28 Annex - Consumer and health protection

211. THE LAW ON THE PREVENTION OF POPULATION AGAINST INFECTIVE DISEASES

THE LAW ON THE PREVENTION OF POPULATION AGAINST INFECTIVE DISEASES¹

I GENERAL PROVISIONS

Article 1

This Law shall determine infective diseases endangering the heath of the population of the Republic of Montenegro (hereinafter: infective disease), as well as the infections arising as a result of discharging health care activities (hereinafter: hospital infections); measures for their prevention and fight; competent authorities for the implementation of measures; the method of securing the funds for implementation of measures, as well as performing the supervision over the implementation of the Law.

Article 2

Infective diseases, in terms of the Law are as follows:

- 1) A 00 Cholera (Cholera);
- 2) A 01 Abdominal typhus and paratyphus (Typhus abdominals et paratyphus);
- 3) A 02 other salmonellas (Salmonelloses aliae);
- 4) A 03 Shigellosis (Shigelloses);
- 5) A 04.3 Intenstine infection caused by enterohaemorrhagic Escherichia Coli (Infectio intestinalis per Escherichiam coli enterohaemorrhagicam);
- 6) A 04.5 Campylobacterial enteritis (Enteritis campyilobacterialis);
- 7) A 04.6 Enteritis caused by versinia enterococci (Enteritis versiniosa enterocolitica);
- A 04.9 Other bacterial intestine infections (Infectiones intestinales bacteriales aliae);
- 9) A 05.0 Food poisoning by staphulococci (Intoxicatio alimentaria staphylococcica);
- 10) A 05.1 Botulism (Botulismus);
- 11) A 05.2-9Other bacterial intestine infections (Intoxicationes alimentarie bacteriales);
- 12) A 06. Amoebiasis (Amoebiasis);
- 13) A 07.1 Lambliasis (Lambliasis);
- 14) A 07.2. Criptosporidiasis (Criptosporidiasis);
- 15) A 09 Diarfhea and gastroenteritis, caused by infective disease (Diarrhoea et gastroenteritis, causa infectionis suspecta)
- 16) A 15-A 19 Tuberculosis (Tuberculosis);
- 17) A 20 Plague (Pestis);
- 18) A 21 Tularemia (Tularaemia);
- 19) A 22 Anthrax (Anthrax);

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¹ Official Gazette of the Republic of Montenegro 32/05 of 27 May 2005

- 20) A 23 Brucellosis (Brucellosis);
- 21) A 27 Leptospirosis (Leptospirosis);
- 22) A 32 Listeriosis (Listeriosis);
- 23) A 33-A 35 Tetanus (Tetanus);
- 24) A 36 Diphtheria (Diphtheria);
- 25) A 37 Whooping caugh (Pertussis);
- 26) A 38 Scarlet fever (Scarlatina);
- 27) A 39 Meningococcal infection (Infectio meningococcica);
- 28) A 40-41 Septicemia (Septicaemia);
- 29) A 48.1 Legionnaires' Disease (Legionellosis);
- 30) A 50-A 53 Syphilis (Syphillis);
- 31) A 54 Gonorrhoea (Infectio gonococcica);
- 32) A 56 Sexual Chlamydialis (Infectiones sexuales chlamydiales);
- 33) A 69.2 Lyme Disease (Morbus Lyme);
- 34) A 70 Ornitosis, psittacosis (Ornithosis, psittacosis);
- 35) A 75 Spotted typhus (Typhus exanthematosus per Rickettsiam prowazeki);
- 36) A 75.1 Brill disease (Morbus Brill);
- 37) A 78 Q fever(Q-febris);
- 38) A 80 Poliomyelitis (Poliomyelitis anterior acuta);
- 39) A 81.0 Crojcfeld- Jakob disease(CJB);
- 40) A 82 Rabies (Rabies-lyssa);
- 41) A 84 Viral encephalitis caused by tick (Encephalitis viralis ixodibus),
 - A 85 Viral encefalitis (Encephalitis viralis);
- 42) A 87 Virali meningitis (Meningitis viralis);
- 43) A 93.1 Fever sant dfly (Febris sant dfly);
- 44) A 95 Yellow fever (Febris flava);
- 45) A 96.2 Lassa haemorrhagic fever(Febris lassa);
- 46) A 98.0 Crimean-Congo Hemorrhagic Fever (Febris haemorrhagica Crim-Congo);
- 47) A 98.3 Marmburg viral disease (Morbus viralis Marmurg);
- 48) A 98.4 Ebola disease (Morbus viralis Ebola);
- 49) A 98.5 Haemorrhagic fever with renal syndrome (Febris haemorrhagica cum syndroma renali);
- 50) B 01 Chickenpox(Varicella);
- 51) B 05 Morbili (Morbilli);
- 52) B 06 Rubella (Rubella);
- 53) P 35.0 Congenitive rubella (Syndroma rubellae congenitae);
- 54) B 15 Acute viral hepatitis A (Hepatitis acuta A);
- 55) B 16 Acute viral hepatitis B (Hepatitis acuta B);

