of risk that the donor's life and health are exposed to is, according to the medical criteria, within the acceptable limits, and also in proportion with the expected benefits for the recipient. A physician is obliged to inform the donor about all relevant details concerning his or her health that are obtained in the process of medical examinations and confirmation of his or her state of health. Accordingly, some comprehensive risk assessment procedures are undertaken relating to the life and health of the donor and recipient respectively.

Transplantation of human body parts is carried out only if this is the only manner to treat a person who suffered a permanent damage of one or more human body parts or facial parts and whose quality of life worsened due to the damage suffered by one or more transplantable parts of the body and who cannot be treated using another comparably efficient method, but only provided that all therapeutic procedures have been previously completed in accordance with medical standards and practice. Transplantation of human body parts is performed as approved by the health institution's Medical Board, an expert advisory body that follows both scientific and professional work and scientific projects relating to clinical medicine and has a cooperation relating to scientific, research and educational activities with medical faculties and other scientific institutions in the country and abroad. The provisions of Article 66 of the Law on Health Protection relating to Medical Board equally apply to this Law. Removal and transplantation of human body parts for therapeutic purposes is performed in public health institutions that meet the applicable space, equipment and staff requirements following a special decision issued by the Ministry of Health.

Each specific case of this kind of treatment is carried out on the basis of a waiting list established by the Ministry, according to the lists of persons composed by health institutions where the removal and transplantation of human body parts is performed, whereby it is confirmed that transplantation of human body part is the only manner of therapeutic treatment; this list is composed according to the types of required human body parts, while the removed human body

parts are allocated to transplant recipients from the List according to transparent, just and generally accepted medical criteria.

Removal and transplantation of human body parts is performed on the basis of freely expressed will, where the patient is fully informed about the nature, purpose, procedure, probability of success and normal risks. However, where due to an emergency situation the life of a transplant recipient is threatened and in case a compatible human body part exists, a doctor may carry out the transplantation even without the transplant recipient's consent in order to save his or her life.

According to this Law, the state of health of the transplant donor and recipient respectively is monitored also after the surgery has been carried out.

This Law is intended to promote and popularize voluntary giving and bequeathing of donor organs during the donor's life, i.e. consent for the donor's organs and tissues to be removed after his or her death. These activities are carried out by the Ministry, health institutions and health workers who take part in the process of removal, transplantation, keeping and exchange of human body parts, and also other health institutions.

A human body part may be removed from a living donor, following a decision issued by the health institution's Committee for Ethical Issues, exclusively to treat the transplant recipient, where no compatible human body part of a deceased donor exists or any other form of medical intervention. The donor must be of full age, able to work and reason, and must issue a written consent statement declaring such an act as an expression of his or her free will. The consent statement may be revoked until the beginning of a surgery.

The health institution's Committee for Ethical Issues may allow removal of regenerative tissue of an underage person or of an adult who is not capable of reasoning provided that the following cumulative requirements have been met: no available donor who is able to give a consent exists; the transplant recipient is the transplant donor's brother or sister; the purpose of organ donation is to save the recipient's life; a valid written approval was obtained from the legal representative, i.e. custodian of the donor, or if not applicable, then an opinion of the competent Center for Social Work, and where the potential donor and recipient have not opposed it. The same Article stipulates that human cells may be removed as donor material for the purpose of saving the recipient's life and following a valid approval of the legal representative, i.e. custodian of the donor, and if not applicable, then an opinion of the competent Center for Social Work, where confirmed that such a removal shall not include other than a minimum risk for and minimum burden on the donor.

Core blood stem cells may also be removed and stored, where removed from a detached umbilical cord of a live born baby, to be transplanted to relatives or other persons.

Voluntary donation means that no compensation shall be received either for giving or receiving human body parts, and no advertising of such offers or demand or mediation in such activities shall be allowed. However, compensation shall not include salaries, travel costs, hospitalization costs, costs of medical examinations, laboratory tests, therapeutic treatments during and following the removal of human body parts, and also damage compensation originating from an inexpert and neglectful therapeutic treatment, against generally accepted medical criteria. According to the law, human body parts of live donors may be removed only at the health institution where the related transplantation will be performed.

Removal of human body parts from a deceased donor shall be carried out according to her or his written consent that was given when he or she was of full age, able to work and reason and deposited with the chosen doctor. Removal of human body parts from a deceased donor shall be carried out by respecting his or her dignity, by respecting the feelings of his or her family, and also by undertaking all necessary measures to have his or her outer appearance restored.

The Law provides for removal of human body parts from an underage donor, in order to be transplanted into another person for therapeutic purposes, only following a written approval of both of his or her parents, i.e. one parent in case the other parent died or was proclaimed dead.

Human body parts of a deceased donor may be taken when his or her death has been properly and with certainty confirmed by the health institution's commission, according to the medical criteria.

It is strictly stipulated by the law that the procedure of removal and transplantation of human body parts is carried out exclusively at the health institutions that meet the necessary requirements for such surgeries. Such procedures include necessary undertaking of standard measures and activities in order to avoid the risk of transmission of contagious or any other diseases to the transplant recipient, or having an impact on the state of preservation of the human body parts intended for transplantation.

Before the transplantation, human body parts need to be tested at a laboratory that meets the requirements relating to optimal application of valid medical standards, area size, professional staff, technical and other specifications. A decision confirming that these conditions have been met is issued by the Ministry.

Removal, transplantation, confirmation of compatibility, preservation and exchange of human body parts is carried out by health institutions or parts of health institutions meeting the applicable standards relating to area size, equipment and professional staff. In such health institutions a coordinator is appointed, as a person responsible for the implementation of the procedure of removal and transplantation of human body parts. The coordinator organizes the cooperation with health institutions carrying out the procedure of removal, transplantation, confirmation of compatibility, preservation and exchange of human body parts. In case the transplantation is not carried out at the same health institution where the body parts were removed, the manner of preservation and transport of human body parts intended for transplantation is carried out according to the regulations issued by the Ministry.

It is stipulated by the law that in the procedure of removal and transplantation of human body parts the protection of identity, personal dignity and other personal rights and freedoms are guaranteed both to the donor and the recipient, so that the data concerning the transplant donor and recipient represents a professional secret, while no personal information about the deceased donor is provided to the recipient, and no personal information about the recipient is provided to the family of a deceased donor. Personal details of the donor may be available to the recipient's physician only where justified by medical reasons.

Health institutions performing the removal, transplantation, confirmation of compatibility, preservation and exchange of human body parts keep the records on personal details of donors and recipients, each removal and transplantation of human body parts, exchange of body parts, success of the procedure, possible complications, state of health of the donor and recipient after the procedure has been completed and undertaken measures, so that the quality of a medical intervention is ensured. The coordinator submits this information to the Ministry in an annual report, while the reporting period may also be shorter, if so requested by the Ministry.

The Ministry keeps a register of persons who agreed to have their respective body parts removed in case of their death, to be transplanted into the body of another person who cannot be treated in any other manner.

The adoption of this Law will represent the beginning of implementation of the directives from the foregoing question, as already stated before.

Further concrete actions and implementation of specific activities for the removal, transplantation, confirmation of compatibility, preservation and exchange of body parts shall be identified by secondary legislation to be adopted in order to implement this Law, in addition to the application of guides on good medical practices specifically addressing each organ, tissue and cell, to be applied as recommended by the most eminent experts in this field of activity, so that the procedures are carried out in accordance with the professional standards of medical science, standardized operating procedures and in compliance with ethical principles.

As a part of these activities, by adopting the regulations implementing this Law, the Ministry regulates the following segments: standard measures and activities that shall be undertaken by the health workers participating in the procedure of removal and transplantation of human body parts in order to avoid the risk of having a contagious or another disease transmitted to the recipient and prevent any impact on the state of preservation of human body parts intended for transplantation; manner of and the procedure for compositing of a waiting list, delivery of information by health institutions, waiting time criteria, conditions for the selection of the most

adequate recipient and allocation of removed human body parts for therapeutic purposes; the procedure of issuance of an approval, contents of an approval and the statement whereby an approval for the removal of body parts from a live donor is revoked or modified; the procedure of collection, preservation and utilization of core blood stem cells; the procedure of issuance of an approval to remove body parts from a deceased donor, contents of the approval, manner of identification of the giver of an approval and declaration on its revocation; the procedure of issuance and the contents of the parents' approval to have the body parts removed from a decreased underage person; the manner, procedure and medical criteria for the confirmation of death of a persons whose body parts can be used as transplants for therapeutic purposes, in addition to a more detailed composition of the Commission to confirm the occurrence of death of a person whose body parts may be removed for the purpose of transplantation; form, contents and manner of issuance of an approval for the transplantation of body parts for therapeutic purposes; the requirements relating to area size, equipment and necessary professional staff that must be met by the institutions performing the removal, transplantation, confirmation of compatibility, preservation and exchange of body parts, and also the manner of supervising the quality of work of such health institutions; the manner of perseverance and transport of body parts intended for transplantation, where the transplantation is carried out in a health institution other than the one where the removal of body parts was executed; the conditions relating to an optimum-level application of the applicable medical standards, area size requirements, professional staff, technical and other specifications that must be met by each laboratory performing the analysis of human body parts before their utilization; the activities performed by the coordinator in health institutions carrying out the removal, transplantation, confirmation of compatibility, preservation and exchange of human body parts; and also the manner and procedure of maintenance and registration of persons who agreed to have their respective body parts removed in case of death; data maintenance, preservation and protection; manner of and the procedure to access the data; and also the manner of issuing of an approval for the removal of body parts.

The foregoing regulations are to be adopted within nine months from the day of entry into force of the Law.

c) In cases where neither of the above exist, are there any plans to start preparing proposals? Please explain, also indicating the envisaged timetable.

The response to this question is included into the response under point 52 a)

d) Does your country have the necessary administrative capacity, including human and material resources, to fulfil the requirements laid down in the Community legislation listed above?

At this moment, our country does not have the necessary capacities in full; however, the preparations for their establishment are in progress. By intensifying the activities, especially those relating to the development of administrative capacities and human resources, we expect that those requirements will be met within a relatively short period of time.

According to transitional and final provisions of the Law on Removal and Transplantation of Human Body Parts for Therapeutic Purposes, this Law will be appllied following the expiration of the year of its entry into force. It also specifies that secondary legislation are adopted within nine months following that of its entry into force, while the procedures of removal, transplantation, confirmation of compatibility, storage and exchange of human body parts are carried out by health institutions meeting the requirements of area size, equipment and professional staff, to be specified by the Ministry's decision.

In the process of preparation of the Law, it was assessed that the funds required for its implementation, to equip the health institutions, amounted to EUR 500,000 in 2010 and EUR 500,000 in 2011.

Regarding the Law on Assisted Reproductive Technology, it applies from the eight day following that of its publication in the Official Gazette of Montenegro. The regulations for its implementation are adopted within 90 days following that of its entry into force, while the health institutions that, as

a part of their respective activities, apply the procedures of assisted reproductive technology, will harmonize their activities with this Law within six months as of its entry into force. A decision on the compliance of health institutions with the conditions for execution of such procedures, in terms of area size, equipment and staff, is issued by the Ministry of Health.

53. With reference to the blood transfusion system reform, please answer to the following questions:

The responses are provided here below under item a), b), c), d) and e)

a) Could you explain how you are planning to reform the current blood transfusion system?

A reform of the Blood Transfusion Service in Montenegro was anticipated by the following strategic documents adopted by the Government of Montenegro: Strategy for Safe Blood (2006), the Law on Blood Procurement (2007) and Montenegro Blood Donation Programme (2009).

These documents, based on analysis of the situation and identification of problems and shortcomings in the functioning of the existing blood transfusion system, are planned to overcome such issues and enable the creation of modern blood transfusion systems according to the EU recommendations.

PRESENT SITUATION: The blood transfusion activity is carried out by 9 independent blood transfusion centers of various levels of capacity (300-6,000 collected units per year) and development. All Blood Transfusion Services (BTS) mostly perform all activities normally included in the operating process of blood transfusion: blood collection, blood unit processing and blood grouping in ABO and Rh system, irregular anti body screening, testing for blood-transmitted diseases, separation of blood components (BTC Podgorica separates all components, Bar and Nikšić separate FFP and RC, while other Services apply whole blood or separate plasma by spontaneous sedimentation), blood procurement, transport, and Rh prevention in case of pregnant women. Following an analysis of the situation, such a system was assessed as inefficient and uneconomic.

