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The *Saeima*<sup>1</sup> has adopted and  
the President has proclaimed the following Law:

# Pharmaceutical Law

## Chapter I General Provisions

### Section 1.

The following terms are used in this Law:

1) **means of medical treatment** - medicinal products and medical devices;

1<sup>1</sup>) **active substance** - any substance or mixture of substances intended to be used in the manufacture of medicinal products and production of medicinal products in a pharmacy and that, when used in manufacture or production of medicinal products, becomes an active ingredient of such medicinal products, which is intended to exert pharmacological, immunological or metabolic action with a view of restoring, correcting or modifying physiological functions or to make a medical diagnosis;

2) **non-prescription medicinal products** - medicinal products the pharmacological properties, strength, amount in packaging, method of administration and the possible adverse reaction caused by use of which shall not cause a direct or indirect threat to the health of the patient if they are used in accordance with instructions. In a pharmacy outpatient medical treatment medicinal products shall be issued without a prescription;

3) **pharmacist's practice** - pharmaceutical activities that are performed by a pharmacist individually or together with pharmacy employees in order to ensure pharmaceutical care in accordance with the procedures laid down in law in an equipped and licensed pharmacy;

4) **pharmaceutical care** - a component of health care, which is carried out by a pharmacist within the scope of his or her competence by providing pharmaco-therapeutic consultations, information concerning medicinal products and their use. Within such care is also included supervision of the use of medicinal products by permanent customers, medicinal product and other health care, prophylaxis and promotion of product distribution, preparation of medicinal products, promotion of health and disease prophylaxis popularisation on the basis of the latest scientific achievements and taking into account the interests of the customer, as well as ensuring customer data protection within the scope of his or her competence;

5) **pharmaceutical and veterinary pharmaceutical activity** - a form of commercial activity in the field of pharmaceuticals, which is related to the manufacture, standardisation, quality control and distribution of medicinal products, and for the conduct of which a special permit (licence) is necessary;

5<sup>1</sup>) **subject of pharmaceutical and veterinary pharmaceutical activity** - a merchant or an undertaking owned by a merchant that on the basis of a special permit (licence) is engaged in the manufacture, standardisation, quality control or distribution of medicinal products;

5<sup>2</sup>) **pharmacovigilance** - supervision of safe use of medicinal products;

6) **pharmacy** - research, preparation, manufacture, standardisation, quality control and distribution of medicinal products;

7) **homeopathic medicinal products** - medicinal products which are prepared from homeopathic stocks (products, substances or compounds) in accordance with homeopathic medicinal product manufacturing procedures, which are described in the European Pharmacopoeia or if they are not described in the European Pharmacopoeia in pharmacopoeia, which are officially used in European Union Member States. Homeopathic medicinal products may contain a number of principles;

7<sup>1</sup>) **importing** - bringing of medicinal products in the customs territory of the European Union from states or territories which are not European Union Member States or states of the European Economic Area;

8) **distribution** - purchase, storage, supply, movement across the State border (importation, exportation), sale or transfer for use for a charge or free of charge;

9) **quality** - an indicator of the effectiveness of a medicinal product, which is dependent on the ingredients and on the specific method of manufacturing, and which is determined when evaluating the safety, efficacy, purity, quantitative and qualitative composition, physical, chemical, biological and therapeutical properties and conformity with technical standards documentation or pharmacopoeia requirements of the medicinal product;

10) **quality control** - examination of medicinal product quality parameters (testing), determining its conformity with technical standards documentation or pharmacopoeia requirements.

11) **medicaments** - medicinal products, which are prepared for a specific route of administration in a specific form and which are distributed with a specific name in a specific packaging;

12) **medicinal products derived from human blood or human plasma** - industrially prepared medicinal products, also medicinal products the basis of which are blood components, which contain proteins (albumins), blood coagulating factors and immunoglobulins (except for blood, plasma or blood cells);

12<sup>1</sup>) **practicing veterinarian** - a person who has acquired the right to be engaged in veterinary medicinal practice and is dealing with it;

12<sup>2</sup>) **excipient** - any constituent of medicinal products, other than the active substance or the packaging material;

13) **prescription medicinal products** - medicinal products the pharmacological properties, strength, amount in packaging, method of administration and the possible adverse reaction caused by use without medical supervision of which may cause a direct or indirect threat to the health of the patient. In a pharmacy outpatient medical treatment medicinal products shall be issued only on the basis of a prescription;

14) **veterinary medicinal products** - medicinal products which are intended only for the prophylaxis, diagnosis or medical treatment of animal diseases;

15) [15 December 2005];

16) **substance** - any matter irrespective of origin (human origin, for example, human blood or human blood products; animal origin, for example, micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products; plant origin, for example, micro-organisms, plants, parts of plants, plant secretions, extracts; chemical substances, for example, chemical elements, chemical substances naturally occurring or obtained by chemical change or synthesis);

16<sup>1</sup>) **falsified medicinal products** - any medicinal product with a false representation of its identity (including its packaging and labelling), its name or its composition as regards any of the ingredients (including excipients and the strength of those ingredients), its source (including its manufacturer, its country of manufacturing, its country of origin and its marketing authorisation holder) and its history (including the records and documents relating to the distribution channels used);

17) **medicinal products** - any substance or combination of substances, which presents properties that are needed in order to provide medical treatment for human and animal diseases, or to perform prophylaxis of such diseases, as well as any substance or combination of substances, which may be utilised or administered to humans or animals with the aim of either to restore, correct or change physiological functions causing pharmacological, immunological or metabolic effects or to make a medical diagnosis;

18) **clinical trials of medicinal products** - all investigations conducted on humans (in case of veterinary medicinal products - in trials on animals), the purpose of which is to discover or test clinical, pharmacological and other pharmaco-dynamic activity of medicinal products, to determine the adverse reactions caused as a result of their use, and to investigate their pharmaco-kinetics in order to determine the safety and efficiency of use of medicinal products;

19) **instructions on the use of medicinal products** (hereinafter - the instructions for use (package leaflet)) - information provided for the user, which are added to medicinal products;

19<sup>1</sup>) **adverse reactions caused by the use of medicinal products** - harmful and undesirable reaction of the human body caused by the use of medicinal products;

20) **observational studies** - the documentation of observations regarding the effects of medicinal products registered in the Republic of Latvia, which does not affect the planning of and the course of their use;

21) **manufacturing of medicinal products** - the purchase of materials and products, manufacturing process, quality control, release, storage and distribution activities and control associated with them.

[19 March 1998; 1 June 2000; 14 June 2001; 16 April 2003; 15 December 2005; 24 April 2008; 28 October 2010; 29 November 2012]

## Section 2.

The purpose of this Law is to regulate the activities of natural and legal persons in the field of pharmaceuticals, as well as to ensure the manufacture and distribution of medicinal products which are qualitative, medically appropriate and of an appropriate prophylactic, treatment and diagnostic level.

[16 April 2003]

## Chapter II Competence of State Institutions Regarding Supervision and Control of Pharmacy

### Section 3.

The Ministry of Health shall be responsible for the supervision and control of the pharmacy system in the Republic of Latvia in the field of medicinal products for human consumption, but in the field of veterinary medicinal products - the Ministry of Agriculture.

*[16 April 2003; 28 October 2010]*

#### **Section 4.**

(1) Supervision and control of the manufacture of medicinal products and the distribution of medicinal products to wholesalers and pharmacies shall be conducted by the Health Inspectorate of Latvia.

(2) The Food and Veterinary Service shall supervise and control the manufacture and distribution of veterinary medicinal products, as well as the use of medicinal products intended for human consumption on animals.

*[1 June 2000; 16 April 2003; 15 December 2005; 27 September 2007; 28 October 2010]*

#### **Section 5.**

The Cabinet shall determine:

1) the procedures for issuing, suspending, renewing, re-registering and revoking special permits (licences) for pharmaceutical activities and veterinary pharmaceutical activities, professional qualification certificates for pharmacists, the procedures for commencing operating and operating pharmacies, as well as the procedures for commencing operating of medicinal product and veterinary product wholesalers, medicinal product veterinary product manufacturing or importing, operating and conformity assessment;

2) and shall approve, according to a recommendation from the Ministry of Health, a list of those medicinal product quality control institutions which are entitled to give an official opinion regarding the results of the quality control of medicinal products, including also medicinal products derived from human blood or human plasma and homeopathic medicinal products;

3) the procedures for manufacturing, labelling, registering, control, distributing, importing and exporting medicinal products;

4) the principles for the formation of the pricing of medicinal products, except veterinary medicinal products;

5) the procedures for advertising medicinal products;

6) the procedures for conducting clinical trials and observations of the use of medicinal products, as well as the procedures for monitoring of adverse reactions caused by the use of veterinary medicinal products;

7) the procedures for acquiring, storing and using medicinal products by medical treatment institutions and social care institutions;

8) the procedures for determining the minimum assortment of medicinal products for general (open) type pharmacies;

9) *[19 March 1998]*;

10) the classification of medicinal products;

11) the restrictions on the use of medicinal products for animals;

12) the requirements to be met for instructions for use (package leaflet) of medicinal products;

13) the procedures for issuing good manufacturing practice certificates to medicinal product manufacturers;

14) the procedures for evaluating conformity of distribution of medicinal products (except veterinary medicinal products) with the requirements of good distribution practices;