- 56) B 17.1 Acute viral hepatitis C (Hepatitis acuta C);
- 57) B 17.2 Acute viral hepatitis E (Hepatitis acuta E);
- 58) B 18 Chronic viral hepatitis B, C, (Hepatitis viralis chronica B,C);
- 59) B 19 Non-specific virusni hepatitis (Hepatitis viralis non specificata);
- 60) B 20-B 24 HIV disease (Morbus HIV);
- 61) B 26 Mumps (Parotitis);
- 62) B 27 Infective mononucleosis (Mononucleosis infectiva);
- 63) В 50-Б 54 Malaria (Malaria);
- 64) B 55 Leishmaniasis (Leishmaniasis);
- 65) B 58 Toxoplasmosis (Toxoplasmosis);
- 66) B 67 Echinococcosis (Echinococcosis);
- 67) B 75 Trichinellosis (Trichinellosis);
- 68) B 77 Ascariasis (Ascariasis);
- 69) B 80 Enterobiasis (Enterobiasis);
- 70) B 86 Scabies (Scabies);
- 71) B 96.3Disease caused by haemophilus influenzae (Haemophilus influenzae)
- 72) G 00. Bacterial meningitis (Meningitis bacterialis);
- J 02.0, J 03.0 Streptococcal pharingitis and tonsillitis (Pharingitis et tonsillitis streptococcica);
- 74) J 10 J 11 Flu (Influenza), and
- 75) J 12, J 12.9, J 13, J 14, J 15, J 84. Pneumonia (Pneumonia viralis et bacterialis).

Should there be any danger of an infective disease which was not stated in paragraph 1 of this article, and which may endanger the health of the population of the Republic of Montenegro (hereinafter: the Republic), for the prevention of population against a such disease the Government of the Republic of Montenegro (hereinafter: the Government), at the proposal of the competent government authority for health administration (hereinafter: competent government authority), may decide to apply all or certain measures prescribed by this Law, other measures for the prevention of population against infective diseases and other measures pertaining to the nature of a such disease, as well as the measures prescribed by the international health and sanitary conventions and other international deeds.

The proposal of a competent government authority from paragraph 2 of this article is made based on the opinion of Public Health Institute (hereinafter: the Institute), and it contains the name of an infective disease, the measures for its prevention and fight, the method of implementation of the regulation and necessary funds needed for the implementation of such measures.

The decision from paragraph 2 of this article shall be published in the Official Gazette of the Republic of Montenegro.

Article 3

The prevention of population against infective diseases consists of planning, programming, organization, implementation and supervision over the implementation of the measures for the prevention, fight, removal and eradication of infective diseases, as well as securing material and other funds for the prevention of population against infective diseases and it has the precedence in regard to other health care measures.

Everyone has the right for prevention against infective diseases and hospital infections, as well as an obligation to protect his/her own health and the health of others against these diseases.

Health institutions, legal entities and citizens are obliged to cooperate with competent government authorities, as well as with competent health institutions and to provide them with discharging prescribed medical examinations, taking necessary material and implementing other measures for the prevention of population against infective diseases and hospital infections prescribed by this Law.

Article 4

International obligations regarding the prevention, fight, removal and eradication of infective diseases from article 2 of this Law, are to be fulfilled in compliance with international health regulations, the programs of the World Health Organization and other international deeds.

Article 5

Terminology used in this Law shall have the following meaning:

The prevention of population against infective diseases represents an organized and overall activity with the aim to prevent and fight against infective diseases, as well as to remove and eradicate certain infective diseases.

The prevention of the outbreak of an infective disease represent a set of measures which are constantly being implemented in order to preclude the infections i.e. the infective diseases.

The fight against infective diseases entails a set of measures which have been implemented against already present infective disease, in order to cure the infected persons and to reduce its frequency rate.

The removal of a certain infective disease is a condition when there are no more outbreaks of indigenous cases of infection in certain territory, although the infective agent is still present in the given territory, due to which it is necessary to further execute the measures of prevention.

The eradication of certain infective disease is a condition when in a certain territory there are no more outbreaks of indigenous cases of infection, because the infective agent has been completely destroyed and due to which constant measures of prevention and fight are no longer needed.

The epidemic of infective disease means the increase of infection frequency rate, complications or death against an infective disease which is higher than the usual for certain population group and certain time period.

The infected area is an area in which there are one or more reservoirs i.e. the sources of infective agent of the disease and the conditions for transmitting the disease.

Endangered area is an area in which the disease can be spread out from the infected area and in which the conditions for spreading of such a disease exist.

Zoonosis is an infective disease which can be transmitted from animals (vertebrates) to humans under certain conditions.

Health care institution is a legal entity which in compliance with the separate law has been established for discharging health care activities.

Health care education represents a process by which certain individuals and group of people learn to behave in a way directed towards the improvement and sustainability of health, as well as to the prevention and fight against infective diseases.

Immunoprophylaxis means a measure for the prevention of sensitive individuals against infective diseases by applying vaccines or specific immunoglobins.

Haemoprophylaxis denotes a measure for the prevention of senstitive individuals against infective diseases by applying chemicals, antibiotics included.

Health care supervision represents a measure by which the persons, who are coming from the areas infected with cholera, plague , haemorrhagic fever (except for haemorrhagic fever with renal syndrome) and other infective diseases established by a competent government authority, are ordered to report daily to a appropriate health care institution for medical checkups , without limitations to freedom of movement.

Quarantine corresponds to a measure by which freedom of movement is restricted and compulsory medical checkups of healthy persons, who were in contact with infected persons or are doubted to be infected with quarantined infection are determined.

Quarantine diseases are diseases whose infective agents are airborne or contact transmitted and contain a high mortality rate, i.e.which represent extreme danger for the health of the population of the Republic. In the case of the outbreak or even in the shadow of its doubt, the quarantine measures and strict isolation (plague, hemorrhagic fever except for hemorrhagic fever with kidney syndrome, as well as other infective disease determined by a competent government authority) are enforced.

