

## **28 Annex - Consumer and health protection**

### **209. HEALTH INSPECTION LAW**

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## **HEALTH INSPECTION LAW<sup>1</sup>**

### **Subject**

#### **Article 1**

The inspection control over the implementation of laws and other regulations within the field of health protection, as well as over the implementation of the prescribed health protection measures shall be done by the Ministry in charge of health affairs (hereinafter: the Ministry).

### **Inspectors' competence**

#### **Article 2**

The affairs of the inspection control from Article 1 of this Law shall be directly performed by a health inspector.

Health inspector shall have authorizations determined by the Health Inspection Law (hereinafter: the Law) while performing the inspection.

### **Protecting identity of person submitting initiative**

#### **Article 3**

Health inspector shall keep the identity of the person submitting the initiative, which indicates the violation of the law and other regulations from the area of health protection, strictly confidential.

### **Inspectors' authorization to enter premises of entity under inspection**

#### **Article 4**

Health inspector shall be authorized to enter, without a previous notice, business premises, in line with the law.

If it is necessary for the inspector, to inspect the residential dwellings where health related work is being practiced, and the entity under inspection is opposed to it, he shall obtain a court decision from the competent court.

### **Health inspectors' authorizations**

#### **Article 5**

While performing inspection, besides the authorizations determined by law, a health inspector shall:

- 1) check whether the health service institution fulfills conditions for exercising health related work prescribed by law and other regulations from the field of health protection;
- 2) get insight into the health protection implementation and the patients' rights in a health service institution;

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<sup>1</sup> Official Gazette of Montenegro 79/08 of 23 December 2008.

- 3) act upon the complaints of citizens who are deprived of their right to health protection, or those who are not satisfied with the provided health care or procedure of the health worker or other worker in a health service institution;
- 4) control the implementation of the instruments and methods for performing lab analysis and other diagnostic methods, their alignment with the corresponding standards;
- 5) control the way of conducting and using medical documentation and records;
- 6) control the way of prescribing medicine;
- 7) control the conditions and way of dispensing medicine;
- 8) take samples of galenic, magistral or finished medicine, as well as certain kinds of medical materials which are in retail and wholesale distribution in the quantities necessary for the control of quality;
- 9) control the production and releasing into circulation of medicine for human use and medical materials, in line with the Law on Medicine and the Law on Medical Materials;
- 10) control the accuracy of medicine announcement;
- 11) control advertisement of prescription medicines or medicines containing psychotropic substances or narcotics, that is, the medicines which are not licensed to be released in circulation or whose license has expired;
- 12) control the prohibition of advertising tobacco products, prohibition of smoking tobacco products while appearing in the media, prohibition of publishing, in the press, the photographs or drawings of persons smoking and the obligation of putting the signs of banned smoking in public places.

### **Health inspectors' prohibitions**

#### **Article 6**

When, in the process of inspection control, the health inspector estimates that the law or some other regulations have been violated, besides the administrative measures, the inspector shall:

- 1) prohibit performance of activities or certain activities in the health service institution;
- 2) prohibit the health worker to perform health related activity or certain health related activities;
- 3) prohibit performance of activities and undertake other measures, in line with the law, against physical entities who perform health related activities, and who are not health workers or health associates;
- 4) send the health worker or health associate to be examined with the aim of evaluating health ability, when suspecting the lack of health ability to perform health related activity, or certain health related activities;
- 5) prohibit the independent work to a health worker who did not get or renewed the independent work license, or whose work license is taken, under conditions prescribed by law;
- 6) prohibit issuing medicine if the procedure of issuing is not in line with the law;
- 7) prohibit retail and wholesale distribution of finished drugs, if they do not fulfill conditions for releasing the drugs into circulation, prescribed by law;
- 8) prohibit retail and wholesale distribution of finished drugs which do not fulfill conditions as regards the drugs quality, in line with the law;
- 9) stop or order removal from retail and wholesale distribution of magistral, galenic, or finished medicine, or their whole series in cases foreseen by law;
- 10) order destruction of defective medicines or medicines with expired dates of consumption found in retail and wholesale distribution;

11) prohibit advertising of tobacco products, prohibit smoking tobacco products while appearing in the media, prohibit publishing, in the press, the photographs or drawings of persons smoking and order the obligation of putting the signs of banned smoking in public places.

In cases from items 2, 4, and 5 of this Article, the health inspector shall inform the competent chamber.

The prohibition from paragraph 1 of this Article shall be valid until the defects or conditions, because of which the prohibition has been pronounced, are removed.

The legal entity, the responsible person in legal entity, or a physical person shall act in line with the measures ordered by the health inspector from paragraph 1 of this Article.

### **Submitting documentation to competent chamber**

#### **Article 7**

When in the process of the inspection control, the health inspector estimates that the code of medical ethics has been violated, or that these has been a professional negligence by a health worker, the health inspector shall inform the competent chamber about it and shall submit the necessary documentation for undertaking measures in line with the law.

### **Submitting reports**

#### **Article 8**

The health inspector shall submit the report on work to the Ministry about the performed health inspection:

- at least once a month, until the fifth day in month for the previous month;
- annual report on work until 15 January of the current year for the previous year;
- on each performed inspection control on initiative;
- when necessary, at the request of the main inspector.

The Ministry shall prescribe the way, procedure and contents of the form to which the report from paragraph 1 of this Article is to be submitted.

### **Records**

#### **Article 9**

The health inspector shall keep records on performed inspection and undertaken measures.