NEW SYSTEM anticipates unification of the scattered Blood Transfusion Service in Montenegro which is functioning, as previously mentioned, in the form of 9 independent Services of on various levels of development, by creating a uniform Blood Transfusion Service of Montenegro.

This understands the establishment of an Institute for Blood Transfusion of Montenegro, operating through is functional units – regional units in medical institutions using blood for therapeutic purposes.

This reorganization of blood transfusion service foresees the collection of cost-free blood from volunteers in the entire territory of Montenegro, mostly through organized on-site activities and partly in the premises of the Institute for Blood Transfusion, complete processing of blood units by the Institute for Blood Transfusion in Podgorica (blood grouping in ABO and Rh system, testing for blood-transmitted diseases, separation of blood into components, labeling, distribution to regional units according to the needs of host hospitals, standard record keeping, monitoring of blood trace, education and motivation activities involving the population, work with blood donors, introduction of apheresis and cytapheresis procedures and other anticipated activities according to internal regulations of the Institute.

Regional units shall be responsible for education and motivation activities in their respective regions, organization of DDK activities, clinical transfusion medicine (patients' KG, interactions, immunohematology diagnostics, rational application of blood and blood components, participation in the activities of the Committee for Blood Transfusion, monitoring of adverse reactions). Additionally, they will submit regular reports to the Institute for Blood Transfusion on all conducted activities.

In addition to this, a uniform register of blood donors will be established, especially of non-remunerated and non-affiliated ones, and also a uniform information system for the monitoring of all segments of blood transfusion activity.

b) Critical elements of the EU Blood Directive are: Competent authority – inspections – traceability – reporting of serious adverse reactions/events – which need to be incorporated while carrying out this reform.

All these elements of EU Directives have been included into the Law on Blood Procurement, while their detailed implementation is set forth by the Law on the Protection of Population against Communicable Diseases, Rulebook on the Manner of Reporting Communicable Diseases, Hospital Infections, Conditions and Death Caused by Communicable Disease.

- Competent authority for the blood transfusion is the Ministry of Health of Montenegro (The Law on Blood Procurement, Chapter III Part 1 – Blood Collection, Article 7 paragraph 5; Part 2 - Testing, Storage and Distribution, Article 19 paragraph 4; Part 3 - Blood Trace Monitoring, Article 19 paragraph 4, and Part 4 - Blood Application, Article 23 paragraph 4)
- Inspection control (supervision) falling under the competence of the Ministry of Health is regulated under the Law on Blood Procurement (Chapter V, Articles 32 and 33)
- The followability is stipulated by the Law on Blood Procurement (Chapter III, Part 3 -Blood Trace Monitoring, Articles 17,18,19,20 and 21)
- Reporting on serious harmful reactions and occurrences is stipulated by the Law on Blood Procurement, which is done by developing a system of reporting on adverse effects and reactions, as identified under this Law, starting from the local level and up to the national one. A physician working with blood will be obliged to report, using a special form prescribed by the Ministry of Health, each adverse effects or reaction to the regional unit of the Institute and the Committee for Blood Transfusion at his or her institution. He or she will be obliged to maintain, as prescribed, the records on adverse effects and reactions and report accordingly on regular basis to the Institute for Blood Transfusion – referenced institution in Podgorica. The Institute for Blood Transfusion will further on submit an annual report to the Ministry of Health of Montenegro, including the number and type of reactions/effects. (Chapter III, Part 4 - Blood Application, Articles 22, 23, 25, and 26.).

c) Montenegro adopted a Strategy for Preserving an Improvement of Reproductive Health. Concrete guidelines e.g. on quality and safety (main EU concern) and legislation in this field are missing in that strategy.

The National Reproductive Health Protection and Advancement Strategy lied down the performance guidelines in this area, according to which the protection of reproductive health of women depends inter alia, on the legal framework. In accordance with the mentioned Strategy, the Law on the Conditions and Procedure for Pregnancy Interruption, while the Law on Treatment for Infertility Using Assisted Reproductive Technology has been drafted and forwarded to the National Parliament for adoption. Following these laws, a number of secondary legislation will be developed whereby the required high standards relating to the quality and safety of patient treatment will be ensured and unified.

Additionally, the health system reform anticipates a more advanced preventive protection of vulnerable groups within the reproductively capable population, and also obligatory examination of women once every 3 years, for the purpose of prevention and screening for cervical cancer, while the pap screening programs have already been initiated.

d) Do you have any plans to transpose the relevant EU legislation in this field ?

During the preparation of the Law on Pregnancy Interruption, attention was paid to the right of women to decide about the reproduction, and also to protect the rights of especially vulnerable population categories such as underage persons and persons under guardianship. A procedure enabling the enforcement of rights was identified, paying special attention to patient safety and clearly stipulating the conditions that must be satisfied in terms of safety and quality, and the level of technical and staff equipment (secondary health level institution, staff training, obligatory patient monitoring, intervention recording in compliance with the right to privacy protection, right to appeal

with a guaranteed limit for its consideration and delivery of a decision, reporting complications following an intervention and adverse effects).

The Law on Assisted Reproductive Technologies is currently in the parliamentary procedure. This Law was drafted paying attention to the existing legal solutions in the EU countries, and also the adopted Tissue Directive: Directive 2004/23/EC, including the subsequently adopted technical directives: Commission Directive 2006/17/EC and Commission Directive 2006/86/EC of 24 October 2006.

The Law stipulates who and under which conditions has the right to application of assisted reproductive technologies, the process of licensing of institutions implementing assisted reproductive technologies (ART), and specific ART activities that may be undertaken by such institutions, obligatory annual inspection control of licensed institutions, defined responsibility and responsible persons in licensed centers (responsible persons in tissue authority or ART centre), anticipated fines for offenders, anticipated voluntary reproductive cell donation, guaranteed right to patient privacy and data protection and donor anonymity, with obligatory reporting of each ART procedure and introduction of a central register on the level of the Ministry, i.e. of the State.

Considering a continuous advancement in the area of ART, more detailed regulations on necessary technical and staff prerequisites for license issuing will be adopted by the ART Commission of the Ministry of Health, and subsequent regulations will be issued by the Ministry within 60 days following the adoption of the Law by the National Parliament. The regulations include compliance with staff and technical particulars from the last two directives of 2006. In the sense of compliance with the principles of quality and safety, the following shall be prescribed: necessary level of professional qualifications of staff in ART centers; continuous staff education and training; licensing procedure for particular activities for which both staff and equipment capacities exist at a center; description of all operating procedures; registration of all executed ART procedures; patient data protection; reporting adverse effects; obligatory biological testing of patient or cell donor; conditions for storage, marking and transport of cells, embryos and tissues (coding and tracking system); description of activities of the Department of Biomedicine as the Competent Authority in the sense of data collection, reporting, supervision and inspection of ART centers.

The Department of Biomedicine of the Ministry of Health will be the competent authority responsible for the implementation of legislation, inspection and control of all licensed ART centers or tissue establishments.

e) Are you planning to develop any legislation in the field of non-reproductive tissues and cells?

Since the Law on Blood Safety and the Law on Removal and Transplantation of Human Body Parts for Therapeutic Purposes do not include the following groups of cells and tissues: umbilical cord blood and stem cells, bone - marrow stem cells, foetal tissues and cells, adult stem cells and embryonic stem cells, and considering a fast advancement of biotechnology in this field, the Ministry of Health plans to have the laws regulating this matter adopted as a part of its activities for the following year, aiming to regulate human application of these (above named) cells and tissues, ensure application of the latest medical achievements and accelerate scientific development in this field, complying with the applicable EU criteria on quality and safety in human applications, in addition to all requirements and recommendations provided under the Tissue Directive and Technical Directives.

Additionally, legal regulations relating to removal of biological material and genetic privacy will be prepared by the Ministry of Health until the end of 2009.

E. Mental health, socio-economic determinants of health, health inequalities, drug abuse prevention, healthy lifestyle, nutrition, alcohol abuse prevention, cancer screenings, and healthy environment including prevention of injury and promotion of safety

54. With reference to the following list of EU Council Recommendations, Council Resolutions and Council Conclusions in the field of public health, please answer to the below questions a) to d):

Mental Health

The Council Resolution of 18 November 1999 on promotion of mental health, in which the Council explicitly recognizes that 'mental health is an indivisible part of health' and underlines that 'problems of mental health are often linked to, among other factors, unemployment, social marginalisation and exclusion, homelessness and drug and alcohol abuse.'

The Council Conclusions of 15 November 2001 on combating stress and depression related problems, in which it underlines that "stress and depression-related problems are common, cause human suffering and disability, increase the risk of social exclusion, increase mortality and have negative implications for national economies."

Following these recommendations, the issue of mental health represents an integral part of the new health strategy.

For these reasons, Montenegro is a signatory of the Helsinki Declaration, and after that the Ministry of Health initiated a series of activities aimed at raising public and professional awareness about the people suffering from mental disorders and ensuring their proper treatment in the society. In order to remove numerous obstacles, stigma and discrimination, the Ministry initiated drafting of the Strategy for Enhancement of Mental Health, adopted by the Government of Montenegro and the Law on Protection and Enforcement of the Rights of Mentally-ill Persons in Montenegro, which entered into force as of 1 January 2006.

In addition to these documents, the following documents were adopted in 2008: the National Strategic Response to Drugs for the period 2008 -2012 and within this document the Action Plan for 2008/2009.

Following the adoption of these documents, priority activities were defined both within the healthcare system and in other segments of social development with the following goals:

- Promotion of mental health of all citizens;
- Tackling serious mental disorders and offering support to vulnerable groups;
- Enhancing the quality of life of people with mental disorders and disabilities through social inclusion and protection of their rights and dignity;
- Reduction of burden of depression and reduction in the incidence of suicide;
- Protection of rights of the people with mental disorders;
- The following activities derived from the existing Strategy:
- Mental Health Centers and Units were opened within the following Health Centers (Podgorica, Kotor, Herceg Novi, Berane, Rožaje, Nikšić, Bijelo Polje, Budva, Danilovgrad, Mojkovac, Ulcinj, Bar)
- Significantly enhanced conditions in which the patients of the largest psychiatric institution in the country have been treated and have lived - Psychiatric Specialized Hospital in Kotor
- Reduced number in hospital beds in this facility
- Reduced number of average days spent in hospitals;

- Enhanced conditions in the social welfare institution - Home for the Elderly in Risan, where alos the people with mental disorders have been living
- The Center for Rehabilitation of Drug Addicts in Kakarica Gora in Podgorica opened - Diagnostic procedures in Montenegro are highly improved in recent years and are characterized by rapid and sophisticated diagnostics, for example: brain scanner, nuclear magnetic resonance, hormone blood screening, fast biochemical analysis, good psychological tests and other diagnostic procedures that are available to all citizens.

Therapeutic approaches are numerous, while the coverage of the latest generation of expensive drugs used in the modern world is very good, and in this respect, Montenegro is not a lot behind more developed countries.

Health Inequalities

One of priority goals of health development in Montenegro is reduction of disparities in health. The aim of the health policy is to prevent further deepening of health disparities, and reduce them by means of targeted and active measures of redistribution of health goods and resources towards vulnerable parts of the society.

In order to achieve this goal, the Government of Montenegro, through the Ministry and through the health system reform process of Montenegro, ensured equal access to health care to all the Montenegrin citizens regardless of gender (women even have the right to choose two doctors), age (children and the elderly as vulnerable groups are protected in respect of enhancement and preservation of health through a number of documents that are based on the Law on Health protection and Law on Health Insurance.

Above all, this process is directed to the following:

- Development of financially sustainable health system, along with equal access to healthcare services;
- Enhancement of the quality of healthcare services and reduction of inequalities in the healthcare services;
- Activities aimed at removing the existing barriers to access to specific health care services such as waiting time, the burden of costs for drugs and treatment as well as administrative and geographical difficulties for attaining access to health care services, and finally the removal of physical barriers to access to healthcare services.

