Regulations of the Health Inspectorate

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Decree on Health Inspectorate *[Veselības inspekcija]*

Issued pursuant to Article 16, Part I of the Act on National Administration Procedures[Valsts pārvaldes iekārtas likums]

I. General Provisions

1. The Health Inspectorate (hereinafter referred to as the inspectorate) is a direct administration institution subordinated to the Minister of Health *[Veselības ministrs]*.

2. The purpose of the inspectorate is to fulfil functions of public administration in the supervision and control of the health sector, in order to ensure compliance with the regulatory requirements in the said area, as well as their implementation, for quality and highly-qualified healthcare, as well as in order to ensure a safe and healthy living environment.

II. Functions, tasks and rights of the inspectorate

3. The inspectorate shall have the following functions:

3.1. to monitor the implementation of regulatory enactments binding on medical institutions in the field of health care and within the field of assessment of work capacity/ability, as well as to monitor the quality of healthcare examinations in relation to professional and work capacity/ability;

3.2. to monitor the implementation of pharmaceutical legislation concerning the circulation and advertising of medicinal products and active substances for human use, circulation of narcotic and psychotropic substances and drugs, circulation of alcohol, and circulation of precursors;

3.3. to monitor the compliance of high-risk subjects, environmental factors affecting public health, chemicals available on the market, chemical mixtures (including biocides and detergents), cosmetics, tobacco products (including newly introduced tobacco products), herbal smoking products, electronic cigarettes and refill vials with the requirements specified in regulatory enactments;

3.4. to monitor compliance with requirements stipulated in respect to medical devices;

3.5. to maintain the registry of medical institutions, medical practitioners and medical support persons;

3.6. to make decisions on reimbursement of expenses or refusal to pay reimbursement from the Medical Risks Fund *[Ārstniecības riska fonds]*;

3.7. to perform the tasks assigned to the competent authority in accordance with the requirements of the following legislation:

3.7.1. Regulation (EC) No. 2006/2004 of the European Parliament and of the Council of October 27, 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (Articles 4, 7, 9, 11 and 14);

3.7.2. Regulation (EU) No. 2016/793 of the European Parliament and of the Council of May 11, 2016 on avoiding trade diversion into the European Union of certain key medicines (Article 9, Part I);

3.7.3. Regulation (EC) No. 816/2006 of the European Parliament and of the Council of May 17, 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (Article 14, Part I);

3.7.4. Regulation (EC) No. 273/2004 of the European Parliament and of the Council of February 11, 2004 on drug precursors (Article 10, Part II);

3.7.5. Regulation (EC) No. 111/2005 of the European Parliament and of the Council of December 22, 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (Article 26, Parts I, II and III);

3.7.6. Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of November 30, 2009 On cosmetic products (Article 34, Paragraph 1);

3.7.7. Regulation (EU) No. 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices and amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EC and 93/42/EEC (Articles 93, 94, 95 and parts I and II of Article 97);

3.7.8. Regulation (EU) 2017/746 of the European Parliament and of the Council of April 5, 2017 on*in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision (Articles 88, 89, 90);

3.7.9. Regulation (EC) No. 765/2008 of the European Parliament and of the Council of July 9, 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93 (Articles 19 and 26);

4. In order to fulfil its functions, the inspectorate shall have the following tasks:

4.1. to conduct audits, examinations and provide opinions on the quality of health care and examinations of work capacity/ability;

4.2. to control the compliance of medical institutions with the regulatory enactments regulating the field of health care and to control whether the medical practitioners have the medical practitioner's certificates issued by the certification authority. To control that medical institutions meet the minimum requirements set for medical institutions and their departments (including in relation to compliance with procedures for circulation of medicinal products and the provision of quality and highly-qualified health care services), and stop unauthorized treatment practices;

4.3. to control the compliance of pharmaceutical companies with the regulatory enactments regulating the field of pharmacy;