Isolation is a method of isolating infected persons i.e. animals during the infection period in such a way and under such conditions in order to prevent and restrict direct, i.e. indirect transmitting of the infective disease agent from infected person or animal to a sensitive person.

Strict isolation represents one type of isolation applied to persons i.e. animals, who are infected or are doubted to be infected or they suffer from an infective agent of the infective disease causing high mortality rate in humans and is easily airborne or contact transmitted.

Epidemiological supervision denotes a constant or extraordinary collecting, analyzing and distributing the epidemiological data in order to monitor infective diseases trends and to undertake the prevention and fight measures against infective diseases and epidemics of such diseases.

Epidemiological testing represents a procedure of field i.e. administrative collecting and analyzing the epidemiological data on reservoir, source of infection and transmitting method of infective disease agent, as well as data on characteristics of infective disease agent and exposed population group with the aim to undertake appropriate prevention and fight measures against such disease.

Disinfection is a procedure to reduce the number or destroy infective disease agent present onto the surface of human body, clothes and environment by using chemicals or by physical means.

Disinfestation is also a procedure of disinfesting or removing undesirable arthropoda present in humans, clothes and in the environment surrounding humans or domestic animals by using chemicals or physical means.

Deratization is a procedure of destroying small animals, especially rodents, present in the environment surrounding humans or domestic animals by using chemicals or physical means.

Institutions under health care supervision are the structures used for the production and sale of medicaments, medical supplies, provisions (food, drinking water, water used for food preparing (and cosmetic supplies; structures where children are educated and accommodated, as wll as elders; structures where patients are diagnosed, treated and care discharged as well as traditional and alternative treatments, care and cosmetic body and face treatments and non-medical interventions where skin integrity may be damaged are rendered.

Closed and open public institutions denote areas earmarked for collective accommodation of people including the areas where educational, community restaurant arrangements are made, cultural, entertainment and other events are held, performances and competition and other gatherings are organized.

II COMPETENCIES

Article 6

In providing and implementing the prevention of population against infective diseases the following institutions shall participate: local government bodies and state government bodies; health care institutions and other entities discharging health care activities in compliance with the separate law; health care workers and associates, organizations of health insurance; educational, sports and other institutions and organizations rendering services; legal entities and entrepreneurs; humanitarian, religious and other organizations, associations and citizens.

Article 7

Competent government authority monitors the infective diseases trends in the territory of the Republic, proclaims epidemics of infective diseases of a greater epidemiological importance, proclaims infected, i.e. disease-stricken area, orders the measures which must be implemented in such case.

A competent government authority shall pass a decision from the paragraph 1 of this article at the proposal of the Institute.

Institute's proposal must contain the name of an infective disease, the markings of infected, i.e., disease-stricken area, the measures which must be implemented, the method of their implementation and the funds necessary for implementing such measures.

Article 8

The Institute shall monitor and examines the infective disease trends in compliance with the Law, international regulations and programs of World Health Organization, and inform on this a competent government authority, other competent authorities and other entities in the country and abroad with the aim of early warning and the exchange of information.

Based on the information from paragraph 1 of this Article, and in compliance with the Health Development Strategy of the Republic of Montenegro, the Institute, in cooperation with Clinical Center of Montenegro and special hospital for lung diseases, has been preparing programs for prevention, fight, removal and eradication of infective diseases, as well with the competent government authority for veterinary care in the cases of zoonosis outbreak.

A competent government authority shall pass the programs from paragraph 2 of this article for each year or for a longer period of time.

The programs of measures from the paragraph 2 of this article must include their implementers, necessary period for implementation, material and other funds necessary for implementation.

Article 9

Health care institutions and other entities discharging health care activity, must keep prescribed records, register and data base on infective diseases which are connected into a unique information system in compliance with the Law.

The entities from paragraph 1 of this article shall immediately inform on the outbreakt of an infective disease, i.e. hospital infection, health care unit organized in their territory.

A health care unit, through its departments and especially through sanitary-epidemiology department, shall perform an epidemiological supervision and directly implement the measures of prevention, fight, removal and eradication of infective diseases, in the territory of local government unit, where it was organized.

Health care unit shall inform on infective diseases trends the Institute, competent local government units and other entities with the aim of early warning and information exchange.

Article 10

The prevention of population against zoonosis is organized and implemented in cooperation with

local government unit competent for veterinary care.

Health care institutions, competent authorities and organizations from the veterinary area shall be

responsible to mutually exchange information on the outbreak and trends of infective diseases from the

paragraph 1 of this article, and to comply with the organization and implementation of epidemiological i.e.

epizootic, sanitary and other measures for their prevention, fight, removal and eradication.

The form and method of cooperation from the paragraph 1 of this article are prescribed by a competent government authority and government body competent for veterinary care.

III MEASURES FOR PREVENTION AND FIGHT AGAINST INFECTIVE DISEASES

Article 11

The prevention of population against infective diseases is discharged by implementing general, special and other measures in compliance with this Law.