Ensuring the opportunity to freely choose the provider of services in the institutions that are distant from the user for more than 10 km, along with provided access to the service provider, telephone appointments, home visits and preventive work in the counseling, the programme aimed at overcoming health inequalities in Montenegro has been implemented successfully.

Prevention of medicine abuse and reduction of harm caused by their consumption

The Agency for Pharmaceuticals and Medical Devices in the process of obtaining permits for putting pharmaceuticals on the market based on the data from relevant documents, expert assessments and advisory role of the Medicines Commission, is conducting a classification of pharmaceuticals for the purpose of establishing the rules concerning the issuance of the approval for putting the pharmaceuticals on the market (pharmaceuticals registration).

Pharmaceuticals that have low toxicity, high therapeutic scope, are safe in overdose, have minimal interaction, whose indications are well-known to the patient-user and are used for self-medication, are issued in pharmacies without a prescription.

Pharmaceuticals containing narcotic drugs or psychotropic substances, in accordance with international conventions in this field, are issued in accordance with a specific regime of the issuance of licenses for putting these pharmaceuticals on the market.

Pharmaceuticals can not be issued or sold contrary to the conditions specified in the license for their marketing.

Also, the Agency provides information and education about pharmaceuticals and provides information important for the implementation of measures for rational use of pharmaceuticals, which contributes to reduction of their abuse.

Articles 86 to 90 of the Law on Pharmaceuticals (Official Gazette of the Republic of Montenegro 80/04, Official Gazette of Montenegro 18/08) define competences of the Agency for Pharmaceuicals and Medical Devices of Montenegro in the area of pharmacovigilance. The Law clearly defines responsibilities of health workers on one side and representatives of pharmaceutical industry on the other side when it comes to the notice of manifested side effects after the application of pharmaceuticals. Information on safe application of pharmaceuticals makes sufficient grounds for the Agency to undertake regulatory measures in order to preserve public health.

Pharmacovigilance Department within the Pharmaceuticals and Medical Devices Agency of Montenegro is an associate member of the Collaborating Centre for Monitoring of Adverse Effects of the World Health Organization. Full membership is expected in the last quarter of the current year (2009).

The Rulebook on the method of data collecting and the method of monitoring of side effects of pharmaceuticals applied in human and veterinary pharmaceuticals will more closely define duties and responsibilities of all participants in pharmacovigilance system. Its adoption is expected in the last quarter of the current year.

The Law on Pharmaceuticals and Draft Rulebook are harmonized with:

- *Directive 2001/83, Title IX*
- *(EC) Regulation No 726/2004, Chapter 3 Articles 21-29*

In the area of reduction of harmful consequences of drug abuse, the programme of methadone treatment and detoxification has been conducted in the Health Center of Podgorica since 2006. Until 2008 the programme included a total of 164 patients, of which 145 (88.5%) men and 19 (11.5%) women. In June 2009 methadone treatment included 45 patients, of which 8 women (17.8%), and 37 men (82.2%). The National HIV / AIDS Strategy, and the National Strategic Response to Drugs 2008-2012 “foresee the establishment of two more methadone treatment centers in the country - in the coastal and the northern region”.

There are also the so-called “low threshold programmes” which involve exchange of sterile needles and syringes and they are carried out by some NGOs. From February 2005 to March 2009 the Health Center of Podgorica also implemented the programme of exchange of needles and syringes.

Some NGOs have implemented harm-reduction programmes and 778 intravenous drug users, 75 commercial sex workers who are at the same time IVDA were contacted and the total of 26,000 syringes and 36,000 needles and 14,121 condoms and 20,000 informative and educational material were distributed (mid 2007 - end of 2008). These NGOs are still conducting outreach activities.

Nevertheless, the activities aimed at prevention of drug abuse are being conducted especially when it comes to school and university students - the groups that need special protection from the influence of drugs and drug addiction. These preventive activities are carried out in several ways:

- Through the concept “Community policing”,
- Activities of officers for juvenile delinquency, which are aimed at early detection and prevention of cases of sale and consumption of drugs in school facilities and school yards / the Project “School police officer” in primary and secondary schools,
- Participation in educational workshops, seminars, round tables, etc. when, for the purpose of preventive police action, knowledge and experiences are shared with the school population,
- Cooperation with municipal offices for prevention of drug abuse in organizing informative discussions in all towns of Montenegro,

- Permanent presence of the Special Officer for Combat against Drugs in the field, and collection of information about particularly vulnerable areas and taking preventive measures,
- COUNCIL *RECOMMENDATION of 18 June 2009 on the prevention and the reduction of health-related harm associated with drug dependence (2003/488/EC.)*

Healthy lifestyles

In 2003 the Government of the Republic of Montenegro adopted the Action Plan for Drug Use Prevention among Children and Youth from 2003-2006 - which resulted in a significant media campaign dedicated to the problems of drug abuse and its prevention, as well as the whole set of the activities aimed at better informing of children and young people in the first place about the problem of drug abuse;

In 2001 after training courses organized for teachers and following the development and printing of manuals for teaching staff, classes of *Prevention of Drug Abuse* were introduced in primary schools.

In 2006 high school peer education about drug abuse prevention titled *Healthy lifestyles against drug abuse* was organized in cooperation with some NGOs ('CAZAS'), and for the needs of implementation of this programme the following materials were developed and printed:

a) Handbook for Trainers

b) Handbook for Pedagogues - Psychologists;

c) Manual for Peer Educators and

d) Guide for Parents and the conducted education of peer educators.

In May 2008 after conducting the situational analysis about the problem of drug abuse in Montenegro and following the public debate the Government of Montenegro adopted a new strategy – the National Strategic Response to Drugs from 2008-2012 within which the activities aimed at further informing and educating the population of Montenegro regarding the problem of drug abuse are foreseen. The Drug Division / National Office for Drugs were established within the Ministry of Health in order to coordinate activities.

Policy of Montenegro in the field of fight against drugs and prevention of drug abuse is defined in the National Strategic Response to Drugs, adopted by the Government of Montenegro in May 2008, which is based on the principle of "4 pillars": prevention, treatment and rehabilitation of drug users, harm-reduction area, and "reduction of drug supply" which includes police and customs interventions.

Characteristics of the state policy in this area are as follows:

- Constitutionality and legality,
- Protection of human rights,
- Comprehensive and continuous monitoring and solving drug-related problems,
- International, cross-border and regional cooperation,
- Safety guarantees
- Tailoring it to address the needs of various population groups,
- Provision of healthy environment and healthy lifestyles,
- Partnership,
- Integrated and complementary approach,
- Central coordination.

The Government policy is aimed at two directions - reduction of drug supply and drug demand reduction. Target population is practically the entire population of Montenegro, with special emphasis on children and youth.

The Scope of work of the Police activities has been defined by the Law on Police, the Criminal Code and the Criminal Procedure Code, on the basis of which all necessary measures to reduce drug supply are undertaken such as breaking of international smuggling channels that lead to Montenegro or across Montenegro to other countries; their work also includes daily activities aimed at reduction of the volume of “street drugs sale”.

Regarding the demand for treatment of addictions, the new Law on Data Collections in the Field of Health Care was adopted in December 2008, enabling the introduction of a new system of data collection and reporting of medical and non-medical treatment centres about drug users in Montenegro. In collaboration with EMCDDA experts, in accordance with the activities planned by the National Strategic Response to Drugs 2008-2012 and the Action Plan for 2008/2009, a new application form for drug users was developed in line with EMCDDA standards and recommendations for collection of data on demand for treatment of addictions, and a new register of drug users which will be based on this form. / Pompidou form /. It is being harmonized. This will enable a better monitoring of trends in demand for treatment of drug addiction. According to the current data on clients who have applied for treatment in health care facilities in Montenegro, the situation is as follows: in 2003, 305 treated drug users were registered, in 2004 it was 562 drug users, in 2005 it was 516 treated drug users registered, in 2006 it was 526 drug users, and in 2007, 603 treated drug users were registered in health institutions in Montenegro. As for drug users treated in the Special prison hospital at the Institute for Execution of Criminal Sanctions in Podgorica, in 2006 44 drug users were treated, in 2007 it was 60 drug users, while until 1 July 2009 10 drug users were treated in this institution.

The Programme of methadone treatment and detoxification is conducted at the Health station Podgorica from 2006. Until 2008 the programme included a total of 164 patients, of which 145 (88.5%) men and 19 (11.5%) women. In June 2009 methadone treatment included 45 patients, of which 8 women (17.8%), and 37 men (82.2%).

The National HIV / AIDS Strategy and the National Strategic Response to Drugs 2008-2012 foresees establishment of two more MMT centres in the country. As for non-medical forms of treatment of drug users, in the Public Institution for Accommodation, Re-Socialization and Rehabilitation of Drug Users “Kakaricka Gora” first clients were admitted in September 2008, while in June 2009 there were 39 clients in treatment. There are also the so-called “low threshold programmes” which involve exchange of sterile needles and syringes and are carried out by some NGOs.

The National Office for Drugs at the Ministry of Health has established collaboration with WHO.

A significant cooperation is established with UNDP. In that sense we should mention cooperation, established through the National Office for Drugs at the Ministry of Health, in the project of opening two more centers for methadone substitution therapy.

The government’s view is in this respect is that reduction of demand can be best achieved through a systematic preventive work because the application of repressive measures only cannot give any results. That is why Montenegro has integrated into the school curricula courses that educate young people about harmfulness of drugs. Media are engaged to carry out information campaigns in order to provide objective information to parents and young people and the entire population about risks and harmful consequences caused by use of drugs.

Reduction of drugs demand includes interventions that are implemented in the following areas:

a) prevention of drug use

b) treatment, rehabilitation and re-socialization

c) reduction of harmful effects of drug use.

Both state institutions and civil society of Montenegro are involved in prevention of drug use in Montenegro. Municipal Offices for Prevention of Drug Addiction operate at the local community level.

Back in 2000 the Ministry of Education and Science of Montenegro, the Institute for Education, UNICEF and the Municipal Secretariat for Labour, Health and Social Policy developed the Drug

Abuse Prevention Programme for Primary Schools targeting pupils of V to VIII grade of primary school. More than 150 teachers and professional staff were trained to implement the programme, which has been implemented in 60 out of 160 elementary schools in Montenegro so far: in the period from 2001 to 2004 in 95 schools, in 2005 in 48 schools, in 2006 in 52 schools, and in 2007 in 46 schools.

Since the 2004/2005 school year, the Drug Abuse Prevention Programme for Primary Schools has been extended through the school projects: the idea was to have the students develop school projects that will require establishment of cooperation between at least the two schools and with other community stakeholders. In the year 2004, 4 such projects were conducted and involved 10 schools, in 2005 24 projects involivng 52 schools, in 2006 there were 23 school projects with participation of 46 schools and in 2007, 13 school projects were implemented.

Curriculum for the optional subject “Healthy lifestyles” was adopted in 2007, and since the 2008/2009 school year it has beeb introduced in a regular school system. This subject is designed for students of VIII and IX grade of primary school and currently it is studied by 1000 students in 22 schools in Montenegro. The capital of Podgorica is an ECAD member /European Cities Against Drugs /.

In the field of prevention 9 Municipal Office for Prevention of Drug Abuse operate in local communities; these are the city of Podgorica, Niksic, Cetinje, Zabljak, Kotor, Bijelo Polje, Berane, Bar and Pljevlja. General goal of these offices is prevention of drug use among young people by raising awareness of drugs and consequences of drug use through public lectures, public debates, media activities, public events, etc. These offices conduct surveys on drug use in local community. They also conduct educational and advisory work with parents, and some of these offices distribute drug presence control tests, they organize support to work of self-help groups etc.

In the area of research of the problem of abuse of psychoactive substances among young population, the most important achievement in the previous period was integration of Montenegro into the network of European countries which participate every four years in the survey on alcohol and drug abuse among secondary school students (ESPADA - The European School Survey Project on Alcohol and Other Drugs). In September 2009 representatives of Montenegro participated in international ESPADA meeting in Warsaw where ESPADA 2011 was planned, which will contribute to having a better insight into the problem of drug use and thus serve to a further planning of interventions in this field.