4.4. to control the circulation of narcotic and psychotropic substances and medicinal products as well as precursors;

4.5. to control compliance with the procedure for reimbursement of expenses for purchase of medicinal products and medical devices intended for out-patient treatment in the pharmaceutical activities of enterprises;

4.6. to monitor compliance with drug distribution and advertising requirements;

4.7. to control the implementation of regulatory measures for the prevention of infectious diseases and anti-epidemic measures, as well as compliance with hygiene requirements in high-risk subjects;

4.8. in the cases specified by regulatory enactments or upon request of a natural or legal person, to issue conditions for compliance with hygiene requirements, as well as to assess the conformity of the building design project and the construction object with hygiene requirements;

4.9. assess environmental health risk factors and their impact on human health and quality of life (including risks caused by chemical substances to human health);

4.10. to control the fulfillment of drinking water safety and quality assurance requirements in public drinking water supply facilities from the water uptake site to the consumer, as well as to control compliance with drinking water uptake protection requirements, organize and perform monitoring of quality of drinking water and water at bathing sites;

4.11. to control the conformity of chemical substances, chemical mixtures (including biocides and detergents) and cosmetics on the market (both being marketed and distributed) with the requirements specified in regulatory enactments;

4.12. to control compliance of the information provided, and tobacco products, herbal smoking products, electronic cigarettes, refill vials and newly introduced tobacco products placed on the market, with the requirements specified in regulatory enactments;

4.13. participate in the rapid alert system for non-food products and services between the European Commission and member states (RAPEX), to provide information on dangerous goods found on the Latvian market and to verify information received on dangerous goods;

4.14. to control the use and operation of medical devices in medical institutions and the conformity of medical devices placed on the market with regulatory enactments;

4.15. to register medical institutions, medical practitioners and medical support persons, to supplement and maintain the data of the respective registers, to ensure their public access, as well as to perform analysis of the data of the registers;

4.16. issue documents for recognition of professional qualifications abroad and in Latvia and perform the tasks assigned to the Competent Authority in the Internal Market Information System for medical practitioners in the regulated profession in the field of health care in accordance with the regulatory enactments regarding regulated professions and in accordance with the recognition of professional qualifications;

4.17. to perform expert examinations, provide opinions within the framework of the Medical Risks Fund *[Ārstniecības riska fonda]* regarding the existence of the damage to the health and life of a person, the amount of the damage and compensation, as well as to evaluate the connection of medical expenses of reducing or eliminating the consequences of harm to the patient;

4.18. contribute to the implementation of international health regulations in the field of health enforcement;

4.19. to, within its competence, provide support to the National Health Service *[Nacionālais veselības dienests]* for the operation of the cross-border healthcare contact point;

4.20. to include medical institutions in the list of health tourism providers;

4.21. to perform other tasks specified in regulatory enactments.

5. In order to carry out its tasks, the inspectorate shall have the following rights:

5.1. to request and to receive, free of charge, information and documents (including medical documents) necessary for the performance of the tasks from state and local government institutions, medical treatment institutions, as well as from natural persons and legal persons of private law;

5.2. to receive documents (including medical documents) and to obtain certified copies thereof;

5.3. to request and receive explanations from those responsible for compliance with regulatory requirements;

5.4. to, in cases provided for in regulatory enactments, instruct natural or legal persons to cease actions or omissions of actions that are harmful to the interests of the society and to the individuals, to their health and life, as well as to eliminate established non-conformities. To control the performance of the tasks assigned to such persons;

5.5. to make proposals to the competent authorities regarding the necessity to suspend or revoke special permits (licenses) and certificates of professional activity in case of violations in the areas of competence of the inspectorate;

5.6. to, in the cases specified in external regulatory enactments, issue administrative acts or administrative decisions, as well as to carry out proceedings of administrative violations;