1. GENERAL MEASURES

Article 12

General measures shall include:

- 1) Educating the population on health care;
- 2) Securing sanitary-technical conditions in structures under health care supervision and other structures where public activities have been performed and in public places;
- 3) Disposing of human and animal secretion corpses, body parts and tissues, waste water and other waste matter in a way and under the conditions which do not endanger the health of population, and
- 4) Implementing the measures of preventive disinfection, disinfestations and deratization (hereinafter: DDD), in populated areas, public areas, buildings, public transportation system, structures under the health care supervision in their close vicinity.
- 5) Local government bodies, government bodies, health care institutions, corporate entities, entrepreneurs, other legal entities and citizens are responsible for organizing i.e. implementation of the measures from the paragraph 1 of this article in compliance with this and special laws.

Health care institutions, legal entities and entrepreneurs meeting the requirements in regard to personnel, equipment and means should perform preventive DDD measures from the paragraph 1, subsection 4 of this article.

Competent government authority shall prescribe closer requirements in regard to the personnel, equipment and means, which the entities need to meet from paragraph 3 of this article and article 13, paragraph 3 of this Law.

Competent government authority shall determine which health care institutions, legal entitites and entrepreneurs meet the requirements for execution of DDD measures.

The deed from paragraph 5 of this Article is published in the Official Gazette of the Republic of Montenegro.

Health care institutions, legal entities and entrepreneurs from the paragraph 5 of this article are obliged to inform the competent government authority on any changes in the conditions for the execution of DDD measures to as prescribed by this law.

2. SPECIAL MEASURES

Article 13

Special measures for the prevention and fight against infective diseases shall include:

- 1) Immunoprophylaxis and haemioprophylaxis;
- 2) Medical checkups of certain population categories with counseling;
- 3) Health care supervision and quarantine;
- 4) Laboratory testing in order to identify infective disease agents and epidemic agents;
- 5) Early detection and reporting of infective diseases and epidemiological supervision;
- 7) Epidemiological testing;
- 8) Health care education of the infected, members of their families and other persons who are at a risk to get a disease, and
- 9) Disinfection, disinfestation and deratization as per epidemiological indications.

Health care institutions and other entities performing health care activities organize and implement the measures determined in the paragraph 1 subsection from 1 to 8 of this article in compliance with the Law.

Health care institutions, commercial entities, entrepreneurs and other entities meeting the requirements regarding personnel, equipment and means shall execute the measures in the paragraph 1 subsection 9 of this article.

Article 14

Special measures from article 13 of the Law are determined and executed in compliance with

special programs and professional-methodological instructions.

Programs and professional-methodological instructions from the paragraph 1 of this article are adopted by a competent government authority.

Article 15

The funds for the implementation of special measures for the prevention and fight against infective diseases established in the article 13 paragraph 1 of the Law except for the medical checkups of the certain population categories with counseling and for vaccination of persons in international traffic are secured in compliance with the laws competent in the area of health care prevention and health care insurance.

1) Immunoprophylaxis and haemoprophylaxis

Article 16

The immunoprophylaxis is discharged with vaccination (hereinafter: the vaccination) and with specific immunoglobins.

The vaccination is compulsory against the following diseases:

- 1) Tuberculosis, diphtheria, tetanus, pertussis, poliomyelitis, varicella, epidemic pumps, , skarlet fever, viral hepatitis "B" and haemophilus influenza type "B", for all persons of certain age;
- 2) Hepatitis "B", tetanus, rabies, influenza, haemophilus influenza type "B", streptococcal pneumonia, meningococcal diseases, abdominal typhus, yellow fever, tick-borne encephalitis and hepatitis "A" for all person for whom it is determined to have clinical and epidemiological reasons, and
- 3) Other infective diseases for which an efficient vaccine exists and which is incorporated in a Program for compulsory immunization by a competent government authority.

The prevention with specific immunoglobulins is compulsory according to epidemiological indications for persons who were exposed to the infective agents of tetanus, rabies, hepatitis "B" and other infective diseases, for which specific immunoglobulins exist and which is to be incorporated in a Program for compulsory immunization by a competent government authority

Article 17

Haemoprophylaxis is discharged in a prescribed way for all persons who have been disposed to the infection of tuberculosis, meningococcal meningitis, malaria, and according to epidemiological indications also for the persons who have been exposed to other infective diseases.

Article 18

The immunoprophylaxis and haemoprophylaxis are discharged by health care workers and institutions in compliance with the Law.

A competent government authority, at the proposal of the Institute, shall prescribe more detailed requirements in regard to the organization and method of implementation of immunoprophylaxis and haemoprophylaxis, and shall also adopt the annual Program for compulsory immunization in the territory of the Republic.

2) Medical checkup of certain population categories with counseling

Article 19

The following categories of population are subject to a compulsory medical checkup with counseling in a prescribed way:

- 1) Pregnant women;
- 2) The donors of blood, semen, egg-cells, tissues and parts of human bodies;
- 3) Persons treated with haemodialysis;
- 4) Employed in the production and sale of medicaments, medical supplies, provisions and cosmetics;
- 5) Employed in educational and pedagogic and other institutions for children and youth and in the Institutions for collective accommodations of elderly persons;
- 6) Employed in discharging medical checkups, treatment, care of patients, as well as sanitary maintenance;
- 7) Employed in discharging the following services: traditional and alternative treatment methods, face and body care and beautifying and non-medical interventions which may damage skin integrity;

- 8) Persons still at school but discharging their compulsory practice prescribed in subsection 4 to 7, of this paragraph;
- 9) Persons entering the Republic from the countries reporting cholera, plague, viral hemorrhagic fevers (except for hemorrhagic fever with renal syndrome) or malaria, and according to the epidemiological indications the persons who may import other infective diseases determined by a competent government authority, and
- 10) Persons secreting the infective agents of abdominal typhoid, paratyphoid, other salmonellas, shigelloses, yersiniosa and campyilobacrerialis.