The Ministry shall prescribe the contents of the form in which the records from paragraph 1 of this Article shall be kept.

### **Penal provisions**

#### **Article 10**

Legal entity shall be penalized for the offense by a fine from fifty-fold to two hundred-fold amount of the minimal wage rate in Montenegro, if:

- it does not act in line with the measures ordered by the health inspector (Article 6 paragraph 1).

Responsible person within the legal entity shall be penalized by a fine from ten-fold to twenty-fold amount of the minimal wage rate in Montenegro, if:

- he does not act in line with the measures ordered by the health inspector (Article 6 paragraph 1).

#### **Article 11**

Physical entity shall be penalized for the offense by a fine from ten-fold to twenty-fold amount of the minimal wage rate in Montenegro, if:

- he does not act in line with the measures ordered by the health inspector (Article 6 paragraph 1, items 3, 4 and 5).

#### **Article 12**

For the offense from Article 6, paragraph 1 of this Law, the health inspector may pronounce a fine on the spot to a physical entity and the responsible person within a legal entity, at the amount of three-fold amount of the minimal wage rate in Montenegro.

#### **Coming into effect**

#### **Article 13**

This Law shall become valid on the eighth day from the day of its publishing in The Official Gazette of Montenegro.

### **STATEMENT OF REASONS**

#### **I CONSTITUTIONAL BASIS FOR PASSING THE LAW**

The constitutional basis for passing this Law is contained in Article 16, paragraph 1, item 5 of the Constitution of Montenegro which prescribes that the Law, in line with the Constitution, shall also regulate the other issues of interest for Montenegro.

#### **II REASONS FOR ADOPTION**

The proposed Law is a new project with clearly defined rights and duties of health inspectors, health service institutions and parties in the procedure of inspection control, which fully realizes the legal principle implementation, the protection of the citizens' rights and the public interest, as well as the right for health protection granted by the Constitution.

The strategy of health care development has opened the process of necessary reforms, which should provide a higher quality of health care and health conditions of the population.

In that sense, a whole series of new reform laws has been adopted in the health field (Law on Health Protection, Law on Medicines, Law on Protection and Exercising Rights of the Mentally Disabled Persons, Law on Protection of Population from Infectious Diseases, Law on Blood Provision, Law on Emergency Medical Assistance and Law on Limited Use of Tobacco Products), which prescribe that the Ministry in charge of health affairs, shall perform the control of these laws implementation, through health inspectors.

Basic provisions of the Law on Inspection Control are also applied to the health inspection during the process of control procedure, except for certain issues which refer directly to the performance of inspection in the area of health legislation.

**The basic reasons** for proposing this Law are a significant number of laws and by-laws which are subject to the inspection control by the health inspector.

**The goal** of the inspection control performed by the health inspectors, in line with their authorization, by a direct control through the administrative and other measures and actions with the controlled entities, is removing irregularities as regards keeping the law and other regulations, in order to remove the determined irregularities in line with the corresponding regulations.

**The contents** of this Proposal include: the subject of its regulations, the competence of inspectors, protecting identity of the person submitting initiative, the authorization of inspectors to enter the premises of the controlled entity, temporary prohibition of work by health inspector, the prohibition duration, the obligation of submitting the report and keeping records on performed controls and undertaken measures

### **III HARMONIZATION WITH EUROPEAN LEGISLATION AND APPROVED INTERNATIONAL CONVENTIONS**

This regulation has no direct foundation in a document of the European Union, but its solutions are based on the recommendations and guidelines of the World Health Organization.

### **IV BASIC LEGAL INSTITUTES EXPLANATION**

This Proposal regulates the inspection control over the implementation of the laws and other regulations in the area of health protection, as well as over the implementation of the prescribed health protection measures as regards keeping the laws and other regulations from the area of health legislation.

The work of inspection control is performed directly by health inspectors who are authorized for the inspection by a special Law on Inspection Control.

Having in mind the character and the importance of performing inspection control, the inspectors are obliged to strictly protect the identity of the person submitting the initiative. The initiative indicates the violation of the law regulations and the inspection control has been performed based on it.

In line Article 4 of the Proposal, the inspector is authorized, without a previous notice, business premises, to perform control.

However, if it is necessary for the inspector, to inspect the residential dwellings where health related work is being practiced, and the entity under inspection is opposed to it, he is obliged to obtain a court decision from a competent court.

Articles 5 and 6 of the Proposal state the cases where the health inspector can temporarily prohibit the work when, during the inspection control, he determines that the law and other regulations have been violated. In line with the provisions from Article 6, the prohibition of work will last until the irregularities are removed or during the existence of conditions because of which the prohibition has been ordered.

The same provision foresees the provision for the controlled entity to undertake the measure and action at the order of the inspector.

According to Article 7 of the Proposal, if the health inspector determines that the code of medical ethics has been violated, or that there has been a professional negligence by a health worker, the health inspector shall inform the competent chamber about it and shall submit the necessary documentation for undertaking measures in line with the law.

Article 8 of this Proposal establishes the obligation of the inspector to submit the report on work to the Ministry about the performed inspection, at least once a month, until the fifth day in month for the previous month, an annual report on work until 15 January of the current year for the previous year, on each performed inspection control on initiative, and when necessary, at the request of the main inspector.

The amount of fine from Articles 10, 11 and 12 of this Proposal is in line with the Law on Offenses.

For the implementation of this Law, it is necessary to provide the funds for the salaries of the newly employed health inspectors.