As for the field of treatment in Montenegro hospital treatment of persons dependent on psychoactive substances is provided in the Specialized Psychiatric Hospital “Dobrota” in Kotor, whose total capacity is 20 beds in the ward for treatment of addictions / 9 for drug addicts/; in the Clinical Centre of Montenegro - Psychiatric Clinic 5 beds are designated for hospital treatment of psychoactive substances addicts and in the General Hospital Niksic - Psychiatric Hospital 30 beds, of which 2 beds for the treatment of psychoactive substances addicts. Therefore, the total capacity of Montenegrin hospitals for treatment of addictions is 16 beds. For outpatient treatment, psychoactive substance users in Montenegro can address the Centre for Mental of the Health Station Podgorica and Kotor, and psychiatric wards in other health centers in the Republic. Detoxication units for overdosed drug users are established in seven general hospitals in Montenegro (Clinical Centre Podgorica and General Hospital Niksic, Bar, Kotor, Bijelo Polje, Berane and Pljevlja).

Regarding the rehabilitation and re-socialization of drug users, this kind of treatment is provided in a Public Institution for Accommodation, Re-Socialization and Rehabilitation of Drug Users “Kakaricka Gora”: it is a stationary-type facility, its capacity is 80 clients and it provides the programme for a period of 24 months which is conducted under the expert supervision. Two thirds of the price of a monthly treatment in the Institution is covered by municipality of Podgorica and the Ministry of Labor and Social Welfare, and one third is paid by the client. The Public Institution “Kakaricka Gora” admitted its first clients in September 2008, while in June 2009 it had 39 clients aged 23 to 43. It can be concluded that chances for treatment, rehabilitation and re-socialization in public health care institutions exist and are available to all interested addicts.

In accordance with the National Strategy cooperation with civil society is active, that is, it is established with a number of NGOs which deal with this issue and which implement activities in the area of drugs.

- *COUNCIL RECOMMENDATION of 18 June 2009 on the prevention and the reduction of health-related harm associated with drug dependence (2003/488/EC).*

Parliament of the Republic of Montenegro adopted the Law on Limiting Use of Tobacco Products (Official Gazette of the Reupbic of Montenegro 27/2004) which prohibits consumption of tobacco in most indoor public places and health care facilities. This Law, in order to protect life and health, prescribes measures for tobacco control: the reduction and limitation of the use of tobacco products and prevention of harmful consequences caused by the use of tobacco products (Article 1). Here are some of most interesting articles of this Law:

1) CONTROL OF HARMUL CIGARETTE SUBSTANCES AND COMPULSORY LABELLING ON TOBACCO PRODUCTS

Manufacture and trade of cigarettes that contain more than 10 mg tar, 1 mg nicotine and 10 mg of carbon monoxide per cigarette is prohibited (Article 7).

It is prohibited to trade cigarettes that are not labeled with information regarding the amount of harmful substances (Article 8) and tobacco products which do not have on the package printed in the Law clearly defined warnings about the hazards of smoking (Articles 9 to 13).

For cigarettes that are available in Montenegro the manufacturer, that is, importer of cigarettes must provide, at least once a year, upon the request of the competent inspector, measuring of substances referred to in Article 7 of this Law (Article 14) as well as information about toxic ingredients (Article 15).

At least once a year the Institute informs the Ministry and public about the results of the measurements carried out on cigarettes that are manufactured and sold in Montenegro and on the contents of harmful substances of tobacco products with toxicological details (Article 16).

2) MEASURES TO REDUCE AND LIMIT THE USE OF TOBACCO PRODUCTS

It is prohibited to sell tobacco products to the persons under the age of 18, they are prohibited to sell tobacco products and to use tobacco products in public places (Article 17). A sign must be displayed in locations where the retail sale of tobacco products is carried out concerning prohibition of sale of tobacco products to the persons under the age of 18 (Article 18).

The sale of tobacco products is prohibited in and near schools, hospitals, pharmacies, sports facilities, self-service, from vending machines as well sale of products that by their name create delusion about being less toxic (Article 19), toys and other products that associate to cigarettes and cigarette brands (Article 20); advertising and promotion of tobacco products or smoking is prohibited (Articles 21 and 22) as well as showing in media persons smoking (Article 23).

Smoking in public places (health care facilities, education facilities, means of public transport such as air and road travel, gatherings, food facilities and service restaurants - discos, pastry, pizza and fast food facilities, Article 24)

Regulating the right to clean air for non-smokers in the rest of the public (Articles 25 to 27), and work space (Article 29) by the physical division of space and provision of adequate ventilation.

Obligatory display of information about prohibition of smoking (Article 28)

Compulsory education in schools about the hazards of smoking (Article 30)

3) INSPECTORIAL SUPERVISION

It is carried out by health, sanitary, market and tourism inspectors (Article 31).

4) PENALTY PROVISIONS

For violation of the provisions of this Law pecuniary fines in the amount of 25 Euros for smokers to 15,000 Euros for legal persons or entrepreneurs (Articles 32-35) are prescribed.

Activities aimed at informing the citizens are being implemented, primarily through the regular celebration of the international day of Fight against Tobacco Smoking (31 May) at the event of which media campaigns are organized in order to reduce tobacco consumption. In this sense the NGO Montenegrin Association for Fight against Cancer has organized many media campaigns. Their most recent campaign was “Smoke Free Zone - Health on the Throne”.

In cooperation with UNICEF the programme “School without violence – creating safe and protective environment for children” is being implemented. The programme teaches the children and adults how to resolve conflicts in non-violent ways and how to act when violence has already happened. It is intended for students, teaching and non-teaching staff, parents, and the entire community. The programme aims to reduce and prevent violence among school children in Montenegro, and to promote ideas of peace and tolerance in schools. Other schools are expected to take part in this project or to log on UNICEF’s web address: www.unicef.org/montenegro.

Also, as of 1999, in cooperation with UNICEF, the programme “Baby Friendly Hospitals” and breastfeeding of babies until 6 months of age has being implemented. The aim of the programme is to inform and educate pregnant women and mothers about the necessity of exclusive breastfeeding of babies until they reach at least six months of age. This programme is applied in 7 maternity wards and other 3 are preparing for it. Special courses for pregnant women are planned to be organized within several health stations.

Based on the Strategy for Prevention and Control of Chronic Non-Communicable Diseases, it is planed to implement by 2020 a set of activities aimed at popularization of healthy life styles among various sectors of society.

The Institute of Public Health in cooperation with electronic media organizes from time to time programmes on healthy lifestyles (avoiding smoking tobacco, drug use and excessive use of alcohol, healthy nutrition, the necessity of regular physical activity, etc.).

In 2009 in cooperation with the Ministry of Education and Science the optional subject Healthy Life Styles has been introduced in primary schools (VIII and IX grade) for which a special curriculum was developed as well as a manual for those who are going to deliver that programme and a textbook for students; they are planned to be published in November 2009. The programme is comprehensive and covers topics on the basis of anatomical-physiological functioning of the human body and its needs, personal and communal hygiene, healthy nutrition, healthy physical activity, injury prevention, mental health and social skills, prevention of abuse of psychoactive substances (tobacco, alcohol and drugs), prevention of violence, reproductive health and prevention of unwanted pregnancy and sexually transmitted infections.

Obesity and nutrition

The Strategy for Non-Communicable Diseases from November 2008 in Item 3.2.4 addresses the issues related to nutrition and physical activity in the prevention of chronic non-communicable diseases.

Conclusions of the Council on obesity, education on proper nutrition and physical activity with special attention to vulnerable categories of population (infants, children, preschool and school age children, adolescents and older age groups) have been incorporated in the Action Plan for the Nutrition of the Population in Montenegro for the period 2010 to 2014. This Action Plan was developed by a multi-sectoral working group established by the Ministry of Health, Labour and Social Welfare and it is expected to be adopted as soon as possible. This Action Plan was developed in collaboration with WHO Office and consultants engaged by the WHO.

To promote proper nutrition and physical activity in order to treat obesity as a risk factor for aetiology of chronic non-communicable diseases, a specialist clinic “Counselling for Proper Nutrition” has been established and is operating within the Institute for Public Health in Podgorica. This counselling has been working for six years now and in the last three years (2006, 2007 and 2008) over 11,000 patients were examined of which over 3,700 patients came for the first time.

The 2009 Health Care Programme provided establishment of counselling within the Centres for Prevention.

Alcohol abuse prevention

Alcohol use is a risk factor for the development of mental disorders, liver cirrhosis, hypertension, stroke, certain forms of cancer, and all injuries, especially injuries in traffic, while in pregnancy it may lead to the birth of children with feta alcohol syndrome.

As for the drinking habits of young people (aged 15) according to the study of the European School Survey on Alcohol and Other Drugs (ESPAD) conducted in Montenegro in 2008 on the population of the first grade students of secondary school, there were about 74% of students who had at least one alcoholic drink so far. More than half of the interviewed students consumed alcoholic beverages 3 to 40 times. Students included in this survey usually drink at home - one quarter of them. 16% of students, of which 57% boys, were drunk at least once in their lifetime while 4% of students, of which 84% boys, were drunk ten or more times.

The survey on alcohol use included the students of the first grade of secondary school in the capital of Montenegro - Podgorica. The results of the survey on alcohol consumption by young people show that the consumption of alcohol beverages is a widespread phenomenon among young people as among all other population groups, because it is an acceptable phenomenon in our society. One out of ten respondents replied that in their families alcohol drinks are never used, and the survey has shown that there is a connection between the students' alcohol consumption with the habit of using alcohol in the family. Data of this research show that, in addition to the family, the formation of students' behaviour is undeniably influenced by their immediate surrounding. In that sense the survey examined behaviour of students in relation to their consumption of alcoholic beverages defined primarily by behaviour of their peers. Domestic production of alcohol was reported by almost half of the respondents.

For monitoring of alcoholism as a public-health problem, liver cirrhosis is considered a disease indicator.

The consideration on how much the genesis and development of addiction illnesses are actually related to behavioural component has been more taken into account. Substance abuse and selection of a specific lifestyle is often associated with other problems. Because of this, it is a general stand of professionals that young people should be oriented towards healthy life styles grounded in knowledge, values and critical attitude towards reality so that every young person is self-powered to make constructive decisions in life. This has been supported by introducing a subject of "Healthy Lifestyles" to all schools in Montenegro. The attitude that NON-DRINKING is a normal and desirable model of behaviour is developed, which young people should accept as a most desirable standard of social behaviour.

International regulations, whose signatory is Montenegro, concerning children and youth protection against alcohol use, are the following

Convention on the Rights of the Child *1. Convention is adopted by the UN General Assembly, at the sitting held on 20 November 1999*

Pursuant to the Convention, a child means every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier (Article 1). Every child has the inherent right to life, and the state is required to ensure to the maximum extent possible the survival and development of the child. Every child is entitled to life (Article 6). The Convention particularly tackles the issue of the child’s access to healthcare services. Thus, the Convention ensures that the child has the right to attainment of the highest possible level of health and health protection and that the state is obliged to devote special attention to primary health care and disease prevention (Article 24). The Convention also envisages child’s protection from the illicit use of narcotic drugs psychotropic substances. States are required to take all appropriate measures, including legislative, administrative, social and educational measures, to protect children from the illicit use of narcotic drugs and psychotropic substances as defined in the relevant international treaties, and to prevent the use of children in the illicit production and trafficking of such substances (Article 33).

The World Health Organization, within its Programme “Health for All by the Year 2000”, formulated a set of health objectives, of which the 17th objective reads as follows: “By 2000, health consequences caused by consumption of alcohol, tobacco and other psychoactive substances and

their production must be significantly reduced in all countries." The objective of this goal is aimed reducing alcohol consumption for at least 25% in comparison to the current situation, and particularly at reducing harmful consequences for health as a result of alcohol use. Having in mind these goals, the World Health Organization, in December 1995 in Paris, at the Conference "Health, Society and Alcohol" adopted the first European Alcohol Action Plan ("EAAP") and the European Charter on Alcohol, which contain 10 strategic objectives and five ethical principles for combating alcoholism. The firstn EAAP is accepted in more than 50 European countries as a stepping-stone for development of national preventive programmes in those countries.