Health care institutions shall discharge all compulsory medical checkups from paragraph 1 of this article according to the Law.

Medical checkups of persons from the paragraph 1 subsection4 to 8 of this Article shall commence before discharging one's duty, during the discharge as well as at doctor' discretion.

A competent government authority shall prescribe the type, amount, terms and methods of discharging compulsory medical checkups from paragraph 3 of this article, as well as all necessary medical documentation supporting the executed checkups.

3) Health care supervision and quarantine

Article 20

Persons arriving from the countries reporting cholera, plague, yellow fever, viral haemorrhagic fever (except for haemorrhagic fever with renal syndrome) and malaria are to be placed under health care supervision.

A competent government authority, at the proposal of the Institute, may prescribe a supervisory measure also for persons coming from the country where there are also other infective diseases if some of these diseases may put in danger the population of the Republic.

The persons pursuant to paragraphs 1 and 2 of this Article are put under health care supervision on border crossings, i.e. at the place of entrance in the country and are handed in a document stating that they are placed under health care supervision.

A copy of such document is submitted to a health care unit competent for the territory of a person under the supervision within 24 hours.

A health care unit shall report to a competent government authority about a person not abiding by the document, i.e. who do not report to the health care institution for monitoring his/her medical condition.

More detailed requirements regarding the method of organization and implementation of health care supervision from the paragraph 1 of this article shall be prescribed by a competent government authority.

Article 21

Quarantine is organized according to the persons who were or are doubted to have been in contact with the infected or with persons who are suspected to have a quarantine disease.

The period of quarantine duration from paragraph 1 of this article is determined during the duration time of the maximum incubation of a certain disease for which it is quarantined.

A competent government authority, at the proposal of the Institute, shall determine the organization and implementation of quarantine from paragraph 1 of this article.

The person, who is subject to the quarantine measure in compliance with this law, is obliged to abide by the order of a competent government authority under the threat of forceful quarantine restriction.

Quarantine measure is implemented in the structures which meet the requirements for the implementation of such measure prescribed by a competent government authority.

The structures determined under the paragraph 5 of this article are identified by the Government, at the proposal of a competent government authority, prescribing more detailed requirements for the organization and implementation of quarantine.

Commercial entities, entrepreneurs and other legal entities, whose structures are determined for quarantine needs from the paragraph 6 of this article, are obliged to temporary concede their structures for use in order to prevent and fight against infective disease, i.e. the epidemic of such disease.

Money compensation in the amount of real expenses pertains to the owner of the structure which is to be secured from the budget of the Republic for the use of the structure from the paragraph 7 of this article.

The procedure for compensation from paragraph 8 of this article shall be instituted by the owner of the structure, by the request.

The request and necessary documentation are submitted to a competent government authority within 30 days from the day the use of structure for quarantine is terminated.

A competent government authority, at the proposal of the Commission, shall determine the right for compensation of the owner.

The commission from paragraph 11 of this article is formed by a competent government authority.

4) Laboratory testing for identifying infective diseases agents and the agents of epidemics

Article 22

In order to identify the infective disease agents i.e. the cause of epidemic of infective disease (hereinafter: the laboratory testing), laboratory testing shall be done in all cases of outbreak or if there is a doubt of an infective disease, in which the indentification of the infective agent of the disease is necessary in order to make a diagnosis, as well as in cases of outbreak or danger of epidemic.

Laboratory testing from paragraph 1 of this article is done by health care institutions which meet the requirements for performing laboratory testing in the area of microbiology, in compliance with the Law.

Evaluation of laboratory testing from paragraph 2 of this article is done by health care institutions accredited in the area of microbiology in compliance with the Law.

Competent government authorities shall prescribe detailed requirements regarding the procedure of data management on laboratory testing, method of reporting and period of time for issuing information on the given results.

5) Early detection and reporting on infective disease and epidemiological supervision

Article 23

With the aim to execute epidemiological supervision in compliance with the Law, the following items are subject to compulsory reporting:

- 1) Illness i.e. death by infective disease from article 2 of this Law;
- 2) Laboratory identified agent of an infective disease;
- 3) Death by infective 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 infective disease of known or unknown infective agent;
- 6) Hospital infection;
- 7) The secretion of agents of abdominal typhus, paratyphus, other salmonella infections,
- shigelloses, yersiniosa and campyilobacrerialis as well as carriers of antigens of viral hepatitis "B", antibodies to viral hepatitis "C" and AIDS and carriers of parasites-malaria infective agents;
- 8) Every bite i.e. contact with rabid or rabidly 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.

Health care units and other entities which are discharging health care activities shall report from paragraph 1 of this article.

Health care units which have organized sanitary-epidemiological prevention and the Institute shall discharge epidemiological supervision from paragraph 1 of this article.

More detailed requirements in regard to the reporting of infective diseases, hospital infections, conditions and death by these diseases, as well as the execution of epidemiological supervision from paragraph 1 of this article are prescribed by a competent government authority.

6) Transportation, isolation and treatment of the infected

Article 24

A persons ill with an infective disease is transported under the same conditions and method by which further spreading of the disease is prevented.

The infected person or a person of whom it is suspected to be ill with cholera, quarantine diseases and of other diseases of an unknown infective agent shall be transported by ambulance.