5.7. to order the taking of specific measures to remedy the lack of conformity of the goods, and to control the performance of the given tasks, to prohibit or suspend the distribution, to withdraw and recall chemicals or mixtures placed or distributed on the market in the cases provided for by regulatory enactments (including biocides and detergents), cosmetics, tobacco products, herbal smoking products, electronic cigarettes, refill vials, medicines and narcotic and psychotropic drugs, medical devices, as well as to stop water supply;

5.8. to, in the cases provided for in regulatory enactments, visit and control any object throughout the territory of the Republic of Latvia irrespective of its subordination and visiting/access regime without prior notice, special permission, fees and other restrictions, with the exception of places of imprisonment and other restricted access institutions and territories specified by regulatory enactments, the attendance of which are to be coordinated with the administration of the respective institution or administration of the territory;

5.9. to require the controlled natural and legal persons to ensure the presence of a manager, responsible official or other representative of the subject of the control during the process of control;

5.10. to, in accordance with the procedures specified in regulatory enactments, take environmental and commodity samples in the objects to be inspected, organize their laboratory examination or other type of expert examination in accordance with the annual monitoring and control plan (program) or in cases where there are reasonable suspicions that the activity of the relevant object does not comply with the requirements specified in regulatory enactments;

5.11. to carry out measurements and control-purchases;

5.12. charge for services rendered in accordance with the inspectorate fees and charges;

5.13. to, in cases where necessary, invite experts of professional organizations in order to carry out the expertise;

5.14. to verify whether medical institutions, medical practitioners and medical support persons have registered themselves in the relevant registers;

5.15. to develop, within its competence, informative materials to inform or alert the public;

5.16. to carry out other activities specified in regulatory enactments.

III. Organization of Activities of the Inspectorate

6. The work of the inspectorate shall be directed by its head. The head is a civil servant.

7. The head of the inspectorate shall be appointed and dismissed by the Minister for Health*[Veselības ministrs]*.

8. The head of the inspectorate shall determine the organizational structure of the inspectorate.

9. The following officers of the inspectorate shall have the control and supervisory powers: head of the inspectorate, deputy heads of the inspectorate, heads of departments and deputy heads of departments, heads of departments and deputy heads of departments of control and supervision, senior inspectors, inspectors, senior medical experts, medical expert assistants, senior hygienists, hygienic doctors and assistant medical officers, senior technical inspection inspectors, technical inspection inspectors, public health analysts, environmental health analysts. The officials of the Inspectorate shall hold a service card in the performance of their duties.

IV. Ensuring the Legality of Inspectorate's Activities and Reporting

10. The head of the inspectorate shall ensure the legality of activities of the inspectorate. The head of the inspectorate shall be responsible for establishment and operation of the system for verifying administrative decisions.

11. The decisions and actual actions of the inspectorate's officials may be challenged by submitting a relevant application to head of the inspectorate. Decision taken by head of the inspectorate may be appealed in court.

12. Decisions taken by head of the inspectorate (except for the decision mentioned in Article 11 of the present regulations), as well as its factual deeds, may be appealed with the Ministry of Health *[Veselības ministrija]*. Decision taken by the Ministry of Health *[Veselības ministrija]* may be appealed in court.

13. The inspectorate shall, at least once a year, submit to the Minister of Health*[Veselības ministrs]* a report regarding the performance of administrative functions and the use of the state budget resources allocated to the inspectorate.

V. Final Provisions

14. The February 5, 2008 Cabinet of Ministers Regulations No. 76 "Decree on the Health Inspectorate"*["Veselības inspekcijas nolikums"]* (National gazette "Latvijas Vestnesis", No. 22 of 2008, No. 147 of 2009, No. 204 of 2010, No. 66 of 2012, No. 208 of 208) shall be revoked and deemed invalid.

On behalf of the Prime Minister *[Ministru prezidents]* –
Associate of the Prime Minister,
Minister of Justice *[Tieslietu ministrs] J. Bordans [J. Bordāns]*

Minister of Health *[Veselības ministre] I. Vinkele [I. Viņķele]*