UN Declaration of Children Protection

The Declaration is adopted under the title "A World Fit for Children". It has four independent UN priority areas of action in respect of protection of the rights of children such as follows:

- Promoting healthy lifestyles;
- Providing quality education;
- Protecting children against abuse, exploitation and violence; and
- Combating HIV/AIDS

The Declaration particularly tackles protection of children from use of narcotic drugs, psychotropic substances and inhalants. In that sense, the Declaration recommends development and implementation of policies and preventive programmes at national level.

Revised European Charter on the Participation of the Young People in Local and Regional Life

Article 7 item 10 of the Charter, with the aim to ensure the efficient enforcement of the rights of children and youth in care, envisages obligation of the state to ensure special protection from physical and moral hazards to which the children and young people are exposed. Besides, member states are obliged to undertake all necessary measures in order to ensure effective enforcement of the rights of children and young people to grow up in the environment, which encourages full development of their personality and their physical and mental capacities (Article 17 paragraph 1). The Charter recommends local and regional authorities to support organised socio-cultural activities – run by youth associations and organisations, youth groups and community centres – which, together with the family and school or work, are one of the pillars of social cohesion in the municipality or region; these are an ideal channel for youth participation and the implementation of youth policies in the fields of sport, culture, crafts and trades, artistic and other forms of creation and expression, as well as in the field of social action. A separate section (Section I.6) talks about health policy. Pointing out to the fact that local and regional authorities, among other things, are faced with detrimental consequences of alcohol abuse by youth, the Charter proposes introduction, development and promotion of local information policies and counselling facilities for young people affected by these problems, as well as special training policies for young social workers and for voluntary workers and leaders of organisations operating prevention and rehabilitation strategies for the young people concerned. These activities should be carried out in cooperation with representatives of youth organizations and health institutions

- Council Directive 94/33

This Directive refers to protection of young people at work. Within the meaning of this Directive, the employer is required to guarantee that young people have working conditions, which suit their age. It implies that young people are protected against any work likely to harm their safety, health or physical, mental, moral or social development. In addition, free medical assessments are also ensured if necessary to determine mental and physical health of young worker, or to establish if a certain level of risk at work is acceptable for young worker.

Mental Health Declaration for Europe

This document, among other things, points out to linkage between mental health problems and alcohol abuse -related problems. For these reasons, the Declaration states that ministers responsible for health from member countres of the WHO Eurpean Region will commit themselves, in accordance with each country's constitutional structures and policies and national and subnational needs, circumstances and resources, to supporting the implementation of the following

measures, which, among others, are aimed at preventing from alcohol abuse and other substances. At the same time, the Declaraion provides for the support to non-governmental organizations, which are active in combating alcoholism and other disorders related to abuse of substances. In the Item 13 of the Declaration, the Regional Director of WHO for Europe is required to take action aimed at encouraging partnerships in this area with intergovernmental organizations, including the European Commission and the Council of Europe.

European Union Strategy against Aclohol Abuse

This Strategy is adopted in 2006, despite the intensive lobbying both on the part of alchohol producers and on the part of the media against this measure. The Strategy paper says that 195,000 thousand people a year die from alcohol-related harms. According to statictics, about 55 million of adult people, meaning more than 10 percent of the EU population, consume alcohol ecessively. Eccessive alcohol consumption represents the third biggest cause of ill health and early deaths. At least 10,000 people a year are being killed in alcohol-related accidents. The

Strategy papers sets out five priorities on which member states and alcohol producers need to focuss. Protection of children and young people from acohol related harms as well as reduction in number of traffic accidents caused by alcohol is emphasized as one of priorities. In this context, it juvenile drinking and drink driving represent actual problems of public health in Europe. The EU Commission in this document does not provide for the ban on advertising alcohol in the EU countries, but it stands for raising awareness of harmful consequences caused by eccessive alcohol drinking. In addition, the Commission committed itself that it would pressure alcohol producers to “promote responsible drinking”, which means that the alcohol industry should develom a unique code on advertising, as well as establishing dialoge between producers and health institutions. Therefore, the Commission recommends the implementation of programmes aimed at raising public awareness and educating public of all alcohol related harms, as well as pointing out to all examples of good practice in combating alcoholism. These programmes need to be realized in cooperation with all relevant subjects in this area. Alcohol-related harm protection of young people, particularly during driving, is emphasized to be one of the EU future priorities. For this purpose, the Commission committed itself that it would support programmes alcohol related diseases and juvenile consumption of alcohol.

Protection of minors from alcohol abuse, according to international standards and the standards of neighbouring countries with emphasis on the situation in Montenegro

Regulations in Montenegro with regard to the protection of minors from consumption of alcohol

Constitution of Montenegro guarantees special protection of children from psychological, physical, economic and any other exploitation or abuse.

The Law on Health Care (Official Gazette of the Republic of Montenegero 48/92 20, Official Gazette of the Republic of Montenegro 39/90 and 21/91 21 Official Gazette of the Republic of Montenegro70/03) in Article 1 Paragraph 1 Item 4 sets as a priority creation of the conditions for special care of socially vulnerable population categories in the sense of this Law. Article 10 of the Law defines priority health care measures including Paragraph 1 Item 7 which prescribes as a special measure health care of children and young people until the end of legally prescribed regular education. In the field of health care, the state provides, inter alia, funds from the budget for organizing the activities of prevention of alcoholism, smoking, drug abuse and other addictions.

Criminal Code of Montenegro The court pronounces a mandatory medical treatment to an offender who has committed a criminal offence because of addiction of alcohol consumption and if there is a serious danger that s/he might continue committing criminal offences due to this addiction. The sanction mentioned before is carried out in a penitentiary institution or in an appropriate medical or other specialized institution and lasts for as long as there is a need for treatment, but not longer than the pronounced prison sentence. Time spent in an institution for treatment included the imprisonment. If the measure of compulsory treatment is pronounced with a fine, suspended sentence, a judicial reprimand, or exemption from punishment, it is executed at liberty and cannot exceed two years. Also, if the offender, without justifiable reasons, does not take treatment at liberty or leaves the treatment at her/his will, the court shall order the compulsory enforcement of the prescribed measures in an appropriate medical or other specialized institution (Art. 72).

According to current regulations, criminal sanctions cannot be applied to a child, that is, a person who at the time of commission of a criminal offence was under the age of 14. A juvenile who at the time of commission of a criminal offence had reached the age of 14 but not the age of 16 (a young juvenile), can be punished by educational measures only (Art. 80). To a juvenile who at the time of commission of a criminal offence had attained 16 years of age but had not yet reached 18 years of age (a senior juvenile) educational measures may be imposed, and exceptionally a punishment of juvenile imprisonment may be imposed (Article 81). When imposing some of educational measures of intensive supervision, the court can, if so needed for a successful accomplishment of the purpose of the pronounced measure, determine one or more obligations for a juvenile among which one is to refrain from enjoying alcoholic drinks and narcotic drugs or to undergo appropriate treatment (Article 91, Item 1.4).

The National Action Plan for Children (from 2004 to 2010) adopted by the Government of Montenegro in July 2003 was developed based on the UN Declaration and is a framework document for the activities, programmes and strategies that the state and civil society will accept in order to create a world fit for children until 2010. In this sense, the vision of the creator of this document was that "all the girls and boys need to be productive and active participants in all the aspects of our society". This implies an active role against diversity and exclusion in the society, as well as fighting poverty and creating opportunities that all children have the opportunity to be healthy and to fully develop their potential. The document emphasizes the commitment of Montenegro to ensure that all the children have access to effective, equal, permanent and sustainable system of primary health care, access to information, support to a healthy life style, and protection of children and their families from HIV / AIDS infection. Thus, the Action Plan envisages the improvement of activities in the areas of preventive health care, fight against the abuse of illegal substances, reproductive health and health education. Since the implementation of the Action Plan until 2010, reduction of alcoholism among youth by 20% is expected. To achieve this result the following activities are foreseen:

- to have organized implementation of health-promotional and preventive measures for the acquisition of healthy habits in the family, school and community;
- to promote prohibition of sale of alcohol to minors and enforcement of measures, to control stores that sell alcohol, including imposing appropriate sanctions;
- to develop action plans for prevention of youth addictions.

The National Programme of Prevention of Unacceptable Behavior of Children and Young People in Montenegro (adopted in May 2004). According to this document there is a rising trend of the number of underage offenders and the number of recurrences in Montenegro since 2000, and one of the reasons for that is a mild upward trend in the number of young people who are psychoactive substances addicts - such as drugs and alcohol. One of the strategic goals set in this document is to improve the legal framework that applies to all forms of protection of young people, education of people about the risk factors that lead to socially unacceptable behavior of young people on one hand and promotion of healthy lifestyles among young people, on the other hand. Adoption of this document was accompanied by the adoption of the Action Plan for its implementation (for the period 2004-2006), which envisages in order to reduce harmful effects of alcohol and other harmful substances the improvement of implementation of enacted laws that limit the use of these substances.

The National Youth Action Plan in Montenegro. This document was adopted by the Government of Montenegro in October 2006. One of the strategic goals of this document is to inform the youth about harmful consequences of addictions, which includes raising awareness of their causes and their consequences. This document highlights the problem of excessive alcoholism consuming by young people in Montenegro and the increasing trend of alcoholism among girls.

The National Action Plan for Children envisages the improvement of activities in the areas of preventive health care, fight against the abuse of illegal substances, reproductive health and health education. One of the strategic objectives established in this document is to improve the legal framework that applies to all forms of protection of young people, and education of people about the risk factors that lead to socially unacceptable behavior of young people on one hand and promotion of healthy lifestyles among young people on the other hand.

Cancer

Recommendation 03/878/EC: Council Recommendation of 2 December 2003 on preventive search for examination of the presence of cancer.

The Strategy for Prevention and Control of Chronic Non-Communicable Diseases by 2020 the Action Plan for the period 2009 – 2013, adopted by the Government of Montenegro on 24 December 2008, foresees drafting of national programmes for prevention and control of major chronic non-communicable diseases by 2011. Establishment of national screening programmes for early detection of malignant neoplasm of breast, cervical and colorectum is foreseen as a part of development of these programmes. In accordance with the Action Plan underway is development of the national programmes for prevention and control of malignant neoplasm and cardiovascular disease, and a pilot programme of breast malignant neoplasm screening is currently being implemented in municipality of Danilovgrad. After the analysis of the results of the pilot project, establishment of the National Breast Cancer Screening Programme will begin. Technical conditions for implementation of this programme in the centers designated for this programme implementation have already been provided by provision of mamograph.

Questions:

a) Are there legislative, regulatory or administrative provisions in force in your country covering these areas? If yes, please send summaries and, if possible, full texts in one of the official EU languages.

According to the Law on Occupation Health and Safety (Official Gazette of the Republic of Montenegro 79/04) an employer must ensure that people (other than the employees of the employer) are not exposed to risks to their health or safety by implementation of various types of measures. Article 15 stipulates that every employer is obliged to adopt the Risk Assessment Act latest until 31 December 2007 for all the jobs and to establish measures to reduce risk to minimum.

The Rule on the manner and the procedure of risk assessment at workplace (Official Gazette of the Republic of Montenegro 43/07), stipulates the obligation of the employer to adopt the Risk Assessment Act for all the jobs, starting from organization of work, work processes, tools for work, raw materials and materials used in work processes and other elements that can cause a risk of injury, that can harm health or cause an illness of the employee; physical risks include non-ionizing radiation.

The Law on the Road Safety (Official Gazette of the Republic of Montenegro 72/05) defines safety of participants in traffic.

In Montenegro, the area related to the protection from the risk of exposure to electromagnetic and non-ionizing radiation is not properly regulated. Thus, drafting of the Law on Protection from Non-Ionizing Radiation is expected and directives and recommendations on limiting public exposure to electromagnetic fields will be transposed into the new law. However, we cannot say that in Montenegro there is no relevant legislation.

Namely, until the legislation and secondary legislation that will comprehensively regulate this area are adopted, prevention of the impact of electromagnetic radiation is regulated on the basis of the Law Broadcasting (Official Gazette of the Republic of Montenegro 51/02, 62/02, 46/04, 56/04, 77/06, Official Gazette of Montenegro 50/08 of 19.08.2008, 79/08 of 23/12/2008, 53/09 from 7 August 2009) through the Rulebook on maximum radiation forces of radio stations in cities and settlements with Urban Characteristics (Official Gazette of the Republic of Montenegro 21/05).