Health care institution i.e. medical doctor, who determines an infective disease with a certain person or raises a doubt of an infective disease prescribed by paragraph 2 of this article, shall be responsible to secure the ambulance for the transport for hospital treatment of such persons infected with the disease.

Article 25

A person ill or a person of whom it is suspected to be ill with infective diseases must be treated in any case when non-treatment would cause and endanger the heath of other people or cause spreading of the disease.

It is compulsory to put a person of whom it is suspected to suffer from a quarantine disease in a strict isolation and treatment in the health care institutions which meet all the requirements regarding the personnel, space and medical-technical equipment for hospital treatment of the infected with a quarantine disease.

The measure of strict isolation from paragraph 2 of this article is implemented and it will last until the danger of its spreading is still present.

Except for the persons determined in paragraph 2 of this article, the persons, who are suspected to be ill with a disease of unknown etiology which has high mortality rate and which is air-borne and contact transmitted, shall be isolated and treated in health care institutions for hospital treatment of persons ill with a quarantine disease.

The measure of strict isolation from paragraph 4 of this article is implemented and it will last until the diagnosis is made which does not demand a strict isolation.

The persons ill with cholera, yellow fever, abdominal typhoid, anthrax (except for a skin type), tetanus, diphtheria, meningococcal disease, bacterial meningitis, polio, rabies, tick-borne encephalitis, viral haemorrhagic fever with renal syndrome, brucellosis, tularaemia, leptospirosis, malaria, leishmaniasis, (except for a skin type) AIDS illnesses are treated in health care institutions which meet the requirements regarding the personnel, space and medical-technical equipment for hospital treatment of infected persons.

The persons ill with lung form tuberculosis are treated in health care institution for hospital treatment of the persons ill with lung tuberculosis while there is still the danger of its spreading.

The persons who are ill with a disease which is not stated in paragraphs 2, 3, 4, 5 and 6 of this article are treated according to the clinical indications in other health care institution or in a patient's home if there are suitable conditions and no danger for spreading of the disease.

The medical doctor, who determines the disease stated in paragraph 2 and 6 of this article or raises a doubt of the disease stated in paragraph 4 of this article, shall immediately send such person/persons to a health care institution to be isolated and treated of such diseases in compliance with the Law.

A competent government authority shall prescribe more detailed requirements regarding the personnel, space, medical-technical and safety equipment for health care institutions discharging hospital treatment of infected with quarantine and other diseases.

Article 26

In case of epidemic outbreak of a disease to a large extent, the persons who are ill with such a disease may be treated in all structures where the requirements for treatment, i.e. isolation and treatment of the infected for such disease are provided.

The structures from paragraph 1 of this article are prescribed by a competent government authority.

Article 27

Health care institution, in which a foreigner is isolated or admitted and who is ill with the disease from article 25, paragraph 2, 4, 6, 7 and 8 of this Law and in case of disease outbreak to a large extent, is obliged to immediately inform a competent government authority and to a competent police authority.

Article 28

Health care institutions which within their competencies discharge epidemiological supervision over the infected diseases and treat the infected with the diseases shall provide reserves of medications and medical supplies in case of a disease outbreak to a larger extent.

7) Epidemiological testing

Article 29

Epidemiological testing is performed with the aim to identify the infective agent, reservoirs, sources, methods of transmitting infective diseases, as well as their prevention, detection and combat.

The epidemiological testing from paragraph 1 of this article is discharged in health care units containing sanitary-epidemiological prevention and it shall be executed obligatory in the following cases of:

1. Epidemic outbreak of diseases;

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- 2. A doubt of the cases of cholera, quarantine disease, acute flaccid paralysis, diphtheria, varicella and botulism:
- 3. Outbreak of diseases from article 2 of this Law, and
- **4.** Outbreak of disease of an unknown etiology which may endanger the population of the Republic.

8) Health education of the infected, members of their families and other persons who are at a risk of a disease

Article 30

Health care institutions where the infected are directly treated against a disease and health care units where sanitary-epidemiological prevention is organized shall discharge health education to the infected, members of their families and to other persons who are at a risk of such a disease.

9) Disinfection, disinfestations and deratization according to epidemiological indications

Article 31

When there is a threat of transmitting such a disease, it is compulsory to disinfect against secretions, personal and other objects, as well as to disinfect the vehicles where that person stayed at.

Article 32

It is compulsory to do disinfection of rooms, clothes, personal belongings, home and business premises, as well as vehicles in cases of infective disease transmitted by arthropoda.

Article 33

It is compulsory to do deratization of inhabited places, ports, airports, ships and other public transportation means, as well as warehouses and commercial premises in case of an outbreak of a disease transmitted by rodents.

3. OTHER MEASURES FOR THE PREVENTION OF POPULATION AGAINST INFECTIVE DISEASES

Article 34

In order to prevent bringing in the country, transmitting and fighting against infective diseases, a competent government authority may order other measures for the prevention of population against infective diseases, such as:

- 1) Determine travel arranements for persons traveling to contaminated areas or coming from such:
- 2) Restrict i.e. prohibit migration of population into contaminated or endangered area;
- 3) Prohibit gathering of population in closed and public places, and
- 4) Restrict or prohibit the trade of certain goods and products.

The measures from paragraph 1 of this article may last until there is a danger of bringing in the disease in the country the longest, i.e. transmitting the disease for which the measures was implemented.