15) the procedures for evaluating conformity of clinical research of medicinal products (except veterinary medicinal products) with the requirements of good clinical practices;

16) the criteria for the location of pharmacies and pharmacy branches (except veterinary pharmacies);

- 17) the procedures for registering pharmacists and pharmacist's assistants;
- 18) the procedures by which veterinary medical care institutions and practicing veterinarians purchase, store, record and use medicinal products;
- 19) the amount of the State fee to be paid for the issuance and re-registration of special permits (licences) for pharmaceutical and veterinary pharmaceutical activities, and the procedures by which such will be collected;
- 20) the procedures for compensating expenditures for the acquisition of medicinal products and medical devices intended for out-patient medical treatment;
- 21) the procedures for collecting and compiling the information and forming statistics in the field of circulation of veterinary medicinal products; and
- 22) for a person the requirements of professional qualification necessary for distribution of veterinary medicinal products, the procedures for evaluating qualifications and the procedures for issuing a certificate for the distribution of veterinary medicinal products, for extending the term of validity and revoking thereof, as well as the procedures for registering a certified person;
- 23) the requirements and procedures for importing and distributing active substances and the procedures for registering importers, manufacturers and distributors of active substances;
- 24) the procedures for pharmacovigilance;
- 25) the procedures for and amount of wholesale data necessary for analysis of availability of medicinal products;
- 26) the food products to be distributed in pharmacies.

*[19 March 1998; 1 June 2000; 14 June 2001; 16 April 2003; 15 December 2005; 23 October 2008; 1 December 2009; 28 October 2010; 29 November 2012]*

## **Section 6.**

The Minister for Health shall, within the scope of his or her competence:

- 1) implement the policy of the Government in the field of pharmaceuticals, organise the preparation of draft laws and regulations, necessary for the regulation of pharmaceuticals, and the control of conformity with the requirements of the laws and regulations in force, and approve the systems of classification and coding of medicaments in the pharmaceutical sector;
- 2) [15 December 2005];
- 3) organise the attestation of inspectors of the Health Inspectorate of Latvia and co-ordinate the preparation of pharmaceutical specialists, issue permits for conducting the training process, for students of higher educational institutions or pupils of secondary specialised educational institutions, in pharmacies, medicinal product wholesalers and medicinal product manufacturing, based on recommendations from the higher or secondary specialised educational institutions;
- 4) regulate the conditions for the manufacture, storage, control and distribution of particular medicinal products or groups of medicinal products;
- 5) ensure that the special permits (licences) provided for in the regulations of the Cabinet are issued;
- 6) [17 December 1998];
- 7) approve the model by-law for the medicinal products clinical trials ethics committees and the membership of such committees;
- 8) [15 December 2005];
- 9) [15 December 2005];
- 10) [15 December 2005].

[19 March 1998; 17 December 1998; 1 June 2000; 14 June 2001; 16 April 2003; 15 December 2005; 27 September 2007; 23 October 2008]

## **Section 6.<sup>1</sup>**

The Minister for Agriculture shall, within the scope of his or her competence, implement the State policy in the field of veterinary medicinal products, organise the development of draft laws and regulations governing the circulation of medicinal products intended for animals and the control of implementation of laws and regulations.

*[28 October 2010]*

**Section 7.** [15 December 2005]

## **Section 8.**

The State Agency of Medicines and the National Health Service are State administration institutions under the supervision of the Ministry of Health.

*[15 December 2005; 1 December 2009; 29 November 2012]*

**Section 9.** [15 December 2005]

## **Section 10.**

The Agency shall, within the framework of its competence, perform the following functions:

1) organise the collection of information regarding current issues in the field of quality control of medicinal products, as well as the formation of medicinal product consumption statistics in the State using information provided by pharmacies, medicinal product wholesalers, medicinal product manufacturers, medicinal product importers, medical treatment institutions, practicing veterinarians and veterinary medical care institutions, and the compilation and distribution of such information;

1<sup>1</sup>) provide information regarding wholesale data of medicinal products necessary for analysis of availability of medicinal products (except veterinary medicinal products) according to the international non-proprietary name of medicinal products;

1<sup>2</sup>) publish the maximum permissible prices of medicinal products in pharmacies on its website;

2) create and regularly update the Medicinal Product Register of Latvia, grant medicinal product registration numbers and medicinal product codes, develop and maintain a database for medicinal product consumption statistics, as well as for the clinical trials of medicinal products and observational studies;

3) evaluate and register medicinal products;

4) perform the quality expert-examination of medicinal products, also upon request of the Health Inspectorate of Latvia;

5) ensure co-operation with the institutions of the European Union, competent authorities in other states and international organisations in the field of the evaluation, registration, quality expert-examination of medicinal products, clinical trials and pharmacovigilance, in the field of licensing and conformity assessment of pharmaceutical activity, in issues related to bringing in, bringing out, transit and distribution of medicinal products, in the field of registering medical devices, clinical trial and supervision of safe use, as well as in the field of supervision of safe use and conformity assessment of human blood, tissues, cells and organs;

6) co-operate with the public organisations of physicians and pharmacists;

7) in accordance with the procedures laid down in laws and regulations, issue medicinal products, as well as preparations intended for clinical trials import, export, transit and distribution permits. Issue medicament distribution permits for medicinal products registered and used in foreign states (if such are essential for ensuring the medical treatment process, are intended for the treatment of rare diseases and are to be distributed in restricted quantities, or are to be used in cases of emergencies, natural disasters or an outbreak of an animal infectious disease):

a) if the medicament is necessary for the treatment of an individual patient or animal, is not registered in the Republic of Latvia, and, due to the medical indications of the medicaments included in the Medicinal Product Register

of Latvia, cannot be administered for the treatment of the concrete patient or animal - on the basis of a prescription or request issued in conformity with laws and regulations,

b) if the medicament is necessary for the medical treatment of a particular disease or performance of a medical manipulation in a particular medical institution or social care institution, or for the medical treatment of a particular animal disease or performance of manipulation, is not registered in the Republic of Latvia, and the medicaments included in the Medicinal Product Register of Latvia due to their medical indications cannot be administered for medical treatment, or their usage is restricted - on the basis of a written request by a medical treatment institution or social care institutions, or a practicing veterinarian, or a veterinary medical care institution, and, if necessary, an opinion of the professional association of physicians or the veterinarian professional section,

c) if the medicament is necessary for the provision of medical assistance in cases of emergencies, natural disasters or epidemics, and is not registered in the Republic of Latvia - pursuant to a decision of the Minister for Health,

d) [28 October 2010];

8) prepare and submit to the Ministry of Health recommendations regarding the inclusion of laboratories, institutes and other institutions in the list of such institutions as are entitled to give official opinions on issues regarding the quality of medicinal and pharmaceutical products;

9) issue permits for the performance of clinical trials of medicinal products and supervise their procedures;

10) [1 December 2009];

11) evaluate the conformity of clinical trials of medicinal products with the requirements of good clinical practice;

12) evaluate the conformity of medicinal product wholesalers, manufacturers (also foreign manufacturers) and importers, examine the conformity of the qualification and experience of the responsible official with the requirements laid down in laws and regulations regarding manufacture and distribution of medicinal products, and issue special permits (licences) for pharmaceutical activities, as well as special permits (licences) for pharmaceutical activities in which the manufacture, importing and distribution of veterinary medicinal products is specified as the field of a special activity;

12<sup>1</sup>) evaluate and check the conformity of manufacturers and importers of medicinal products, including the manufacturers and importers of medicinal products referred to in Section 51.<sup>2</sup> of this Law, with the requirements of good manufacturing practice and issue certificates of good manufacturing practice;

12<sup>2</sup>) evaluate and check the conformity of manufacturers and importers of active substances with the requirements of good manufacturing practice and issue certificates of good manufacturing practice;

12<sup>3</sup>) evaluate and check the conformity of distributors of medicinal products and active substances with the requirements of good distribution practice and issue certificates of good distribution practice;

13) determine whether a medicinal product belongs to non-prescription or prescription medicinal products in accordance with the procedures stipulated by the Cabinet;

14) perform conformity assessment and registration of medical devices, establish and update the register of medical devices of Latvia, issue permits for performance of clinical researches of medical devices and supervise the proceedings thereof, perform the supervision of safety of use of medical devices, create and maintain a database regarding observed adverse reactions caused by use of medical devices;

15) perform conformity assessment and supervision of centres for acquiring and storage of tissues, cells and organs, blood rooms of medical treatment institutions, blood preparation divisions and the State Blood Donor Centre;

16) assess submissions submitted in order to receive a special permit (licence) for operating of a general type pharmacy or operating of a closed type pharmacy with certification regarding compliance of premises, equipment, personnel and documentation to the requirements laid down in the laws and regulations regarding operating of pharmacies and distribution of medicinal products and issue special permits (licences) for operating of general type pharmacy or for operating of closed type pharmacy;

17) assess submissions submitted in order to register manufacturers, importers and distributors of active substances, and register them in accordance with the procedures laid down in the laws and regulations regarding registration of manufacturers, of importers and distributors of active substances;

18) perform the functions of pharmacovigilance, including supervision of the adverse effects caused by the use of medicinal products, create and maintain a database in relation to supervision of safe use of medicinal products.

*[19 March 1998; 1 June 2000; 14 June 2001; 16 April 2003; 15 December 2005; 27 September 2007; 23 October 2008; 1 December 2009; 28 October 2010; 29 November 2012]*

#### **Section 11.**

The National Health Centre shall perform the following functions within the scope of its competence:

- 1) perform economic evaluation of medicinal products, medical devices, medical technologies and health care services to be paid by the State budget funds;
- 2) draw up the guidelines in the field of health economics;
- 3) determine the prices of medicinal products and medical devices intended to be compensated in outpatient medical treatment and draw up a list of medicinal products and medical devices intended to be compensated in outpatient medical treatment;
- 4) perform the settlement of accounts with pharmacies for the issued medicinal products and medical devices within the scope of the procedures for compensating the expenses for the purchase of medicinal products and medical devices intended to be compensated in outpatient medical treatment;
- 5) draw up a list of medicinal products to be used in inpatient medical treatment institutions.

*[29 November 2012]*

#### **Section 12.**

(1) The Food and Veterinary Service shall, within the competence thereof, conduct the following functions:

- 1) assess, classify and register veterinary medicinal products;
- 2) establish and update the Veterinary Medicinal Product Register of the Republic of Latvia, grant registration numbers and codes for veterinary medicinal products, establish and maintain a data base regarding observed adverse reactions caused by veterinary medicinal products, regarding clinical investigation of veterinary medicinal products and observations of use thereof;
- 3) organise collection of information, compile information and form statistics in the field of circulation of veterinary medicinal products using the information provided by veterinary medicinal product manufacturers, importers, distributors, practicing veterinarians and veterinary medical care institutions;
- 4) ensure the quality control of veterinary medicinal products;
- 5) ensure the co-operation with competent institutions of other countries in the field of assessment, registration and control of veterinary medicinal products;
- 6) issue permits for importation, exportation and distribution of veterinary medicinal products, as well as of the veterinary medicinal products intended for clinical investigations, except the permits for importation, exportation and distribution of veterinary narcotic and psychotropic medicinal products;
- 7) issue permits for distribution of veterinary medicinal products for veterinary medicinal products other than registered in the Republic of Latvia if:
  - a) veterinary medicinal products are necessary for treatment of a particular animal, treatment of particular animal disease or performance of medical manipulations and the medicinal products included in the Veterinary Medicinal Product Register of Latvia may not be used due to medical indications - on the basis of a written request of a practicing veterinarian and, if necessary, of an opinion of the Latvian Association of Veterinarians,
  - b) veterinary medicinal products are necessary for provision of veterinary medical care in case of disaster, natural disaster or threats of spread of dangerous animal infectious diseases - on the basis of a decision of the State Chief Veterinary and Food Inspector;
- 8) prepare and approve the list of those institutions which are entitled to provide official opinion regarding quality issues of veterinary medicinal products;

9) assess the conformity of veterinary pharmacies, veterinary medicinal product wholesalers, manufacturers (also foreign manufacturers) and importers, check the conformity of the qualification and experience of the responsible official with the requirements laid down in laws and regulations, and issue special permits (licences) for veterinary pharmaceutical activities. This requirement does not apply to the medicinal product manufacturers and importers referred to in Section 51.<sup>2</sup> of this Law;

10) issue permits for the importation into the Republic of Latvia of diagnostics for the needs of approbation and the acquiring, introduction and use of new methods;

11) assess the conformity of veterinary medicinal product manufacturers and importers with the requirements of good manufacturing practice and issue attestations of good manufacturing practice for veterinary medicinal products. This requirement does not apply to the medicinal product manufacturers and importers referred to in Section 51.<sup>2</sup> of this Law.

(2) The Cabinet shall determine the types of paid services of the Food and Veterinary Service and the procedures for performance of payment for the activities provided for in this Law.

*[1 June 2000; 16 April 2003; 15 December 2005; 23 October 2008; 28 October 2010; 29 November 2012]*

### **Section 13.**

The Health Inspectorate of Latvia is a direct administration institution subordinate to the Ministry of Health.

*[16 April 2003; 15 December 2005; 27 September 2007]*

### **Section 14.**

Officials of the Health Inspectorate of Latvia, but in respect of the circulation of veterinary medicinal products the Food and Veterinary Service inspectors shall, within the scope of their competence, have the right to:

1) for the purpose of the supervision of pharmacy, supervise and control legal persons, which are engaged in activities with medicinal products and active substances, including pharmacies, medicinal product wholesalers, medicinal product manufacturers and importers, medical treatment institutions, social care institutions, veterinary medical care institutions, customs warehouses in which medicinal products and active substances are stored, and natural persons who work in the field of pharmacy, irrespective of their subordination, type and nature of the commercial activity, evaluate the conformity of medicinal product distribution with the requirements of laws and regulations, as well as give, within the scope of their competence, binding orders on pharmaceutical issues to the persons referred to in this Clause;

2) perform the evaluation of premises, equipment, personnel and documentation regarding conformity with the work to be performed and its volume;

3) control that the procedures provided for the reimbursement of expenditures for the acquisition of medicinal products and medical devices in outpatient medical treatment are complied with;

4) ensure co-operation with international organisations and the relevant institutions of other states;

5) make control purchases and in cases of doubt or suspicion, remove samples of medicinal products from pharmacies, medicinal product wholesalers, medicinal product manufacturers and importers and send them for quality control to medicinal product quality control institutions. If the medicinal products are not in conformity with the requirements of technical standards documentation or the pharmacopoeia, the expenditures for the quality control of the medicinal product samples shall be covered by the pharmaceutical or veterinary pharmaceutical entity. If the medicinal products conform to such requirements, the expenditures shall be covered from the resources of the authority which performed the control;

6) in accordance with laws and regulations, suspend the pharmaceutical or veterinary pharmaceutical activities of a legal or natural person or suspend distribution of products pending a final clarification of circumstances;

7) prohibit the distribution of any medicinal products, active substances and excipients, if such are determined to be of inferior quality, but in a case, when doubts have arisen regarding their quality - suspend distribution of the relevant medicinal products, active substances or excipients pending a final clarification of their quality;

8) prohibit the manufacture, importing or distribution of medicinal products, withdraw and confiscate medicinal products, if their manufacture, importing or distribution is conducted in violation of the requirements laid down in the laws and regulations in the field of pharmacy;

9) propose that for the violation of pharmaceutical and veterinary pharmaceutical activities the special permit (licence) for pharmaceutical activities or the special permit (licence) for veterinary pharmaceutical activities, or permit for the acquisition of medicinal products be suspended or revoked;

10) monitor advertisements of medicinal products;

11) impose administrative sanctions upon persons guilty of violation of laws and regulations.

*[1 June 2000; 16 April 2003; 27 September 2007; 23 October 2008; 28 October 2010; 29 November 2012]*

**Section 15.** [24 April 2008]

**Section 16.** [19 March 1998]

## **Chapter III Medicinal and Pharmaceutical Products**

### **Section 17.**

(1) Only medicinal products which are registered in the Republic of Latvia and included in the Medicinal Product Register of Latvia or in the Veterinary Medicinal Product Register of Latvia are permitted to be distributed in the territory of the Republic of Latvia, except in the cases referred to in Section 10, Clause 7, in Section 12, Clause 7 and 10 and in Section 20 of this Law.

(2) Medicinal products registered by the centralised procedures of the European Agency for the Evaluation of Medicinal Products may be distributed without such medicinal products being registered.

*[1 June 2000; 16 April 2003; 28 October 2010]*

### **Section 18.**

Provisions for the manufacture, storage, distribution, use, import and export of narcotic and psychotropic drugs and precursors shall be regulated by this Law, the Law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Drugs and the Law On Precursors.

### **Section 19.**

Procedures for the quality control of medicinal products shall be regulated by Cabinet regulations. The person whose activities are controlled, unless otherwise stipulated by Cabinet regulations shall cover the costs of control.

*[16 April 2003]*

### **Section 20.**

Registration of medicinal products and medicinal product substances shall not be required if:

1) the medicinal products are prepared at a pharmacy pursuant to a prescription issued by a physician or a practising veterinarian, or on the basis of a written request from a medical treatment institution or a veterinary medical care institution for an individual patient;

2) the medicinal products are intended for scientific research or clinical tests, which are co-ordinated with the State Agency of Medicines or - with regard to veterinary medicinal products - with the Food and veterinary Service;

3) the substances are intended for the manufacture of other medicinal products;

4) [17 December 1998];

5) [17 December 1998];

6) the medicinal products are prepared at a pharmacy according to the monograph of pharmacopoeia for an individual patient.

*[17 December 1998; 1 June 2000; 16 April 2003; 16 April 2003; 28 October 2010]*

#### **Section 21.**

The distribution and use of medicinal products shall be prohibited, if their quality does not comply with the requirements set out in the documentation of approved technical standards (pharmacopoeia, technical regulations, documentation approved during the registration of medicinal products, and others), or their expiry date has passed.

*[16 April 2003]*

#### **Section 21.<sup>1</sup>**

If veterinary medicinal products necessary for treatment and prophylaxis of animals are not available, a practicing veterinarian is allowed to distribute and use medicinal products intended for human consumption in accordance with the procedures laid down in laws and regulations.

*[28 October 2010]*

#### **Section 22.**

(1) When medicinal products are distributed, they shall be accompanied by directions for use (package leaflet), which conform to the requirements stipulated by the Cabinet.

(2) If medicinal products have been classified as prescription medicinal products, a pharmacy may dispense them only:

1) on the basis of a relevant prescription from a physician or practising veterinarian, which is completed in accordance with the procedures laid down in laws and regulations;

2) for a practicing veterinarian or veterinary medical care institution - on the basis of a written request of a practicing veterinarian.

(3) In the wholesaling of medicinal products and active substances, the good distribution principles and guidelines of medicinal products and active substances shall be ensured in accordance with the guidelines published by the European Commission and in accordance with the legislation of the European Union.

(4) A practicing veterinarian shall observe good distribution principles of medicinal products and veterinary medicinal products.

*[19 March 1998; 1 June 2000; 16 April 2003; 15 December 2005; 28 October 2010; 29 November 2012]*

#### **Section 23.**

Only medicinal products intended for animals may be dispensed on the basis of the receipt of a prescription or request, which has been written by a practising veterinarian.

#### **Section 24.**

*[23 October 2008]*

#### **Section 25.**

The preparation, manufacture, importing and distribution of medicinal products in the Republic of Latvia shall only be allowed if a special permit (licence) has been issued for the relevant form of entrepreneurial activity.

*[29 November 2012]*

#### **Section 25.<sup>1</sup>**

A person who has a special permit (licence) issued in a Member State of the European Union or in a state of the European Economic Area, which gives the right to perform the wholesaling or manufacture of medicinal products, has a duty to provide the State Agency of Medicines or the Food and Veterinary Service - in respect of veterinary medicinal

products - the information laid down in the laws and regulations regarding the distribution of medicinal products in respect of commencing medicinal product wholesaling in the Republic of Latvia. In such case, it is not necessary for the merchant to obtain the special permit (licence) determined in Section 25 of this Law.

*[16 April 2003; 15 December 2005; 28 October 2010]*

### **Section 25.<sup>2</sup>**

Recommendations (guidelines) of the European Commission that have been published in the volumes of the Rules Governing Medicinal Products in the European Community (*Eudralex*) shall be applied in preparing the documentation regarding pharmacovigilance in relation to the medicinal products intended for human consumption and adverse reactions caused by the use of veterinary medicinal products and the documentation pertaining to the manufacture, importing and distribution of active substances, as well as the manufacture, clinical investigation, registration, classification, labelling and instructions on the use of medicinal products.

*[29 November 2012]*

### **Section 25.<sup>3</sup>**

Intermediary transactions involving medicinal products intended for human consumption are permitted, if the person has registered with the State Agency of Medicines in accordance with the procedures laid down in the laws and regulations regarding distribution of medicinal products.

*[29 November 2012]*

## **Chapter IV Evaluation and Registration of Medicinal and Pharmaceutical Products**

### **Section 26.**

The evaluation, registration, re-registration and post-registration supervision of medicinal products shall be conducted by the State Agency of Medicines or the Food and Veterinary Service - in respect of veterinary medicinal products.

*[19 March 1998; 1 June 2000; 16 April 2003; 15 December 2005]*

### **Section 26.<sup>1</sup>**

Clinical trials of medicinal products, involving humans as subjects of the investigation, may not occur if the permission of a clinical medicinal product investigation ethics committee has not been received.

*[19 March 1998; 1 June 2000; 16 April 2003]*

### **Section 27.**

*[19 March 1998]*

### **Section 28.**

*[15 December 2005]*

### **Section 28.<sup>1</sup>**

Documents, which are appended to a registration application, shall be submitted in accordance with the requirements stipulated by the Cabinet regarding the registration of medicinal products and taking into account the guidelines of the European Commission regarding documentation and requirements regarding the quality, safety and efficacy of medicinal products.

*[16 April 2003]*

### **Section 29.**

(1) Costs associated with evaluation, registration, re-registration and post-registration supervision of medicinal products shall be covered by the applicant for registration in accordance with Cabinet regulations regarding a price list for paid public services.

(2) Costs associated with evaluation, registration, re-registration and post-registration supervision of veterinary medicinal products shall be covered by the applicant for registration in accordance with regulatory enactment regarding the procedures for payment of activities of the State supervision and control performed by and paid services provided by the Food and Veterinary Service.

*[19 March 1998; 16 April 2003; 15 December 2005; 28 October 2010]*

### **Section 30.**

The State Agency of Medicines and the Food and Veterinary Service in accordance with the competence thereof shall issue permits and supervise the clinical investigation of medicinal products and veterinary medicinal products.

*[1 June 2000; 16 April 2003; 23 October 2008; 28 October 2010]*

### **Section 31.**

The registration of medicinal products shall be suspended or revoked if:

1) the medicinal products in being used in conformity with the information indicated in the registration documents (instructions for use and other technical standard documentation) are harmful;

2) the medicinal products have no therapeutic effect;

3) the qualitative and quantitative composition of the medicinal products does not conform to the registration documentation;

4) false information has been submitted or the information in the registration documentation is not complete, or controls have not been conducted for the medicinal products and the components thereof in conformity with the information included in the registration documentation;

5) the labelling or the instructions for use (package leaflet) of the medicinal products do not conform to the laws and regulations on the labelling of medicinal products;

6) there is a court judgment regarding the violation of intellectual property rights;

7) the medicinal product registration documentation does not conform to the requirements of European Community legislation;

8) the applicant for registration has submitted an application for the revocation or suspension of the medicinal product registration;

9) the payments associated with the registration of medicinal products determined in Section 29 of this Law have not been performed;

10) the requirements laid down in the laws and regulations regarding pharmacovigilance are not conformed to.

*[19 March 1998; 16 April 2003; 29 November 2012]*

### **Section 32.**

*[15 December 2005]*

## **Chapter V Pharmacies**

### **Section 33.**

A pharmacy is engaged in the preparation of medicinal products pursuant to prescriptions and written requests from medical treatment institutions, in the storage and distribution of medical treatment products, goods to be used for

health care or body care and in the provision of pharmaceutical care, as well as in distribution of the food products determined by the Cabinet.

*[29 November 2012]*

### **Section 33.<sup>1</sup>**

A veterinary pharmacy is engaged in the purchasing, storage and distribution of veterinary medicinal products, instruments and goods that are used in veterinary medicine, goods intended for animal care, as well as preparation of veterinary medicinal products pursuant to the veterinary prescriptions and provision of consultations regarding the use of veterinary medicinal products, instruments and products intended for animal care.

*[23 October 2008]*

### **Section 34.**

Depending on the type of and restrictions on their activities, pharmacies shall be classified as follows:

- 1) general or open-type pharmacies;
- 2) closed-type pharmacies or pharmacies of medical treatment institutions;
- 3) veterinary pharmacies;
- 4) *[28 October 2010]*.

*[19 March 1998; 15 December 2005; 28 October 2010]*

### **Section 35.**

(1) General or open type pharmacies are permitted to:

- 1) package medicinal products in accordance with the requirements of technical standards;
- 2) prepare medicinal products after the receipt of a prescription of a physician or practising veterinarian and a written request of medical treatment institution or veterinary medical care institution;
- 3) issue medicinal products after the receipt of prescription of a physician or practising veterinarian or a written request of practicing veterinarian;
- 4) distribute medicaments to medical treatment institutions and social care institutions;
- 5) distribute medicaments to natural persons.

(2) The activities set out in Paragraph one, Clauses 1 and 2 of this Section shall not be permitted in branches of pharmacies in which there is no pharmacist.

(3) Closed type pharmacies or pharmacies of medical treatment institutions are permitted to:

- 1) package medicinal products in accordance with the requirements of technical standards;
- 2) prepare medicinal products according to the requests of medical treatment institutions;
- 3) distribute medicaments to medical treatment institutions.

(4) Closed type pharmacies or pharmacies of medical treatment institutions are not permitted to distribute medicaments to natural persons.

(5) In veterinary pharmacies:

- 1) prescription and non-prescription veterinary medicinal products shall be distributed;
- 2) goods intended for animal care and instruments and goods that are used in veterinary medicine shall be distributed;

3) prescription veterinary medicinal products shall be delivered against a prescription or a written request by a practising veterinarian;

4) only a pharmacist is entitled to prepare veterinary medicinal products;

5) veterinary medicinal products shall be pre-packed in accordance with the requirements of technical standards.

(6) [28 October 2010]

*[19 March 1998; 1 June 2000; 14 June 2001; 16 April 2003; 15 December 2005; 28 October 2010]*

### **Section 36.**

(1) A pharmacy shall be established in the form of a pharmacist's practice, a joint practice (a Civil Law company) or a capital company. In respect of the performance of pharmaceutical care in a pharmacy owned by a local government or other person other than a pharmacist, an employment contract shall be entered into with a certified pharmacist. An in-patient medical treatment institution or day hospital; may open a closed type of pharmacy.

(2) A pharmacy may operate in the form of a capital company, if at least one of the following conditions is observed:

1) not less than 50 per cent of capital shares (shares) of a capital company are owned by a pharmacist;

2) at least half of the members of the board of a capital company (executive institution) is certified pharmacists.