This Rulebook prescribes the allowed maximum radiation power of fixed radio stations, standards for their placement in cities and urban settlements and safe distance from the sources of electromagnetic radiation in order to prevent creation of unacceptably strong electromagnetic fields harmful to human health and the protection of broadcasting equipment in accordance with relevant standards.

A set of comprehensive national regulations on projects environmental assessment were passed and are in force as of 1 January 2008. These are: the Law on the Assessment of Environmental

Impacts (Official Gazette 80/05), the Decree on projects environmental assessment (Official Gazette of the Republic of Montenegro 20/07 of 4 April 2007), the Rulebook on the contents of documents submitted with the request for making a decision on the necessity for environmental impact assessment (Official Gazette of the Republic of Montenegro 14/07 of 21 December 2007), the Rulebook on the contents of documents submitted with the request for determination of the scope and the content of survey on environmental impact assessment (Official Gazette of Montenegro 14/07 of 21 December 2007) and the Rulebook on the content of the survey on environmental impact assessment (Official Gazette of Montenegro 14/07 of 21 December 2007).

The Council Directive 97/11/EC amending the Directive 85/337/EC on public and private projects environmental impact assessment was transposed into the Law on Environmental Impact Assessment. Also Directive 2003/35/EC of the European Parliament and the Council which allows public participation in decision making and access to information was transposed into the Law. Montenegro ratified the ESPPO Convention on Environmental Impact Assessment in trans-boundary context, together with two amendments (Official Gazette of Montenegro 8/08).

Environmental Impact Assessment Study analyzes and evaluates quality of the segments of environment and their sensitivity in a specific area, mutual impact of the existing and planned activities, predictions of direct and indirect environmental impacts from project implementation, it determines the measures and conditions to prevent, remedy, mitigate or repair harmful effects on environment and human health.

The Decree on projects environmental assessment determines specific projects for which environmental impact assessment is required, that is, may be required. Projects which must have environmental impact assessment are determined in the List I and the projects for which environmental impact assessment may be required are determined in the List II of this Regulation.

The List II of this Decree, among other projects for which environmental impact assessment may be required, includes “telecommunication transmitters and radio relay systems”. For these projects environmental impact assessments is obligatory regardless of power of supply because of their potential impact on human health and environment. This process will enable detailed assessment of the quality of the segments of environment in that specific location; characteristics of equipment to be built in and through the assessment of intensity of electric field and determination of the zones of non-allowed emissions, adequate measures will be determined in order to prevent impact on people and environment.

For the List II projects, total duration of the assessment procedure initiated with competent authorities (does not include the time for creation of documentation for decision making about the need for impact assessment; preparation of documentation to determine the scope and content of the Study; documentation updates; Study development; potential changes of the Study and the like which is the obligation of the Investor) is 173 days maximum (includes all three phases: deciding on the necessity for environmental impact assessment, determining the scope and content of survey on environmental impact assessment and the approval of the study on environmental impact assessment). Considering the fact that according to the Law the Investor does not necessarily have to implement the second phase (determining the scope and content of the Impact Assessment Study) the time required for implementation of the impact assessment procedures for the projects of the List 2 (deciding on the necessity for impact assessment and approving of the Impact Assessment Study) provided that there are no amendments to the submitted documents, or objections of the Commission for Evaluation of the Study is maximum 104 days.

Holder of the project can not start realization of the project without the environmental impact assessment procedure and the approval of the competent body of Environmental Impact Assessment Study (Article 6 of the Law on Impact Assessment).

The rest of the response is contained in the response to the question 54.

b) In case there are no legislative, regulatory or administrative provisions in force, are there any drafts, proposals or programmes for these in the pipeline? If so, give details of these and of the timeline for their adoption.

The Government of Montenegro adopted the Draft Law on Protection against Family Violence is along with the plan of public discusison. The poposer of the Law is the Ministry of Justice.

The Law Non-Ionisation Screening is in the process of drafting. The proposer of the law is the Ministry of Spatial Planning and Environmental Protection.

Strategy on Transport Safety is in the process of drafting. The prosposer of the Strategy is the Ministry of Interior and Public Administration.

c) In cases where neither of the above exist, are there any plans to start preparing proposals? Please explain, also indicating the envisaged timetable.

You may find the response in the responses given to the question no. 54

d) Please describe the administrative capacity, including human and financial resources, to fulfil the requirements laid down in the Community legislation listed above? (Is there any impact observed from the current economic and financial crisis?)

Montenegro faces certain limits concerning the available resources, which have been deepened further due to the effects of the global economic crisis. However, enormous efforts have been invested in order to manage the existing resource in the best possible manner and with the aim to attain the best possible results.

55. With specific reference to mental health, please answer to the following questions:

You may find the response to this question in the the following responses 55a), 55b), 55c) of this Chapter.

a) What are the measures you are taking to support the social inclusion of people with mental health problems? What are the measures taken to reduce the stigma and discrimination of people with mental health problems?

The Law on Social and Child Welfare regulates, among other things, issues of social welfare for people suffering from mental illnesses. On the bases of this Law, social welfare services available to people suffering from mental illnesses consist of the following:

- Personal invalidity allowance;
- Caregiver's allowance;
- Placement in an institution;
- Health care allowance.

The activities of the Public Health Institution (PHI) Special Psychiatric Hospital (the biggest psychiatric institution in the state) aimed at reducing stigma and discrimination of people suffering from mental health problems were and have been implemented through the following activities:

- Organizing Open Days in October 2008, when the institution organized sports and cultural programmes and invited citizens from local communities to visit the institution and in that way to give their contribution to the International Mental Health Day.
- Offering citizens to use, on a daily basis, modern gyms within hospitals and open sports ground with a minimum fee, aimed at breaking stigma and approaching the community to the institution.
- Action aimed at collecting books for renewal of hospital library, which was supported by the local media.

- Inviting guest experts in the field of mental health to the media to talk about mental health related issues.
- Organizing exhibitions of paintings and works of patients of the institution in the City Gallery.
- Activities in the next period 2009-2010 will be carried out through the implementation of MATRA project, including the following activities:

Development of Psychosocial Rehabilitation Programmes

The first step that needs to be taken within this project is aimed at introducing the staff to a conceptual thinking related to psychosocial rehabilitation and starting with implementation of certain elements of rehabilitation within mental health hospitals for the wellbeing of patients with long-term needs. Thus, an adequate number of employees will be prepared to work in accordance with the principles of rehabilitation and be able to overcome the desperate, discouraging situations in which there are patients with long-term needs.

The staff will be trained to conduct a needs assessment among patients with long term needs and based on the assessment results to develop and establish, in cooperation with GGZ Nijmegen experts, rehabilitation services within the hospital.

In addition, the staff will be trained in the field of (partially individual) competences necessary for access to rehabilitation, such as:

- Recognition and use of beneficiaries' experiences
- Use of strengths and opportunities of clients
- Use of support of other relevant parties (for example: family partners)
- Identification of client needs
- Offering support to clients in achieving their personal goals

Once established in hospitals, psychiatric rehabilitation services, in the future, may become an integral part of the development of community-based alternative services in the field of mental health.

Public awareness

Public awareness component of the project proposal is developed in order to start the process of integration of persons with mental healthcare related problems in the community, reducing their stigmatization and removal of walls that still exist between the mental health related institutional care (currently the only existing form of care) and the society.

Activities within this component include the following:

- Training facilitators among the hospital staff to be moderators of public discussions on specific topics related to mental health. Developing and publishing a set of six brochures on specific mental health related issues that need to be distributed in the community. The topics covered are those existing in the Montenegrin society and those that will help the community to tackle these issues. Here is the list of provisionally selected topics: "Once your beloved becomes mentally ill"; "Depression"; "Narcotic Drugs and Alcohol Abuse"; "Nutrition Related Disorders"; "Dementia";" Service provided with the Special Physiatrist Hospital in Kotor/Dobrota";
- Organizing public seminars on specific topics, particularly those that are subject to the above mentioned brochures. Seminars will be held in the room provided by the Municipality of Kotor, with which the hospital in Kotor/Dobrota closely cooperates;
- Organizing two Open Days in the hospital (2009 and 2010), when the hospital will open its doors for all the citizens of Kotor/Dobrota for and any interested persons, with the aim to show its departments, working environment, explain what the daily life in the hospital looks like and in that way reduce the stigma existing nowadays. Designing promotional campaigns related to the services that hospitals can offer to the community. The hospital can be proud not only of their basketball court, but also of pottery workshops and other

activities, which are open to the citizens of Kotor/Dobrota. This campaign should encourage citizens to visit the hospital and use its services. For example, the children from Kotor, who would come to basketball court to play basketball with the patients, would give a contribution to immediate destigmatization.

- Opening telephone lines that would serve the community. A telephone line will be open every working day for an hour so that the citizens from the community could call the hospital and ask questions, for example: how to take care of a person with dementia, or an intoxicated spouse or anorexic daughter.
- Organizing media training for journalists. GIP-Sofia has a unique experience in this area, and having trained groups of journalist together with beneficiaries, journalists were taught to treat mental health issues in a non-stigmatized manner and write balanced articles on mental health issues. Two three day-long trainings will be organized for a group of five beneficiaries and five journalists in an isolated place in Montenegrin mountains, and the training will be run by trainers from Sofia.

in order to have valuable and active community, which takes care of mental health if its citizens and cooperate with civil sector.

The Council of Patients that needs to be established within this Project will eventually lead to the establishment of the organization of beneficiaries, as it is the case in other countries.

b) Do you provide specialized mental health facilities for vulnerable groups such as old people, children and young people?

The Law on Social and Child Welfare provides for a possibility of placement in an institution of "individuals with physical, mental or sensor disabilities who (due to residential, health, social or family conditions) do not receive adequate assistance."

"Geriatric and Nursing Institution – 'Grabovac' in Risan is currently the only institution of this type in Montenegro that accepts "the elderly, the weak, people with chronicle diseases and disabilities." Accommodation capacities of this institution consist of 308 beds, while there are also private geriatric homes. Apart from the Specialized Psychiatric Hospital in Dobrota, there are no other specialized institutions providing accommodation for people suffering from mental illnesses.

The lack of social welfare support services and structures for people with mental illnesses represents the only reason for a long-term institutionalization of these individuals in the Specialized Psychiatric Hospital in Dobrota

There is one specialized residential institution in Podgorica – Public Institution "Komski most" that places children, youth, adults and the elderly with mild, serious and severe mental disabilities. This institution has a capacity of 140 hospital beds.

Still , there has been no department of child psychiatry in Montenegro or knowledgeable specialists in this field. Children and adults with mental disabilities are referred for the treatment to referential institutions in neighbouring countries, while the costs of treatments are covered by the Fund For Health Insurance of Montenegro. In the forthcoming period, the Ministry of Health of Montenegro plans to educate professionals in this field and establish organizational unit for children and adult psychiatry.

In recent years, inclusive education has been introduced as a part of primary education of children with developmental disabilities with the tendency to abolish previous specialized departments and encourage inclusion of these children in the process of regular classes.

c) Do you provide a community based services for people with mental health problems?

Community based services for people with mental health problems have been currently provided with the activities of the existing Mental Health Centres and mental health units within health centres. The process of building personnel, spatial and technical capacities for meeting standards laid down in the Strategy for Enhancement of Mental Health in Montenegro and the primary health care reform are underway.

In this regard and pursuant to the Strategy for Enhancement of Mental Health in Montenegro, the following community based mental health centres and units are opened in Podgorica, Herceg Novi, Bar, Nikšić, Pljevlja, Rožaje, Bijelo Polje, Berane and Kotor providing the following services:

- Primary prevention: health promotion and education
- Diagnostics
- Therapy treatment

*Treatment with medicaments

*Family therapy

*Individual and group psychotherapy

*Crisis interventions

*Occupational therapy

*Counselling-educational work

*Counselling for addiction diseases

*Home visits and home treatment

- Rehabilitation and resocialization

*Training for healthy life

- creating policies and planning activities for improvement of mental healthcare
- establishing cooperation with alike institutions and organizations
- Data bases – keeping records
- Monitoring, evaluation and reporting

Counselling centres for young people within Health Centres in Podgorica, Bar, Kotor, Herceg Novi, Nikšić, Pljevlja, Bijelom Polje, Berane perform the following:

- Individual counselling-therapeutic work with young people;
- Counselling for groups of young people aimed at overcoming developmental problems;
- Organizing specific programmes (workshops) for work with the youth, support to healthy lifestyles
- Developing preventive programmes, coordination and implementation

56. With specific reference to access to health care system, do you have specific measures in place to allow the poorest people, minorities and people living in rural and remote areas to have equal access to the health care system in your country?