The deed from paragraph 1 of this article is published in the Official Gazette of the Republic of Montenegro.

Article 35

Transport and funeral arrangements, as well as excavations and burial of the remains of the diseased are executed in a way and under the conditions which prevent the transmission of the disease.

Transport and burial, as well as excavation, translocation and burial of the remains of the deceased from a disease in the country, translocation of the deceased from abroad and from the country to abroad shall be done upon the approval of a competent government authority.

The method and conditions applied to the transport and burial, as well as excavation, translocation and burial of the deceased from paragraph 1 and 2 of this article are to be prescribed in a detailed way by a competent government authority.

IV PREVENTION AND FIGHT AGAINST HOSPITAL INFECTIONS

Article 36

Health care institutions and other entities discharging health care activities shall secure sanitary-technical conditions and implement appropriate professional, organizational and other prescribed measures in order to prevent emerging, early detection and fight against hospital infections.

With the aim to implement measures from paragraph 1 of this article, health care institutions and other entities discharging health care activities shall adopt the program for monitoring, prevention and fight against hospital infections.

The Program from paragraph 2 of this article must include the following, at least:

- 1) Worked out method of epidemiological monitoring of hospital infections;
- 2) Doctrine of performing all diagnostic, therapeutic, nursing and other procedures discharging at
 - health care institution;
- 3) Doctrine of sterilization, disinfection, cleaning and removing of medical and other waste;
- 4) Doctrine of treating the sick, health care workers and associates who are ill with infective
 - diseases or carriers of infective agents of diseases, and
- 5) Rules and guidelines for the prevention of the employed against infective diseases and hospital infections.

V SUPERVISION

Article 37

A competent government authority shall permorm the supervision over the implementation of this Law and other regulations adopted pursuant to this Law.

Health inspectors shall discharge the activities of inspection supervision from the competencies of a competent government authority from paragraph 1 of this article in compliance with the Law.

Article 38

Beside the administrative measures and actions prescribed by the Law which regulate inspection supervision, a health inspector shall be responsible for undertaking the following administrative measures and actions when he/she establishes that there was a breach of the law or other regulation:

- 1) Persons coming from the countries with cholera, plague, yellow fever, malaria and viral haemorrhagic fever (except for haemorrhagic fever with renal syndrome) should be placed under health supervision on border crossing, i.e., the place of entrance in the country, and
- 2) Prohibit border crossing in both directions when certain disease emerged or was spread in bordering area of the Republic or on certain border crossing of a neighboring country.

VI PENAL PROVISION

Article 39

Health care institution or other entity shall be fined from thirty to sixty times the amount of a minimal wage in the Republic, if

- 1) It does not fulfill the international obligations regarding prevention, fight against, removal and eradication of infective diseases (Article 4);
- 2) The Institute does not monitor, study infective diseases trends in compliance with the Law, international regulations and with World Health Organization Program and if it does not prepare programs for prevention, fight, removal and eradication of infective diseases (article 8 paragraph 1 and 2).
- 3) It acts opposite to article 9 of this Law;
- 4) It acts opposite to article 10 paragraph 2 of this Law;
- 5) It discharges the activity before a competent government authority establishes whether all requirement for the execution of DDD measures are met (article 12 paragraph 5);
- 6) It does not report6 to a competent government authority on the change of conditions of DDD measures (article 12 paragraph 7);
- 7) It acts opposite to article 23 of this Law;
- 8) It does not secure an ambulance for the transport of a person suffering from cholera, quarantine disease and of other disease of unknown agent (article 24);
- 9) It does not secure strict isolation and treatment of persons suffering from or are suspected to suffer from a quarantine disease (article 25 paragraph 2);
- 10) It does not secure strict isolation and treatment of person who is suspected to suffer from an infective disease of unknown etiology containing a high mortality rate and which is airborne and contact transmitted (article 25 paragraphs 2);
- 11) It secures the treatment of persons from article 25 paragraph 6 and 7 of this Law in health care institutions for hospital treatment of persons suffering from infective diseases;
- 12) It does not treat persons suffering from infective diseases from article 25 paragraph 8 of this Law, and
- 13) It acts opposite to article 27 of this Law.A responsible person shall be fined the amount from five to ten times of the minimum wage in the Republic for minor offences from paragraph 1 of this article.

Article 40

Health care institution or other entities discharging health care activities in the Republic shall be fined from seventy to hundred times of the amount of a minimal wage in the Republic for minor offence, if:

1) It does not implement other measures imposed by the very nature of the disease (article 2 paragraph 2);

- 2) It does not cooperate with competent government authority, as well as with competent health institutions and if it does not provide with prescribed medical checkups, taking necessary materials and implementation of other measures for the prevention of population against infective diseases and hospital infections (article 3 paragraph 3);
- 3) The Institute does not submit to a competent government authority a proposal from article 7 paragraph 3 of this Law in case of epidemic of infective disease of a greater epidemiological importance;
- 4) It does not discharge immunoprophylaxis and hemoprophylaxis in a way prescribed by the Law (articles 16 to 18);
- 5) It does not discharge compulsory medical checkups for the persons from article 19 of this Law;
- 6) It hires persons or keeps at work or for obligatory practice and without medical checkups from article 19 paragraph 1 subsections 4,6,7 and 8 and paragraph 2 of this Law;
- 7) It acts opposite to article 20 paragraph 5 of this Law;
- 8) It acts opposite to article 22 of this Law;
- 9) It acts opposite to article28 of this Law;
- 10) It does not do epidemiological testing in cases prescribed by the Law (article 29);
- 11) It acts opposite to other ordered measures for the protection of population against the infectious diseases;
- 12) The transport and burial, as well as the excavation and translocation of the remains of the deceased are not done in a mode and under the conditions which prevent spreading of infective disease (article 35), and
- 13) It does not implement appropriate professional, organizational and other prescribed measures for the prevention of emerging, early detection and fight, hospital infections and if it does not adopt programs for monitoring, prevention and fighting of the same (article 36).