(3) A pharmacy may be established by a pharmacist's assistant who has been registered as an individual merchant or has established a capital company, observing a condition that in a county, county's city or county's parish, where the pharmacy is established, the number of inhabitants does not exceed 4000 and there are no other pharmacies or pharmacy branches within a radius of five kilometres. The provisions of Paragraph one of this Section regarding entering into employment contract with a certified pharmacist shall not apply to such case. A pharmacy in the form of a capital company established by a pharmacist's assistant may operate, if not less than 50 per cent of capital shares (shares) of a capital company are owned by a pharmacist's assistant. A special permit (licence) shall be issued for the operating of a pharmacy for five years. A special permit (licence) may be issued repeatedly. During the term of validity of a special permit (licence) a pharmacy owned by a pharmacist's assistant shall not be taken into account as criterion for location, when granting a special permit (licence) for opening (operating) of the pharmacy conducted by a pharmacist.

(4) A pharmacy may open branches. The branch of a general type pharmacy may be established in a county, county's city or county's parish where the number of inhabitants does not exceed 4000 and there are no other pharmacies or pharmacy branches within a radius of five kilometres. The name of the branch shall indicate the name of the pharmacy, which has established the branch.

*[1 June 2000; 14 June 2001; 16 April 2003; 9 August 2010]*

### **Section 37.**

In order that a pharmacy may commence operations it is necessary to provide for premises, equipment, facilities and personnel complying with the requirements of laws and regulations, as well as to, in accordance with the procedures prescribed by the Cabinet, obtain a special permit (licence) to open (operate) a pharmacy.

*[1 June 2000]*

### **Section 38.**

(1) A pharmacy shall be managed by a responsible manager of the pharmacy who shall be responsible for its work and who has obtained a pharmacist professional qualification certificate.

(1<sup>1</sup>) In a county, county's city or county's parish where the number of inhabitants does not exceed 4000 and there are no other pharmacies or pharmacy branches managed by a pharmacist within a radius of five kilometres, a pharmacy may be managed by and for its work shall be responsible a pharmacist's assistant who has continuous experience of pharmacist's assistant in a pharmacy of at least five years. If in the relevant county, county's city or county's parish where the number of inhabitants does not exceed 4000 a pharmacy or pharmacy branch managed by a pharmacist is established, a pharmacist's assistant shall retain the right to manage a pharmacy and the duty to be responsible for its work until the end of the term of validity of the special permit (licence).

(2) A pharmacist and pharmacist's assistant who work in a pharmacy shall be:

1) registered with the Latvian Pharmacist Society in accordance with the procedures stipulated by the Cabinet and shall observe the ethics code approved by the Latvian Pharmacist Society;

2) raise professional qualifications by taking part in the continuous education process recognised by the Latvian Pharmacist Society.

(3) A pharmacist and pharmacist's assistant who has acquired his or her education in a state which is not a Member State of the European Union or a state of the European Economic Area, as well as in other states as is provided for in international agreements ratified by the *Saeima*, and whose diploma has been recognised in accordance with the procedures laid down in law, in order to commence independent practise in a pharmacy must work for at least one year in a pharmacy under the surveillance of a pharmacist.

*[16 April 2003; 15 December 2005; 9 August 2010; 28 October 2010]*

### **Section 38.<sup>1</sup>**

The laid-down in Sections 33, 36 and 38 of this Law shall not apply to veterinary pharmacies.

*[28 October 2010]*

### **Section 39.**

In cities and other populated areas, in which the number of inhabitants does not exceed 4000, up to 30 June 2004 as a manager of a pharmacy may be a pharmacist's assistant who has at least five years length of service in the speciality, and who has received a permit from the Minister for Health, but from 1 July 2004 as a manager of a pharmacy may be a pharmacist's assistant who is registered with the Latvian Pharmacist Society and who has at five years length of service in management of a pharmacy if his or her pharmacist practice has not been interrupted for longer than five years since the day a submission was submitted to the certification authority for the acquisition of a pharmacist professional qualification certificate.

*[19 March 1998; 1 June 2000; 16 April 2003]*

### **Section 40.**

(1) The manager and deputy manager of one pharmacy may not concurrently be the manager or deputy manager of another pharmacy, or the responsible pharmacist or the deputy responsible pharmacist or department manager of a medicinal product wholesaler, or a head of production or a head of control service of a medicinal product manufacturing undertaking.

(2) A pharmacy is permitted to distribute veterinary medicinal products if:

1) a veterinarian or veterinary paramedic who is engaged in such activities has received a certificate of veterinary medical practice or a certificate for the distribution of veterinary medicinal products issued by the Latvian Association of Veterinarians;

2) a pharmacist, pharmacist's assistant or veterinarian's assistant who is engaged in such activities has received a certificate for the distribution of veterinary medicinal products issued by the Latvian Association of Veterinarians.

(3) If a general or open type pharmacy distributes veterinary medicinal products, then an official, who has a higher education in pharmacy or veterinary medicine, responsible for the circulation of veterinary medicinal products shall be specified therein, and the distribution of veterinary medicinal products shall be specified as a special field of activity in a special permit (licence) to open (operate) a pharmacy. The State Agency of Medicines shall inform the Food and Veterinary Service regarding the issued special permit (licence) and it shall register such a pharmacy in the register of objects under supervision of the Service.

(4) An official, who has a higher education in pharmacy or veterinary medicine, responsible for the circulation of veterinary medicinal products shall be determined in a veterinary pharmacy and a special permit (licence) to open (operate) a pharmacy shall be received.

(5) An official responsible for the circulation of veterinary medicinal products may not concurrently be the responsible official in another pharmacy.

*[19 March 1998; 1 June 2000; 28 October 2010; 29 November 2012]*

#### **Section 40.<sup>1</sup>**

(1) The Latvian Association of Veterinarians shall perform the following State administration tasks:

- 1) issue, re-register and revoke certificates for the distribution of veterinary medicinal products;
- 2) register recipients of a certificate for the distribution of veterinary medicinal products and maintain the register of certified persons;
- 3) draw up and approve a programme for examination of qualifications for a person who is applying for a certificate for distribution of veterinary medicinal products, and evaluate the qualifications of the applicant.

(2) The Cabinet shall determine the fee for issue and re-registration of a certificate for the distribution of veterinary medicinal products.

(3) In performing the tasks referred to in Paragraph one of this Section the Latvian Association of Veterinarians:

- 1) is entitled to issue administrative acts;
- 2) shall be under functional subordination of the Ministry of Agriculture.

(4) The contestation or appeal of the decision taken by the Latvian Association of Veterinarians during the fulfilment of the tasks referred to in Paragraph one of this Section shall not suspend the operation thereof.

*[28 October 2010; 29 November 2012]*

#### **Section 41.**

A pharmacy shall be responsible for the quality of the medicinal products it distributes and the carrying out of pharmaceutical care. It may purchase medicinal products only from medicinal product manufacturing undertakings, medicinal product wholesalers and pharmacies, completing appropriate accompanying documents. Medicinal plants may be purchased also from natural persons, but such may be distributed only if an appropriate permit from the State Agency of Medicines has been received, or - if the plants are intended for animals - a permit from the Food and veterinary Service.

*[1 June 2000; 16 April 2003]*

#### **Section 42.**

In general and closed-type pharmacies, medicinal products may be prepared, controlled and distributed only by specialists who have a pharmaceutical education. At a branch of a pharmacy, which is located in a county, county's city or county's parish where the number of inhabitants does not exceed 4000 and there are no other pharmacies or branches of pharmacies within a radius of five kilometres, medicinal products may be distributed also by health care professionals. The operations of the branch of the pharmacy aforementioned shall be discontinued within one month, if another pharmacy or branch of a pharmacy, in which a specialist with a pharmaceutical education is employed, is opened in this area.

*[16 April 2003; 9 August 2010]*

## **Chapter VI Medicinal product Wholesalers**

#### **Section 43.**

A medicinal product wholesaler is engaged in the purchase, storage and distribution of medicinal products or other means of medical treatment, as well as goods to be used for health care or body care, medical goods intended for the disabled, pharmacy equipment, and medical instruments or apparatus.

*[1 June 2000; 16 April 2003; 23 October 2008]*

#### **Section 44.**

Veterinary medicinal product wholesalers are permitted to purchase, store and distribute only medicinal products, means of medical treatment and goods intended for care of animals. Medicinal products shall be labelled with a notice "Lietošanai dzīvniekiem" [For use in animals].

#### **Section 45.**

In order that a medicinal product wholesaler may commence operations it is necessary to provide for premises, equipment, facilities and personnel complying with the requirements of laws and regulations, as well as to in accordance with the procedures stipulated by the Cabinet obtain a special permit (licence) to open (operate) a medicinal product wholesaler or veterinary medicinal product wholesaler.

*[1 June 2000; 28 October 2010]*

#### **Section 45.<sup>1</sup>**

A medicinal product wholesaler, which has received a special permit (licence) to open (operate) a medicinal product wholesaler, is allowed to distribute veterinary medicinal products, if the distribution of veterinary medicinal products is specified as a special field of activity in the special permit (licence). The State Agency of Medicines shall inform the Food and Veterinary Service regarding the issued special permit (licence) and it shall register such a medicinal product wholesaler in the register of objects under supervision of the Service.

*[28 October 2010]*

#### **Section 46.**

*[22 April 2004]*

#### **Section 46.<sup>1</sup>**

(1) In a medicinal product wholesaler, in respect of the compliance with of good distribution practices, or in a veterinary medicinal product wholesaler, in respect of the distribution of veterinary medicinal products, a responsible official shall be approved:

1) whose education and professional experience complies with the requirements laid down in the laws and regulations regarding the distribution of medicinal products or veterinary medicinal products;

2) who does not suffer from mental illness, addiction to alcohol, narcotic, psychotropic or toxic substances;

3) who has an unimpeachable reputation, which shall be recognised if:

a) this person has been convicted of committing a criminal offence;

b) *[23 October 2008];*

c) this person has not been administratively penalised repeatedly within one year for violations of pharmaceutical or veterinary pharmaceutical activities;

4) *[23 October 2008].*

*[16 April 2003; 15 December 2005; 23 October 2008]*

#### **Section 47.**

A medicinal product wholesaler shall be liable for the quality of the medicinal products it distributes. It may purchase medicinal products only from medicinal product manufacturers, medicinal product importers and medicinal product wholesalers, at the same time receiving documents, which certify the quality of the medicinal products.

*[1 June 2000; 23 October 2008; 29 November 2012]*

#### **Section 48.**

(1) A medicinal product wholesaler is permitted to distribute medicinal products to pharmacies and medicinal product wholesalers, as well as to medical treatment institutions, social care institutions, practising veterinarians, physicians in practises and veterinary medical care merchants to enable their work in accordance with the procedures

stipulated by the Cabinet. A medicinal product wholesaler is allowed to distribute medicinal products to other persons or institutions only if they have a permit issued by the State Agency of medicines for purchase of medicinal products or - with regard to veterinary medicinal products - a permit issued by the Food and Veterinary Service for the purchase of veterinary medicinal products and if the relevant persons and institutions use the medicinal products only for the provision of the operation thereof, but they have no right to distribute these medicinal products.

(1<sup>1</sup>) A medicinal product wholesaler is permitted, in accordance with the procedures laid down in laws and regulations, to supply veterinary medicinal products to the Food and Veterinary Service for the performance of the functions laid down in the Veterinary Medicine Law.

(2) Medicinal products manufactured in foreign states may be imported to and distributed in the Republic of Latvia, if they have been acquired from manufacturers or distributors, which have been permitted to operate by the respective competent state authorities.

*[19 March 1998; 1 June 2000; 14 June 2001; 16 April 2003; 15 December 2005; 23 October 2008; 28 October 2010; 29 November 2012]*

#### **Section 49.**

Means of medical treatments, which are permitted to be distributed outside of pharmacies, may also be distributed by medicinal product wholesalers to other legal persons.

*[19 March 1998]*

## **Chapter VII Manufacturing and Importing of Medicinal Products and Active Substances and Distribution of Active Substances**

*[29 November 2012]*

#### **Section 50.**

A medicinal product manufacturer manufactures and distributes medicinal products and active substances.

*[1 June 2000; 16 April 2003; 23 October 2008]*

#### **Section 50.<sup>1</sup>**

A medicinal product importer imports and distributes medicinal products and active substances.

*[29 November 2012]*

#### **Section 51.**

(1) In order to manufacture medicinal products, it is necessary to provide premises, equipment, facilities and personnel complying with the requirements of laws and regulations, as well as to obtain a special permit (licence) to manufacture medicinal products or veterinary medicinal products in accordance with the procedures stipulated by the Cabinet.

(2) In order to manufacture, import or distribute active substances, it is necessary to provide premises, equipment, facilities and personnel complying with the requirements of laws and regulations, as well as to register the type of activity in accordance with the procedures stipulated by the Cabinet.

*[1 June 2000; 23 October 2008; 28 October 2010; 29 November 2012]*

#### **Section 51.<sup>1</sup>**

The principles and guidelines published in the European Commission Guidelines to good manufacturing practice for medicinal products shall be conformed to in the manufacture of medicinal products and active substances and in the control of the manufacture of medicinal products.

*[29 November 2012]*

### **Section 51.<sup>2</sup>**

A manufacturer or importer of medicinal products intended for human consumption is allowed to manufacture or import veterinary medicinal products, if the manufacture or importing of veterinary medicinal products is indicated as a field of activity of the special permit (licence) in the special permit (permit) to manufacture or import medicinal products. The State Agency of Medicines shall inform the Food and Veterinary Service regarding the issued special permit (licence), and it shall register such a medicinal product manufacturer and importer in the register of objects under supervision of the Service.

*[29 November 2012]*

### **Section 51.<sup>3</sup>**

In order to import medicinal products, it is necessary to provide premises, equipment, facilities and personnel complying with the requirements of laws and regulations regarding manufacture and control of medicinal products or veterinary medicinal products and to obtain a special permit (licence) to manufacture or import medicinal products or veterinary medicinal products, in accordance with the procedures laid down in the laws and regulations regarding licensing pharmaceutical or veterinary pharmaceutical activity, in which importing of medicinal products or importing of veterinary medicinal products is indicated as the field of activity.

*[29 November 2012]*

### **Section 52.**

In a medicinal product manufacturing undertaking in respect of the manufacture of medicinal products a qualified person shall be designated the qualifications and professional experience requirements of whom, shall be determined by the Cabinet.

*[19 March 1998; 16 April 2003]*

### **Section 52.<sup>1</sup>**

In a medicinal product importing undertaking an official responsible for importing of medicinal products shall be determined, whose qualifications and professional experience conform to the criteria for qualifications and professional experience of an official responsible for manufacturing of medicinal products laid down in the laws and regulations regarding manufacturing and control of medicinal products and veterinary medicinal products.

*[29 November 2012]*

### **Section 53.**

A medicinal product manufacturer shall ensure, in conformity with the approved documentation of technical standards, the quality control of medicinal products during the manufacturing and storage process, and shall be liable for the quality of the medicinal products manufactured irrespective of whether the full manufacturing process was performed on site or whether other natural or legal persons were also involved in it.

*[19 March 1998; 23 October 2008]*

### **Section 54.**

A medicinal product manufacturer or importer is permitted to distribute manufactured medicinal products only to other medicinal product manufacturers or importers, licensed medicinal product wholesalers, licensed pharmacies, medical treatment institutions and institutions of veterinary medicine.

*[29 November 2012]*

### **Section 55.**

A medicinal product manufacturer may also distribute means of medical treatment, which are permitted to be distributed outside of pharmacies, to other legal persons.

*[19 March 1998; 1 June 2000; 23 October 2008]*

**Section 56.**

A medicinal product manufacturer or importer has the right to give, in accordance with the procedures stipulated by the Cabinet, free samples of medicinal products to physicians and practising veterinarians, as well as to medical and veterinary medical educational and scientific institutions, informing the State Agency of Medicines in writing regarding such, but with respect to veterinary medicinal products - to the Food and Veterinary Service.

*[1 June 2000; 16 April 2003; 23 October 2008; 29 November 2012]*

## Chapter VIII Licensing and Certification

**Section 57.**

The Cabinet shall determine procedures according to which special permits (licences) and certificates shall be issued and revoked.

**Section 58.**

(1) A person has the right to receive a pharmacist professional qualification certificate:

1) who has acquired a higher pharmaceutical education in the Republic of Latvia or in a foreign state and whose acquired education and length of professional experience is recognised in accordance with the procedures laid down in laws and regulations. For the recognition of professional experience it is necessary that:

a) the pharmacist has uninterruptedly worked for three years in a pharmacy in the Republic of Latvia, a Member State of the European Union or a state in the European Economic Area. Professional experience gained in a foreign state shall be certified by a certificate or other document, which has been issued by the competent professional organisation of the relevant state,

b) the practice of the pharmacist in a pharmacy shall not be interrupted for longer than five years since the day when the submission to the certification authority was submitted for the acquisition of a pharmacist professional qualification certificate;

2) who does not suffer from mental illness, addiction to alcohol, narcotic, psychotropic or toxic substances;

3) who has an unimpeachable reputation, which shall be recognised if:

a) this person has been convicted of committing a criminal offence,

b) a court has not recognised this person as an insolvent debtor,

c) this person has not been administratively penalised repeatedly within one year for violations of pharmaceutical activities.

(2) The Latvian Pharmacist Society shall establish and maintain a pharmacist and pharmacist's assistant register and shall certify the length of his or her professional experience.

*[19 March 1998; 14 June 2001; 16 April 2003; 15 December 2005]*

**Section 59.**

*[28 October 2010]*

**Section 60.**

*[22 April 2004]*

**Section 60.<sup>1</sup>**

A special permit (licence) for opening (operating) a medicinal product wholesaler or for opening (operating) a veterinary medicinal product wholesaler may be obtained by a person, which complies with the requirements regarding

the distribution of medicinal products or veterinary medicinal products laid down in the laws and regulations governing the pharmacy or veterinary pharmacy.

*[16 April 2003; 23 October 2008]*

#### **Section 61.**

(1) Legal persons who have provided the necessary conditions for the manufacturing or importing and control of medicinal products and who have the personnel laid down in laws and regulations, have the right to receive a special permit (licence) to manufacture or import medicinal products.

(2) Legal persons who have provided the necessary conditions for the manufacturing or importing and control of veterinary medicinal products, as well as participation of the relevant specialists have the right to receive a permit (licence) to manufacture veterinary medicinal products. The licence shall indicate the veterinary medicinal products or pharmaceutical forms, which are permitted to be manufactured or imported.

*[29 November 2012]*

#### **Section 61.<sup>1</sup>**

(1) If the examination results of a manufacturer of medicinal products and active substances confirm the conformity with good manufacturing practice, the State Agency of Medicines shall issue an attestation of good manufacturing practice not later than within 90 days after receipt of the submission.

(2) If the examination results of a medicinal product wholesaler and a medicinal product manufacturer confirm the conformity with good distribution practice, the State Agency of Medicines shall issue an attestation of good distribution practice not later than within 90 days after receipt of the submission.

*[29 November 2012]*

#### **Section 62.**

A pharmacy, medicinal product wholesaler, medicinal product manufacturer, medicinal product importer, medical treatment institution, social care institution and veterinary medical care institution shall submit, respectively to the Ministry of Health, the State Agency of Medicines, the Food and Veterinary Service, the Health Inspectorate of Latvia and the Latvian Pharmacist Society, such information regarding their pharmaceutical activities and medicinal products as is necessary for the performance of the functions laid down in this Law and in other laws and regulations regarding the distribution and control of medicinal products.

*[1 June 2000; 14 June 2001; 16 April 2003; 27 September 2007; 23 October 2008; 28 October 2010; 29 November 2012]*

## **Chapter IX Liability for Failure to Observe the Pharmacy Law, Taking of Decisions and Control**

*[15 December 2005]*

#### **Section 63.**

For violations of this Law, persons shall be subject to liability as set out by law.

#### **Section 64.**

(1) The State Agency of Medicines, the National Health Service, the Health Inspectorate of Latvia and the Food and Veterinary Service in the performance of the functions laid down in laws and regulations shall take decisions in accordance with the procedures and time periods laid down in law insofar as this Law does not lay down otherwise.

(2) The State Agency of Medicines shall:

1) not later than within 90 days, examine and take a decision in respect of a submission regarding a reduction in the base price to be compensated for medicinal products and medical devices; and

2) not later than within 180 days, examine and take a decision in respect of a submission regarding the inclusion of medicinal products and medical devices in the list of medicinal products intended to be compensated in out-patient medical treatment.

(2<sup>1</sup>) The State Agency of Medicines shall review the submission regarding the commencement of the clinical investigation of medicinal products and shall take a decision not later than within 60 days.

(2<sup>2</sup>) The State Agency of Medicines shall review the registration form and the documents appended thereto and take a decision to perform an examination or to register the manufacturer, importer or distributor of active substances not later than within 60 days.

(3) Decisions taken by the State Agency of Medicines, the National Health Service and the Health Inspectorate of Latvia may be disputed to the Ministry of Health, but decisions taken by the Food and Veterinary Service - to the Ministry of Agriculture.

(4) Decisions of the Ministry of Health and the Ministry of Agriculture, which are taken regarding the decisions of the institutions referred to in this Section, may be appealed to a court in accordance with the procedures laid down in the Administrative Procedure Law.

(5) The dispute of the decisions referred to in Paragraph one of this Section and the appeal of decisions referred to in Paragraph four of this Section shall not hold the implementation of the relevant decision.

*[15 December 2005; 27 September 2007; 24 April 2008; 29 November 2012]*

#### **Section 64.<sup>1</sup>**

(1) The State Agency of Medicines and the Food and Veterinary Service shall, not later than within 90 days after receipt of a submission, take a decision to issue a special permit (licence) to manufacture or import medicinal products or veterinary medicinal products or to refuse to issue a licence.

(2) The State Agency of Medicines and the Food and Veterinary Service shall, not later than within 30 days (in an exceptional case - not later than within 90 days) from the day of receipt of a submission, take a decision to re-register a special permit (licence) to manufacture or import medicinal products or veterinary medicinal products, if it is necessary to make changes in information:

1) on the manufactured or imported medicinal products, pharmaceutical forms, location where they are manufactured or controlled, as well as on the qualified person;

2) on the premises which are intended for manufacturing or importing activities of medicinal products, on technical equipment and control possibilities in the manufacturing, quality control and storage process of medicinal products;

3) in relation to investigational medicinal products - on the types and forms of investigational medicinal products to be manufactured or imported, manufacturing and importing activities and manufacturing process (as in cases with deactivation of viruses or non-traditional agents), as well as on the location where investigational medicinal products are manufactured, on the premises which are intended for manufacturing or importing activities of investigational medicinal products, on technical equipment and control possibilities in the manufacturing, quality control and storage process of investigational medicinal products and on the qualified person.

(3) The State Agency of Medicines and the Food and Veterinary Service shall, not later than within 90 days after receipt of a submission, take a decision to issue a special permit (licence) to open (operate) a medicinal product or veterinary medicinal product wholesaler or to refuse to issue a licence.

*[29 November 2012]*

## **Chapter X**

### **Suspension of the Activity of Subjects of Pharmaceutical and Veterinary Pharmaceutical Activity**

*[24 April 2008]*

#### **Section 65.**

The decision regarding suspension of the activity of the subject of pharmaceutical and veterinary pharmaceutical activity, if the laws and regulations governing the field of pharmacy and veterinary pharmacy have been violated, in conformity with their competence, shall be taken by the manager of the Health Inspectorate of Latvia, deputy managers thereof, managers of territorial divisions of the Health Inspectorate of Latvia and deputy managers thereof or by the State chief food and veterinary inspector of the Food and Veterinary Service, senior inspectors and inspectors of the Food and Veterinary Service.

*[24 April 2008]*

#### **Section 66.**

(1) If the inspector of the Health Inspectorate of Latvia or the Food and Veterinary Service in conformity with the competence thereof has determined a violation of the laws and regulations governing the field of pharmacy and veterinary pharmacy, he or she shall express a written warning to the relevant subject of pharmaceutical and veterinary pharmaceutical activity. All of the determined violations of the laws and regulations governing the field of pharmacy and veterinary pharmacy shall be indicated in the warning and recommendations shall be provided, and the term for the elimination of violations shall be set.

(2) Taking into consideration the actual possibilities for the elimination of the violation, the term for the elimination of violations included in the warning shall be set to be not shorter than:

1) two years, if capital construction is necessary for the elimination of the violation;

2) six months, if partial reconstruction of buildings or renovation of equipment is necessary for the elimination of the violation.

(3) In other cases that are not referred to in Paragraph two of this Section, the inspector of the Health Inspectorate of Latvia or the Food and Veterinary Service, in conformity with the competence thereof and taking into consideration the actual possibilities for the elimination of the violation, shall set the term for the elimination of the violation to be from one month up to three months.

(4) If the violations indicated in the warning have not been eliminated within the specified term, the officials referred to in Section 65 of this Law shall take a decision to suspend the activity of the relevant subject of pharmaceutical and veterinary pharmaceutical activity.

(5) The suspension of the activity of the subject of pharmaceutical and veterinary pharmaceutical activity shall be ensured by the owner or a person authorised by the owner, if there is such, with the participation of the official who took the decision to suspend the activity, or an official authorised thereof.

(6) The suspension of the activity of the subject of pharmaceutical and veterinary pharmaceutical activity shall be carried out in such a manner that:

1) it is possible to eliminate the determined violations without hindrance;

2) the deterioration of premises and equipment due to meteorological circumstances or under the influence of corrosion is reduced as much as possible; and

3) the activity of other structural units and equipment is hindered as little as possible.

(7) The control of the suspension of the activity shall be ensured by an official who took the decision to suspend the activity or by a person authorised thereof.

(8) The activity of the subject of pharmaceutical and veterinary pharmaceutical activity may be suspended without a previous warning, if due to the violation of the laws and regulations governing pharmacy or veterinary pharmacy:

1) medicinal products not conforming with the quality or not allowed in Latvia are distributed;

2) the manufacture and distribution of separate medicinal products is carried out without a special permit (licence) or other permit, if such is necessary in accordance with the laws and regulations governing pharmacy or veterinary pharmacy;

3) dangerous substances, disease causing agents may reach foodstuffs of animal origin or environment and health or life of humans or animals is endangered.

(9) An official, who has the right to take the decision referred to in Paragraph eight of this Section regarding the suspension of the activity, shall take this decision not later than within three working days after the violations referred to in Paragraph eight of this Section have become known to him or her, and it shall be complied with immediately. The term for the elimination of other determined violations of the laws and regulations governing pharmacy or veterinary pharmacy shall be set in accordance with Paragraphs two and three of this Section.

*[24 April 2008]*

#### **Section 67.**

(1) The subject of the pharmaceutical and veterinary pharmaceutical activity shall notify in writing the official who took the decision to suspend the activity, regarding the elimination of the determined violations. Within five working days after the receipt of the notification, this official shall check whether the relevant violations have been eliminated.

(2) If all of the violations referred to in the warning or decision to suspend the activity have been eliminated, the relevant official shall provide a written permit for the renewal of the activity not later than within three working days after the performance of the check.

(3) If all of the violations referred to in the warning or decision to suspend the activity have not been eliminated, the relevant official shall refuse the renewal of the activity.

*[24 April 2008]*

#### **Section 68.**

(1) The submission in which the decision to suspend the activity without expressing a previous warning is contested shall be reviewed and a decision shall be taken within 10 working days after receipt of the submission.

(2) Contesting and appeal of the decisions of the Health Inspectorate of Latvia and the Food and Veterinary Service referred to in this Chapter shall not suspend the activity thereof.

*[24 April 2008]*

## **Transitional Provisions**

1. [19 March 1998]

2. Permits (licences) for establishing (operating) pharmacies, which have been issued to medicinal product wholesalers or medicinal product manufacturing undertakings, and permits (licences) for pharmaceutical activities prior to the coming into force of this Law shall retain their period of validity.

3. Certification of pharmacies, medicinal product wholesalers and medicinal product manufacturing undertakings, and professional qualification certification of pharmacist shall be commenced after the issuance of relevant Cabinet regulations.

4. Section 6, Clause 6; Section 7, Clause 2 and Section 20, Clauses 4 and 5 of this Law shall be in force until 1 January 2000.

*[17 December 1998]*

5. Section 59, Clause 3 of this Law shall be in force until 1 January 2000.

*[17 December 1998]*

6. With the coming into force of this Law, Cabinet Regulations No. 101, Pharmacy Regulations (*Latvijas Republikas Saeimas un Ministru Kabineta Ziņotājs*, 1996, No. 10) issued in accordance with Article 81 of the Constitution, is repealed.

7. Section 39 of this Law shall be in force until 31 December 2004.

*[19 March 1998]*

8. Permits for the distribution of medicaments, which were issued until 1 January 2000 pursuant to Section 6, Clause 6 of this Law, shall be in force until 1 July 2000.

9. Section 20, Clause 6 of this Law shall come into force on 1 January 2003.

*[1 June 2000]*

10. The branches of pharmacies, which do not comply with the requirements laid down in Section 36, shall terminate their operations by 31 December 2000.

*[1 June 2000]*

11. The Cabinet shall by 1 March 2002 issue regulations that regulate:

1) the procedures for conformity assessment of the pharmacies, medicinal product wholesalers and medicinal product manufacturing undertakings referred to in Section 5, Clause 1 of this Law;

2) the labelling of medicinal products referred to in Section 5, Clause 3 of this Law.

*[14 June 2001]*

12. The Cabinet shall by 1 July 2002 issue regulations that regulate the requirements to be met by medicinal product instructions for use (package leaflet) referred to in Section 5, Clause 12 of this Law.

13. The Cabinet shall by 1 January 2002 issue regulations that govern:

1) the procedures for conformity assessment of good distribution practices referred to in Section 5, Clause 14 of this Law;

2) the procedures for conformity assessment of good clinical practices referred to in Section 5, Clause 15 of this Law.

*[14 June 2001]*

14. [9 August 2010]

14.<sup>1</sup> Pharmacies, which have received a licence for establishing (operation) of a pharmacy the term of validity of which terminates by 31 December 2010 and the operation of which does not conform to the requirements laid down in Section 36, of this Law, have the right to receive an extension of licence until 31 December 2011.

*[9 August 2010]*

15. Until the establishment of the "Valsts zāļu aģentūra [State Agency of Medicines]" is the representative of the holder of the State capital share in the State Agency of Medicines.

*[16 April 2003]*

16. The Cabinet shall by 1 January 2004 issue regulations that govern the procedures for the registration of pharmacists and pharmacist's assistants referred to in Section 5, Clause 17 of this Law.

*[16 April 2003]*

17. The coming into force of Section 17, Paragraph two; Section 22, Paragraph three; Section 25.<sup>1</sup>; Section 31, Clause 7; Section 38, Paragraph three; Sections 46.<sup>1</sup> and 60.<sup>1</sup> shall be laid down by a special law.

*[16 April 2003]*

18. The repeal of Sections 46 and 60 of this Law shall be laid down by a special law.

*[16 April 2003]*

19. Permits for the management of pharmacies issued by the Ministry of Welfare up to 31 January 2003 are in effect until the end of the time period referred to in the permit.

*[16 April 2003]*

20. A pharmacist's assistant who has received a permit for the management of a pharmacy issued by the Ministry of Health, but does not conform to the requirements, which in accordance with Section 39 of this Law are required by a manager from 1 July 2004, may manage a pharmacy until the end of the time period referred to in the permit.

*[16 April 2003]*

21. Section 39 of this Law is in force until 31 December 2010.

*[16 April 2003]*

22. By the day when the Cabinet Regulation referred to in Clause 1, Section 5 of this Law governing the procedures for issuing, suspending, re-registering and revoking special permits (licences) for pharmaceutical activities and of professional qualification certificates for pharmacists, as well as the requirements for commencement of operating and operating of pharmacies, medicinal product wholesalers and medicinal product manufacturing, and the procedures for conformity assessment, and the Cabinet Regulation referred to in Clause 14, Section 5 of this Law governing the procedures for evaluating conformity of distribution of medicinal products (except veterinary medicinal products) with the requirements of good distribution practices shall come into force, but not longer than until 1 April 2010 the following shall be applicable:

1) Cabinet Regulation No. 248 of 6 July 1999, Procedures for Certification of Professional Qualification of Pharmacists;

2) Cabinet Regulation No. 227 of 22 May 2001, Requirements for Opening and Operating of Pharmacies;

3) Cabinet Regulation No. 229 of 1 April 2004, Procedures for Issuance, Suspension, Re-registration and Revoking of Special Permits (Licences) for Veterinary Pharmaceutical Activities; and

4) Cabinet Regulation No. 415 of 26 June 2007, Procedures for Issuance, Suspension, Re-registration and Cancellation of Special Permits (Licences) for Pharmaceutical and Veterinary Pharmaceutical Activities, Paying of State Fee for Issuance and Re-registration Thereof, as well as Conformity Assessment of Pharmacies, Medicinal Product and Veterinary Medicinal Product Wholesalers and Medicinal Product and Veterinary Medicinal Product Manufacturing Undertakings and Goods Distribution Practices of medicinal Products, in so far as they are not in contradiction to this Law.

*[23 October 2008; 12 March 2009]*

23. By the day when the Cabinet Regulation referred to in Clause 15, Section 5 of this Law governing the procedures for evaluating conformity of clinical research of medicinal products (except veterinary medicinal products) with the requirements of good clinical practices shall come into force, but no longer than until 1 April 2010 the Cabinet Regulation No. 172 of 28 February 2006, Regulations Regarding the Conduct of Clinical Trials and Non-interventional Trials, the Procedures for the Labelling of Investigational Medicinal Products and the Procedures for Inspection of Conformity with the Requirements of Good Clinical Practice shall be applicable insofar as they are not in contradiction to this Law.

*[23 October 2008; 12 March 2009]*

24. New wording of Section 36, Section 38, Paragraph 1.<sup>1</sup> of this Law and amendments to Section 42 in respect of substitution of words and figure "rural area, where...5" with words and figure "in a county, county's city or county's parish where the number of inhabitants does not exceed 4000 and ...five" shall come into force on 1 January 2011.

*[9 August 2010]*

25. A person, who is distributing veterinary medicinal products in a pharmacy which has started operation thereof until 31 December 2010, is entitled to distribute veterinary medicinal products without a certificate for the distribution of veterinary medicinal products until 1 July 2012.

*[28 October 2010]*

26. Until 31 January 2013 the Cabinet shall make amendments to Cabinet Regulation No. 758 of 4 October 2011, Procedures for Issuing, Revoking and Extending the Term of Validity of a Certificate for Distribution of Veterinary Medicinal Products and for Registering the Certified Person, laying down the procedures by which assessment of qualification shall be performed.

*[29 November 2012]*

27. Section 10, Clause 1.1 of this Law shall come into force on 1 July 2013.

[29 November 2012]

## Informatve Reference to the European Union Directives

[29 November 2012]

This Law contains legal norms arising from:

- 1) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products;
- 2) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;
- 3) Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products;
- 4) Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use;
- 5) Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

This Law has been adopted by the *Saeima* on 10 April 1997.

President G. Ulmanis

Rīga, 24 April 1997.

## Transitional Provisions Regarding Amendments to the Pharmacy Law

### Transitional Provisions

(regarding amending Law of 1 June 2000)

With the coming into force of this Law, the Cabinet Regulation No. 428, Amendments to the Pharmacy Law issued in accordance with Article 81 of the Constitution (*Latvijas Republikas Saeimas un Ministru Kabineta Ziņotājs*, 2000, No. 2) is repealed.

### Transitional Provisions

(regarding amending Law of 14 June 2001)

This Law shall come into force on 1 July 2001.

### Transitional Provisions

(regarding amending Law of 16 April 2003)

With the coming into force of this Law, the Cabinet Regulation No. 3, Amendments to the Pharmacy Law issued in accordance with Article 81 of the Constitution (*Latvijas Vēstnesis*, 2003, No. 4), is repealed.

## **Transitional Provisions**

(regarding amending Law of 27 September 2007)

This Law shall come into force on the day following the proclamation thereof.

## **Transitional Provisions**

(regarding amending Law of 1 December 2009)

This Law shall come into force on 1 January 2010.

## **Transitional Provisions**

(regarding amending Law of 9 August 2010)

This Law shall come into force on the day following the proclamation thereof.

## **Transitional Provisions**

(regarding amending Law of 28 October 2010)

This Law shall come into force on 1 January 2011.

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<sup>1</sup> The Parliament of the Republic of Latvia

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