In exercising their rights to health care, Montenegrin citizens are equal regardless of nationality, race, sex, age, language, religion, education, social origin, property status and other personal characteristic (the Law on Health Care).

Health care in Montenegro is implemented based on the principles of comprehensiveness, continuity, accessibility and integral approach in primary health care, and specialized approach in specialist-consulting and hospital health care.

The state provides all necessary funds for health care. In addition, the health system reform in Montenegro has significantly improved and simplified access to health care.

Montenegro fully respects the principle of equality and accessibility and thus the network of public health institutions is well developed and people from remote places in Montenegro can access primary health care facilities easily – the maximum distance from a health care facility is less than ten kilometres. General hospitals are arranged so that people from several municipalities can use their services whereas special attention is paid to geographical and climatic characteristics of the

areas whose population gravitates to these hospitals. Clinical Centre in Podgorica is a tertiary level health institution and the entire population of Montenegro gravitates to this hospital.

In order to make health care services accessible to the elderly and the disabled, all chosen doctors are obliged to provide medical services to these patients at home as needed. These patents arrange their medical check-ups with their chosen doctor and as mentioned before some of the check-ups are, as needed, conducted in their homes. Therefore, this population has an easy and full access to health care services.

In cases of emergency, patients are entitled to urgent medical treatment on site that is at the places where they are while being in state of need.

Employees exercise their right to health care based on obligatory payment of health care contributions while the state covers health care services for the unemployed. All the residents of Montenegro - social welfare beneficiaries and others who are not able to pay health care services are provided with free health care services (without paying a fee, which is of a very small amount). All the rights of beneficiaries are defined by a new legislative framework, that is, a set of reform laws, which is a necessary precondition for improvement of health care and stable functioning of a health care system. Montenegro has achieved a remarkable success in passing new health laws and in restructuring this sector.

According to the Statistics Office (hereinafter referred to as "Monstat"), the largest percentage of the poor in Montenegro is amongst the Roma population. On the basis of precise methodology of the World Health Organization, "Monstat" conducts an evaluation on the share of the poor in the whole population for every year. The Ministry of Health has been developing a policy aimed at addressing health needs of this segment of the population.

Montenegro received a huge number of refugees and displaced persons during the recent wars in the region. In the period from 2000 to 2003, 7.1 million euros was spent for health services to refugees and displaced persons in Montenegro. This was a large expenditure for already burdened budget, i.e. system of financing of health care of domestic population.

In order to provide full health care for all, funds for the medical treatment of refugees and displaced persons in public health facilities in the territory of Montenegro are provided from the Budget of Montenegro. This part of population is provided with health care under the same conditions as the Health Insurance Fund beneficiaries.

The Ministry of Health of Montenegro enabled provision of services to the poorest part of population (RAE population) in the places where they live, that is, in the camps. This means full vaccination coverage of children in accordance with a program and calendar of compulsory immunizations. Preventive check-ups of children are also provided as well as monitoring of health condition of children, check-ups for pregnant women, regular referral to hospital for delivery, tracking of post-delivery period, check-ups which are not related to pregnancy and check-ups for the rest of the population.

Health condition of the Roma population is directly conditioned by the level of education, level of poverty and living and housing conditions. The problem is further aggravated by the above mentioned fact that many of the RAE population do not have personal identification documents. In order to overcome this problem they gained the right to use health care services as soon as they officially registered in Montenegro.

Main objectives of the health care policy for the poorest population in Montenegro are as follows:

- Reducing impact of poverty and poor education on health and health care, especially preventive health care of vulnerable groups;
- Preserving and improving healthcare and illness prevention of the Roma and other vulnerable population that is, improving the quality of health care for this population in general.

These objectives will be implemented through the following measures and activities of the Ministry of Health and the Health Insurance Fund of Montenegro:

- Organizing and conduct of detailed medical survey on the condition, problems and needs of the Roma and other vulnerable groups in the area of health and health care;
- Establishing and implementing permanent periodic measures to control the condition of future mothers and children; to provide regular health care to the disabled, elderly and helpless people;
- Personnel and technical strengthening of health centres and clinics in areas where a number of RAE and other vulnerable population lives, including an increase in the number of medical staff in health facilities, especially paediatricians, gynaecologists and internists;
- Implementing medical and educational-correctional programmes to improve reproductive health and ensure healthy offspring of the Roma and other vulnerable population;
- Implementing measures of continuous monitoring and evaluation of health care, which includes the views of beneficiaries in order to remove deficiencies;
- Organizing regular educational-correctional and informational activities and campaigns to raise awareness of the Roma and other vulnerable population about the importance of health care; these activities include informing the Roma population about the rights and duties of the state in the domain of health care.

57. With specific reference to infant mortality, what measure are you taking in the field of reproductive health care and infant health care to decrease the infant mortality rate (7.4 per live births in 2007)?

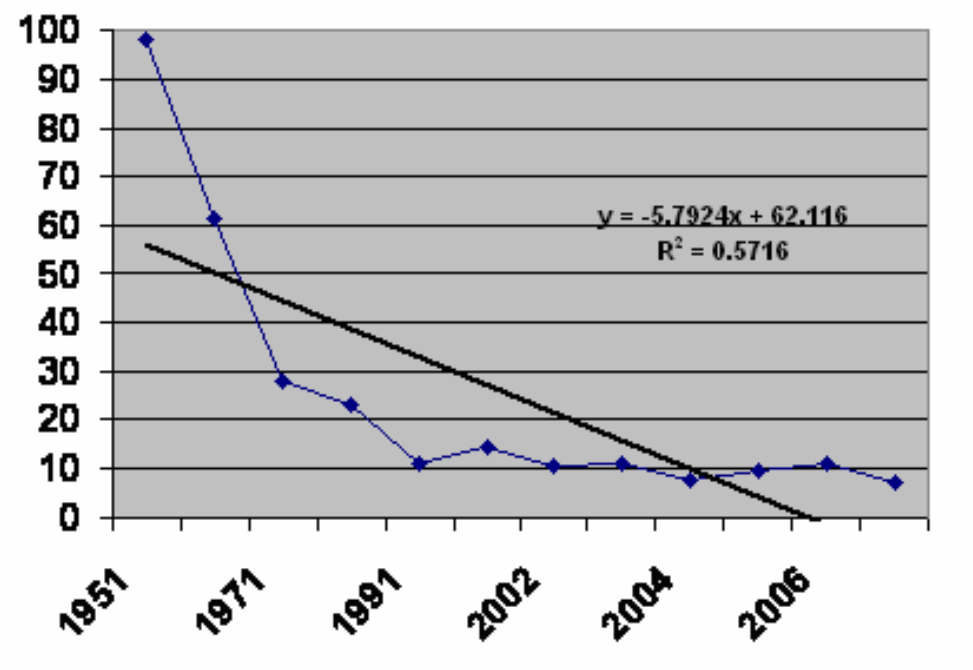
Reducing the infant mortality rate is one of the goals of the Strategy for Preservation and Improvement of Reproductive Health, which was adopted in Montenegro in 2005. Measures that are undertaken in order to achieve this goal are related to the so-called "safe motherhood" area and they include the following:

- Increase in the percentage of pregnant women who have regular gynaecological check-ups during pregnancy (in a new system of primary medical care, the chosen gynaecologist provides health care to pregnant women through the mandatory package of services that includes mandatory preventive examination in the first trimester and four control check-ups of pregnant women and three ultrasound examinations; for high-risk pregnancies the number of examinations is determined by the chosen gynaecologist).
- Pregnant women start going to regular examinations as early as possible. The first examination is done in the first trimester of pregnancy - up to 12 weeks of gestation. - Timely detection of high-risk pregnancies and their referral to secondary level health care.
- Increase in the percent of deliveries in presence of health professionals, that is, reduction of the number of deliveries out of maternity wards.
- Equal access to health care is provided to women especially in primary health care; pregnant women can have preventive examinations in all health centres as well as ultrasound examinations.
- Courses for pregnant women are already organized within the Counsel for Reproductive Health which is established in all health centres. The Counselling is employing full time nurses. This programme is financed by the Health Care Fund, Public Health Institute and the Ministry of Health. During these courses, a team consisting of gynaecologists, psychologists and dentists, informs pregnant women about the importance of regular control, about the impact of unhealthy habits and behaviour on the course and outcome of pregnancy, about proper nutrition during pregnancy, the importance of breastfeeding, etc.
- Promotion of the importance of breastfeeding - breastfeeding has been intensively promoted; this campaign is also run by UNICEF and makes an integral part of its present activities; the idea is to have a higher percentage of babies who are breastfed until they turn 6 months; this project also includes implementation of "baby friendly" method of work in all paediatrician wards.

- Prenatal health care has been additionally improved through the measures of detection of disorders in the developing foetus, particularly those conditioned by genetic factors. For that reasons the Prenatal Diagnosis Committee has been established, which in cooperation with genetic counselling of the Clinical Centre of Montenegro helps to routine referral of all pregnant women older 35 and younger than 18 to the Council for Prenatal Diagnostics which approves and runs invasive diagnostics - cordocentesis or amniocentesis conducted in order to detect genetic disorders that can later affect the infant mortality.
- A special measure that in now often practiced is expert ultrasound examination of pregnant women. It is usually done in 20th to 23rd week of gestation and detects disorders in the developing foetus.
- Early detection of pathological conditions in pregnancy is a measure that existed before. However, special attention and continuous screening have been focused on some pathological conditions such as diabetes mellitus, hypertensive syndrome in pregnancy, Rh-iso-immunization.
- Another special measure is prevention of early childbirth, which is the major cause of infant mortality. In that sense, preventive examinations are conducted, which include taking of microbiological swab, compulsory treatment of vaginal infections, and bacterial vaginosis in pregnant women.
- Measures of postpartum care through obligatory examination of women 6 weeks after delivery. Detection and adequate treatment of complications in puerperium.

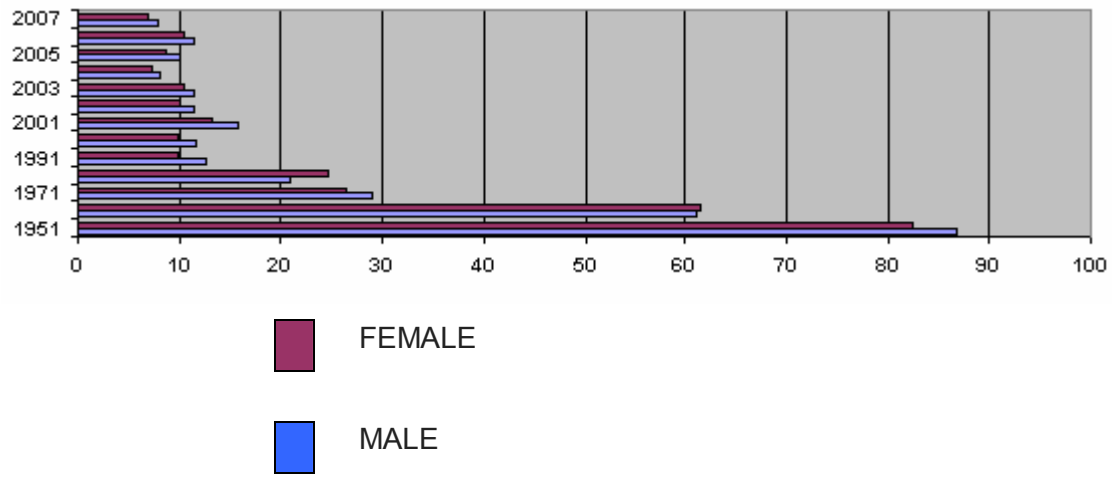
The infant mortality rate significantly changed in the above mentioned period, and the lowest rate recorded was in 2007 - 7.4 per thousand. In general, tendency of a significant fall is apparent from 1951 with critical periods in 2001, 2005 and 2006.