A responsible person shall be fined the amount from ten to twenty times of the minimum wage in the Republic for minor offences from paragraph 1 of this article.

Article 41

A commercial entity, entrepreneur or other legal entity shall be fined the amount of fifty to two hundred times of the minimum wage in the Republic, if:

- 1) It does not cooperate with competent health institutions and does not provide the discharge of prescribed checkups, necessary materials and the implementation of other measures for the prevention against the disease and hospital infections (article 3 paragraph 3);
- 2) It does not provide health care unit to execute epidemiological supervision and directly implement measures of prevention, fight, removal and eradication against infective diseases (article 9, paragraph3);
- 3) It discharges activities before a competent government authority determines that all requirements for DDD measures are met (article 12 paragraph 5);
- 4) It informs a competent government authority on the change of the requirements for execution of DDD measures (article 12 paragraph 7);
- 5) it hires or keeps at work or at practice the persons from article 19 paragraph 1 subsections 4,5,7 and 8 an paragraph 2 of this Law;
- 6) It does not concede its structure for temporary use in order to prevent and fight against infective diseases, i.e. epidemic of certain infective disease (article 21 paragraph 7);

- 7) It does not cooperate and provide with epidemiological testing with the aim to identify the infective agent, reservoirs, sources, mode of spreading the disease, as well as to prevent, identify and fight against the epidemic of infective diseases (article 29 paragraph 1) and
- 8) It does not perform transport and burial, as well as excavation, translocation and burial of the remains of the deceased, in a way and under the conditions enabling the spreading of the infective diseases (article 35)

A responsible person shall be fined the amount from ten to twenty times of the minimum wage in the Republic for minor offences from paragraph 1 of this article.

A physical person shall also be fined the amount from five to fifteen times of the minimum wage in the Republic for minor offences from paragraph 1 subsection 1, 2 and 8 of this article.

Article 42

A physical person, as well as parent or guardian of a minor i.e. of a person disabled for work who made a minor offence, if such an offence was a result of their failure of being a guardian to a minor i.e. to a person disabled for work shall also be fined the amount from two to ten times of the minimum wage in the Republic for minor offences, if:

- 1) He/she refuses immunoprophylaxis and haemoprophylaxis against certain infective disease (art.16 and 17);
- 2) He/she acts opposite to article 19 of this Law;
- 3) He/she acts opposite to article 20 paragraph 1 to 3 of this Law for the duration of health care supervision measure;
- 1) He/she acts opposite to article 21 paragraph 4 of this Law;
- 2) He/she refuses laboratory testing in all cases of the emerging of infective disease or even the doubt of it, where identifying the infective agent is necessary to make a diagnosis, as well as in case of emerging or danger of emerging of epidemic of infective disease (article 22 paragraph 1);
- 3) He/she prevents the transport under the conditions and in a way which hinders the spreading of infective disease (article 24 paragraph 1);
- 4) He/she does not allow treatment measures prescribed by article 25 paragraph 1 to 8 of this law:
- 5) In case of epidemic of infective disease to a larger extent, the treatment is not provided in the structure containing all necessary conditions for treatment, i.e. isolation and treatment of persons suffering from infective disease (article 26 paragraph 1), and he/she does not act on other ordered measures for the prevention of population against infective diseases (article 34).

Article 43

A health care worker shall be fined the amount from two to ten times of the minimum wage in the Republic if:

- 1) He/she does not report of infective diseases in compliance with the Law (article 23);
- 2) He/she does not secure ambulance for the transport of a person suffering from an infective disease to a health care institution for hospital treatment of patients suffering from infective diseases (article 24 paragraph 3), and
- He/she does not immediately send for referral a person suffering from infective disease to a health care institution where such patients are isolated and treated (article 25 paragraph 9).

VII TRANSITIONAL AND FINAL PROVISIONS Article 44

Sub-Acts for execution of this Law shall be passed within one year from the day it came into force

Until sub-Acts from paragraph 1 of this article is passed, the regulations adopted before the day this Law came into effect will be applied if they are not contrary to the provisions of that Law.

Article 45

Legal entities and entrepreneurs performing the activities of prevention of the population against the infective diseases which are endangering the health of the population of the Republic shall be responsible to make their business operation in accordance with the provisions of this Law and regulations adopted based on this Law within two years from the day it came into force.

Article 46

By coming into force of this Law, the Law on the prevention of population against infective diseases shall cease to exist (Official Gazette of the Socialist Republic of Montenegro 53/75, 4/76, 28/87, 29/89 and 39/89 and the Official Gazette of the Republic of Montenegro 48/91 and 27/94) as well as the implementation of the Law on the prevention of population against infective diseases endangering the whole country (Official Gazette of the Socialist Republic of Yugoslavia 46/96, 12/98 and 37/02).

Article 47

This Law shall come into effect on the eighth day when it is published in the Official Gazette of the Republic of Montenegro.