TRENDS IN INFANT MORTALITY RATE IN MONTENEGRO FROM 1951 TO 2007



If we look at the structure of infants who died, it can be noticed that in almos all the analyzed years, there were more boys than girls who died (except in 1961 and 1981). Trends of infant mortality rates by sex are shown in the following chart.

VALUE RATES OF INFANT DEATH BY SEX FROM 1951 TO 2005



The largest number of children dies in perinatal period, which can be seen in the following table.

Infant mortality rates in perinatal, neonatal and post neonatal age

	2000	2001	2002	2003	2004	2005	2006	2007
Perinatal mortality	10.0	13.2	10.8	10.1	9.3	9.1	9.0	6.7
Neonatal mortality	7.5	11.2	8.2	7.8	6.1	7.4	8.2	6.1
Post neonatal mortality	3.5	4.5	2.8	3.2	1.7	2.2	2.8	1.6

Structure of the causes of infant death by disease groups in Montenegro shows that some specific conditions were created in the perinatal period; in the first place in rank, among the first are congenital anomalies, but in recent years more frequent are diseases of the circulatory system and respiratory system, are the symptoms, pathological signs and clinical and laboratory findings also appear and indicate a problem of recording the causes of death.

Major groups of diseases as the cause of death of infants in Montenegro

GROUP OF DESEASES	2006		2007	
	number	rank	number	rank
Situation in the delivery period	61	I	41	I
Diseases of the respiratory system	6	II	3	IV
Diseases of the circulatory system	5	III	2	V
Congenital malformation and chromosomal aberration	4	IV	7	II
Symptoms, signs and pathological clinical and laboratory located	3	V	4	III

58. With specific reference to alcohol abuse, control and prevention, how is the sale of alcoholic beverages regulated in your country?

Alcohol use is a risk factor for the development of mental disorders, liver cirrhosis, hypertension, stroke, certain forms of cancer, and all injuries, especially injuries in traffic, while in pregnancy it may lead to the birth of children with foetal alcohol syndrome.

As for the drinking habits of young people (aged 15) according to the study of the European School Survey on Alcohol and Other Drugs (ESPAD) conducted in Montenegro in 2008 on the population of the first grade students of secondary school, there were about 74% of students who have had at least one alcoholic drink so far. More than half of the interviewed students consumed alcoholic beverages 3 to 40 times. Students included in this Survey usually drink at home - one quarter of them. 16% of students, of which 57% boys, were drunk at least once in their lifetime while 4% of students, of which 84% boys, were drunk ten or more times.

The survey on alcohol use included the students of the first grade of secondary school in the capital of Montenegro - Podgorica. The results of the survey on alcohol consumption by young people show that the consumption of alcohol beverages is a widespread phenomenon among young people as among all other population groups, because it is an acceptable phenomenon in our society. One out of ten respondents replied that in their families alcohol drinks are never used, and the survey has shown that there is a connection between the students' alcohol consumption with the habit of using alcohol in the family. Data of this survey show that, in addition to the family, the formation of students' behaviour is undeniably influenced by their immediate surrounding. In that sense the survey examined behaviour of students in relation to their consumption of alcoholic beverages defined primarily by behaviour of their peers. Domestic production of alcohol was reported by almost half of the respondents.

Liver cirrhosis is considered to be a disease indicator for monitoring of alcoholism as a public-health related problem.

The consideration on how much the genesis and development of addiction illnesses are actually related to behavioural component has been more taken into account. Substance abuse and selection of a specific lifestyle is often associated with other problems. For these reasons, it is a general stand of professionals that young people should be oriented towards healthy lifestyles grounded on knowledge, values and critical attitude towards reality so that every young person is self-powered to make constructive decisions in life. This has been supported by introducing a subject of "Healthy Lifestyles" in all schools in Montenegro. The attitude that NON-DRINKING is a normal and the most desirable model of behaviour has been developed, which young people should accept as the most desirable standard of social behaviour.

International regulations, whose signatory is Montenegro, concerning protection of children and youth from use of alcohol, are the following*:*

Convention on the Rights of the Child. 1. The Convention was adopted at the UN General Assembly in the sitting of 20 November 1999.

The World Health Organization, as a part of the project "Health for All by the Year 2000" formulated a set of health objectives of which the 17th objective reads as follows: "By 2000, health consequences caused by consumption of alcohol, tobacco and other psychoactive substances and their production must be significantly reduced in all countries".

UN Declaration on the Protection of Children.

The Declaration specifically speaks about the protection of children from the use of narcotics, psychotropic substances and inhalants. In that sense, development and implementation of policies and preventive programme at the national level are recommended.

The Revised European Charter on Youth Participation in Local and Regional Life

European Union Directive no. 94/33

Declaration of Mental Health for Europe

EU Strategy against Alcohol Abuse

Protection of minors against alcohol abuse, according to international standards and the standards of neighbouring countries with emphasis on the situation in Montenegro

Regulations in Montenegro with regard to the protection of minors against consumption of alcohol

The *CONSTITUTION* of Montenegro guarantees special protection of children against psychological, physical, economic and any other exploitation or abuse.

The aim of the Law on Health Care (Official Gazette of the Republic of Montenegro 39/2004) is to create the conditions for special care of socially vulnerable population categories in the sense of this Law. Priority health care measures, *inter alia*, are related to health care of children and young people until the end of legally prescribed regular education. In the field of health care, the state provides, *inter alia*, funds from the budget for organizing the activities of prevention of alcoholism, smoking, drug abuse and other addiction illnesses.

The Criminal Code of Montenegro The court pronounces a mandatory medical treatment to an offender who has committed a criminal offence because of addiction to alcohol consumption and if there is a serious danger that s/he might continue committing criminal offences due to this addiction. The sanction mentioned before is carried out in a penitentiary institution or in an appropriate medical or other specialized institution and lasts for as long as there is a need for treatment, but not longer than the pronounced prison sentence.

The National Action Plan for Children (from 2004 to 2010) adopted by the Government of Montenegro in July 2003 was developed based on the UN Declaration and is a framework document for the activities, programmes and strategies that the state and civil society will accept in order to create a world fit for children until 2010. In this sense, the vision of the creator of this document was that "all the girls and boys need to be productive and active participants in all the aspects of our society". This implies an active role against diversity and exclusion in the society, as well as fighting poverty and creating opportunities that all children have the opportunity to be healthy and to fully develop their potential. The document emphasizes the commitment of Montenegro to ensure that all the children have access to effective, equal, permanent and sustainable system of primary health care, access to information, support to a healthy life style, and protection of children and their families from HIV / AIDS infection. Thus, the Action Plan envisages the improvement of activities in the areas of preventive health care, fight against the abuse of illegal substances, reproductive health and health education. Since the implementation of the Action Plan until 2010, reduction of alcoholism among youth by 20% is expected. To achieve this result the following activities are foreseen:

- Having organized implementation of health-promotional and preventive measures for the acquisition of healthy habits in the family, school and community;
- Promoting prohibition of sale of alcohol to minors and enforcement of measures, to control stores that sell alcohol, including imposing appropriate sanctions;
- Developing action plans for prevention of youth addictions.

According to the *National Programme of Prevention of Unacceptable Behaviour of Children* and Young People in Montenegro (adopted in May 2004) from 2000 in Montenegro there is a rising trend of the number of underage offenders and the number of recurrences, and one of the reasons for that is a mild upward trend in the number of young people who are psychoactive substances addicts - such as drugs and alcohol. One of the strategic goals set in this document is to improve the legal framework that applies to all forms of protection of young people, education of people about the risk factors that lead to socially unacceptable behaviour of young people on one hand and promotion of healthy lifestyles among young people, on the other hand. Adoption of this document was accompanied by the adoption of the Action Plan for its implementation (for the period 2004-2006), which envisages in order to reduce harmful effects of alcohol and other harmful substances the improvement of implementation of enacted laws that limit the use of these substances.

The National Action Plan for Children envisages the improvement of activities in the areas of preventive health care, fight against the abuse of illegal substances, reproductive health and health education. One of the strategic objectives established in this document is to improve the legal framework that applies to all forms of protection of young people, and education of people about the risk factors that lead to socially unacceptable behaviour of young people on one hand and promotion of healthy lifestyles among young people on the other hand.

The National Youth Action Plan in Montenegro was adopted by the Government of Montenegro in October 2006 and one of its strategic goals is to inform the youth about the harmful consequences of addictions, which includes raising awareness of their causes and their consequences.

59. With specific reference to non-communicable diseases, as their burden is increasing, what measures are you taking to promote a healthy lifestyle (quit smoking, promote sports, healthy nutrition, fight alcohol abuse) and prevent this type of diseases?

Part of the response to this question was given in the response to the question 54 about healthy lifestyles and screening of certain malignant neoplasm, in the chapter about smoking, diet, prevention of narcotics drug abuse and alcoholism.

In 2008 in accordance with the recommendations of WHO, the analysis was conducted on illnesses and deaths caused by major chronic non-communicable diseases. Based on that analysis the Strategy for Prevention and Control of Chronic Non-Communicable Disease by 2020 with the Action Plan for the period 2009-2013 was developed and adopted by the Government of Montenegro on 24 December 2008.

The Situation Analysis and the results of the National Research on Health Condition of the Population of Montenegro from 2008 were together with the Strategy paper presented in public debates and in electronic media.

The Action Plan for the Implementation of the Strategy for Prevention and Control of Non-Communicable Diseases envisages by 2010 allocation of earmarked funds from the budget for broadcasting of radio and TV shows dedicated to reduction of exposure to major risk factors of chronic non-communicable diseases and programmes in which attention would be paid to how to quitting smoking by choosing "healthy" food and its proper storage and preparation, corrective and relaxation gymnastics, etc.).

In accordance with the Action Plan for Implementation of the above mentioned Strategy the following counselling started working in health centres:

- for the youth (includes a number of other counselling among which HIV / AIDS counselling and the counselling for quitting tobacco smoking),

- for reproductive health
- for diabetes mellitus.

The aim of the counselling is to start integrating preventive activities aimed at reduction of risk factors for major chronic non-infectious diseases at the local level.

Within the Public Health Institute, the Counselling for Healthy Nutrition has been operating for several years now and it has achieved significant results in the treatment of people with excessive weight primarily through establishment of healthy eating habits. Also, in cooperation with agricultural sector and professional associations of food technologists, it has been planned to develop from 2010 recommendations for healthy nutrition of different population groups, and to implement additional education of food technologists in order to reduce salt, sugar, saturated fats and additives in industrially produced foods.

In many municipalities of Montenegro, in order to promote sports, the Government supported building of sports halls. One of important measures in prevention of drug abuse is a promotion of sports in Montenegro. Several non-governmental organizations are included in the process of promotion of recreational - physical activities such as NGO “Montenegrin Association for Fight against Cancer” that was running a media campaign titled *"It is never too late to start exercise"*.

As a part of the activities aimed at reducing tobacco smoking, the International Day against Tobacco Smoking (May 31) is celebrated every year. On this occasion, the media campaigns against tobacco consumption are carried out in which some NGOs take a very active role such as the Montenegrin Association for Fight against Cancer.

The Law on Data Collection in the Area of Health Care that the Parliament of Montenegro adopted in December 2008 (Official Gazette 80/2008), *inter alia*, introduced the obligation of developing registers of chronic non-communicable diseases for the following: malignant neoplasm, diabetes mellitus, acute coronary syndrome, cerebrovascular disease, psychosis. Secondary legislation will define details concerning necessary information to be collected within each of individual registers. In addition to the usual data on characteristics of patients (age, sex, place of residence) and basic characteristics of the disease itself, special attention is planned to be paid to the collection of risk factors for specific diseases in order to explain to the public through additional analysis and presentations the need for reduction of exposure to risk factors, i.e. the adoption of healthy life styles.

The Government of Montenegro in April 2009 adopted the National Programme to Fight Diabetes with the Action Plan for implementation of the activities envisaged by the Programme for the period 2009-2015. Significant projects arising from the above mentioned programme are: establishment of a register of patients with diabetes, primary prevention, successful and quality treatment, public-private partnership and others.

List of Annexes: