

REPUBLIC OF LITHUANIA

LAW ON PHARMACY

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Vilnius

CHAPTER I

GENERAL PROVISIONS

Article 1. Purpose of the Law

1. This Law shall regulate pharmaceutical and other activity related to medicinal investigational products, veterinary pharmaceuticals, active and other medicinal substances as well as medicinal purpose products, veterinary pharmaceutical activity as well as state management and control of the activity.

2. This Law shall not regulate the activity related to precursors of narcotic and psychotropic substances, state management and control of the activity.

3. The provisions of this Law have been harmonized with the legal acts of the European Union specified in Annex to this Law.

Article 2. Definitions

1. **Biological medicinal product** means medicinal product the active substance(s) of which are either biological substance(s) or biological preparations or a mixture of such biological substance(s) and such biological preparation(s).

2. **Community Code of Medicinal Products** means the list of medicinal products which by the decision of the Commission is granted a marketing authorisation in all EU Member States.

3. **Common name of the medicinal product** (hereinafter – common name) means the international non-proprietary name recommended by the World Health Organisation or, if one does not exist, the usual common name.

4. **Decentralised procedure** means the procedure during which the Member States of the European Economic Area (hereinafter the EEA) cooperates in considering applications for granting marketing authorisation of a medicinal product based on an identical dossier when such an authorisation has not yet been granted in any EEA Member State.

5. **Wholesale distribution of medicinal products** means pharmaceutical activity consisting of acquisition, holding, supply or export of medicinal products, except for their supply to natural persons.

6. **Extemporaneous medicinal product** means any medicinal product manufactured in a pharmacy for an individual subject of care based on a recipe on order of a health care establishment (*Magistral Formula*) or a medicinal product manufactured in accordance with the prescriptions of a pharmacopoeia (*Officinal Formula*).

7. **European pharmacopoeia** means the pharmacopoeia drawn up according to the Convention on the Elaboration of a European Pharmacopoeia.

8. **European Medicines Agency** means the Agency established according to the Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

9. **Pharmacy practice** means practice of a pharmacist and of a pharmacist's assistant (pharmacy technician):

- 1) **pharmacist's practice** means pharmaceutical activity carried out by a pharmacist;
- 2) **practice of a pharmacist's assistant (pharmacy technician)** means pharmaceutical activity carried out by a pharmacist's assistant (pharmacy technician).

10. **Pharmaceutical product** means any medicinal product, investigational medicinal product, active substance and excipient entered in the list of the European Commission which are used as starting materials in the manufacture of medicinal products, medicinal purpose product.

11. **Pharmaceutical specialist** means pharmacist, pharmacist's assistant (pharmacy technician) or the person equated to them according to the procedure established by an institution authorised by the Government.

12. **Pharmaceutical information** means information about pharmaceutical, clinical, pharmacological peculiarities of a medicinal product announced and spread in any form and by any means, also the prices of medicinal products in trade catalogues and price lists (if they contain no statements about the peculiarities of medicinal products).

13. **Pharmacy service** means the pharmacist's practice in the pharmacy covering the control, evaluation of prescriptions issued by a doctor, selection of non-prescription medicinal products, supply to the general public, health care professionals and pharmaceutical specialists of pharmaceutical information about medicinal products, as well as provision of consultation to them.

14. **Pharmaceutical activity** means health promotion activity carried out by legal and/or natural persons, covering the manufacture, import from third countries, quality control of medicinal products, investigational medicinal products, active substances and excipients entered in the list of the European Commission which are used as starting materials for the manufacture of medicinal products; wholesale distribution of medicinal products, active substances and excipients entered in

the list of the European Commission which are used as starting materials for the manufacture of medicinal products; parallel import of medicinal products, sale (dispensing) to the ultimate consumer; provision of pharmaceutical information about medicinal products and pharmaceutical waste management, except for its disposal.

15. **Pharmaceutical waste** means medicinal products that are subject to disposal (medicinal products that are defective, past the expiry date, confiscated, collected from the general public or counterfeit or waste materials from investigational medicinal products) and chemical materials used for the conduct of trials of medicinal products or defective chemical materials past the expiry date which were acquired for the purpose of conducting such trials.

16. **Pharmacovigilance** means a system of establishing, evaluating, reporting adverse reactions connected with the medicinal product and of preventing such risks.

17. **Generic medicinal product** means a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

18. **Homeopathic medicinal product** (hereinafter referred to as **homeopathic product**) shall mean any medicinal product prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain more than one component.

19. **Immunological medicinal product** (hereinafter referred to as **immunological product**) means medicinal product used to produce active or passive immunity or to diagnose the state of immunity, egg.: vaccine, toxin and serum, or any medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an eliciting agent, egg. any allergen product.

20. **Information about medicinal products** means public information that may be provided as pharmaceutical information or as advertisement of medicinal products.

21. **Outer packaging** means the packaging into which is placed the immediate packaging.

22. **Clinical trial of a medicinal product** means any biomedical investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal products with the object of ascertaining its/their safety and/or efficacy.

23. **Reimbursable medicinal products** means medicinal products which are entered in the Price List of Reimbursable Medicinal Products and whose purchasing expenses or their part are subject to reimbursement from the budgetary resources of the Compulsory Health Insurance Fund for persons insured by compulsory health insurance.

24. **Medicinal product derived from human blood and plasma** means medicinal product industrially prepared by legal persons having such right.

25. **Republic of Lithuania Register of Medicinal Products** means the totality of legal, organisational, technological measures intended for granting medicinal products marketing authorisation and processing the marketing authorisation data. Entered in the Register shall be medicinal products for which marketing authorisation or marketing authorisation certificate has been issued.

26. **Medicinal purposes product** means a foodstuff having a pharmaceutical form, containing biologically active substances which condition its effect on the physiological functions of the human organism established by clinical trials and/or reasonable scientific literature and which is intended for strengthening the organism, its systems or organs and for maintaining their functioning.

27. **Benefit/risk balance** means the relationship of a beneficial therapeutic effect of a medicinal product and the danger posed to the health of person and society established when evaluating the pharmaceutical product with regard to quality, safety and efficacy.

28. **Adverse reaction** means a response to a medicinal product which is noxious and unintended and which occurs at doses of registered medicinal product normally used in a man intended for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function or any dose of the investigational medicinal product.

29. **Adverse event** means any untoward occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.

30. **Unexpected adverse reaction** means an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics (e.g. summary of product characteristics for an authorised product or investigator's brochure for an unauthorised investigational product).

31. **Package leaflet** means a leaflet containing information for the user which change accompanies the medicinal product.

32. **Periodic safety update report** means a periodic record intended to update the medicinal product safety data and to submit it according to the procedure established by the State Medicines Control Agency.

33. **Abuse of medicinal products** means persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects.

34. **Post-authorisation safety studies** means pharmacological, epidemiological or clinical study performed according to the terms of marketing authorisation of medicinal product in order to establish or quantitatively assess the safety of the medicinal product.

35. **Radiopharmaceutical medicinal product** (hereinafter referred to as **radiopharmaceutical product**) means any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medical purpose.

36. **Radionuclide generator** means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other method and used in a radiopharmaceutical product.

37. **Radionuclide precursor** means any other radionuclide produced for the radio-labelling of another substance prior to administration.

38. **Radionuclide kit** means any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration.

39. **Medicinal product subject to medical prescription** means a medicinal product assignment of which to this group of medicinal products is subject to certification by the State Medicines Control Agency or the European Medicines Agency.

40. **Reference state** means an EEA State which drafts the protocol of assessment of pharmaceutical, pre-clinical and clinical medicinal product research results, on the basis whereof other EEA states taking part in the procedure of mutual recognition or decentralised procedure take a decision on the granting of marketing authorisation of the medicinal product.

41. **Reference medicinal product** means a medicinal product granted marketing authorisation in any EEA State according to its internal legislation brought in line with the requirements of Article 6 of 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, applying the provisions set in Article 8.

42. **Mutual recognition procedure** means procedure in the course whereof the EEA State(es) in cooperation examine the application(identical applications) to recognise the granted another medicinal preparation by an EEA State.

43. **Special validation** means actions whereby the suitability of any procedure, process, equipment, material, activity or system is proved according to the principles of good manufacturing practice for attaining the intended results.

44. **Serious effect of adverse reaction** means an adverse reaction which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.

45. **Serious adverse event** means any ontoward medical occurrence or effect that at any dose results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or in a congenital anomaly or birth defect.

46. **Investigator** means a doctor or a person whose scientific background and the experience in patient care meets the requirements set by the Minister of Health of the Republic of Lithuania (hereinafter referred to as the Minister of Health) for the investigation of medicinal products. The investigator shall be responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the leader responsible for the team and may be called the principal investigator.

47. **Investigational medicinal product** means a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.

48. **Manufacture of an investigational product** means industrial manufacture of an investigational medicinal product or its manufacture by a method involving an industrial process

49. **Traditional herbal medicinal product** (hereinafter referred to as **traditional herbal product**) means herbal medicinal product which meets the criteria set by the Minister of Health and which may be applied the simplified herbal medicinal products registration procedure.

50. **Medicine (medicinal product)** means any substance or combination of substances manufactured and presented for treating or preventing disease in human beings as it meets at least one of the following criteria: 1) has properties which make it suitable for treating or preventing human diseases; 2) due to pharmacological, immunological or metabolic action may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions or to making a medical diagnosis.

51. **Pharmacy** means a legal person performing pharmaceutical activity covering the acquisition, keeping, sale (dispensing) of medicinal products to the ultimate consumer, provision of pharmacy services and/or manufacture, quality control of extemporaneous medicinal products. As used in this Law the term “pharmacy” does not apply to veterinary pharmacies.

52. **Medicinal substance** means any substance irrespective of origin which may be 1) human, e.g. human blood and human blood products; 2) animal, e.g. micro-organisms, whole

animals, parts of organs, animal secretions, toxins, extracts, blood products; 3) vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts; 4) chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.

53. **Pharmacist** means a person who has acquired professional qualification of a pharmacist and awarded MPharm degree or a person equated to him according to the procedure established by an institution authorised by the Government.

54. **Pharmacist's assistant (pharmacy technician)** means a person who has acquired the qualification of a pharmacist's assistant (pharmacy technician) or a person equated to him according to the procedure established by an institution authorised by the Government.

55. **Manufacture of a medicinal product** means industrial manufacture of a medicinal product or its manufacture applying the method embracing industrial manufacture process.

56. **Permit for parallel import of medicinal product** means a document issued by the State Medicines Control Agency, the holder of which is authorised to parallel import a medicinal product and to perform its marketing.

57. **Parallel import of a medicinal product** means import into the Republic of Lithuania outside the distribution network of the authorised distributor of the product granted marketing authorisation in another EEA Member State, which is identical to the medicinal product already granted marketing authorisation in the Republic of Lithuania or sufficiently resembling it.

58. **Free sample of a medicinal product** means free sample of a medicinal product not intended for use, to be provided for acquainting with it a health care professional qualified to prescribe medicinal products.

59. **Name of the medicinal product** means an invented name given to a medicinal product (which shall not be liable to confusion with the common name) or either a common or scientific name, together with a trade mark or the name of the holder of the marketing authorisation.

60. **Registration certificate of a medicinal product** (hereinafter referred to as **registration certificate**) means the document of the State Medicines Control Agency certifying the granting of marketing authorisation in the Republic of Lithuania for a homeopathic or traditional biological medicinal product and issued according to a simplified procedure for registering homeopathic or traditional biological products or a special registration procedure for the homeopathic medicinal products established by this Law.

61. **Marketing authorisation certificate of a medicinal product** (hereinafter referred to as **marketing authorisation certificate**) means the document of the State Medicines Control Agency certifying that a medicinal product holds marketing authorisation in the Republic of Lithuania,

which is issued according to the medicinal products registration procedures established by this Law except for a simplified procedure for registering homeopathic or traditional biological products or a special registration procedure for the homeopathic medicinal products.

62. **Terms of marketing authorisation of a medicinal product** means the totality of data and information of the marketing authorisation and documents on the basis of which it has been issued.

63. **Varying the terms of marketing authorisation of a medicinal product** means a variation in the terms of a marketing authorisation of medicinal products provided for by Commission Regulation (EC) No 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation of medicinal products for human use and veterinary pharmaceuticals granted by a competent authority of a Member State or the varying of the terms of marketing authorisation not attributed to the variations, established by the Minister of Health.

64. **Extension to a marketing authorisation of a medicinal product** means varying the terms of a marketing authorisation of medicinal products provided for by Commission Regulation (EC) No 1084/2003 of 3 June 2003 concerning the examination of changes to the active substance, its pharmacokinetics, strength, pharmaceutical form or change or addition of a new route of administration.

65. **Medicinal product marketing authorisation** (hereinafter referred to as **marketing authorisation**) means a person's right to organise the supply of a medicinal product to the market, advertising and marketing management measures.

66. **Holder of medicinal product marketing authorisation** means a legal person who has been granted the medicinal product marketing authorisation according to the requirements of legal acts.

67. **Representative of the holder of medicinal product marketing authorisation** means the representative appointed in the Member State by the holder of the medicinal product marketing authorisation.

68. **Strength of the medicinal product** means the content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or weight (according to the dosage form).

69. **Pharmacy goods** means goods the list of groups whereof is approved by the Minister of Health and which are allowed to be acquired, kept and sold (dispensed) in pharmacies. The term shall not cover medicinal products.

70. **Advertising of medicinal products** means the spread among the general public, health care professionals and pharmaceutical specialists in any form and by any means of purposive

information about medicinal products, the canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products, including:

- 1) visits by medical sale representatives to persons qualified to prescribe medicinal products;
- 2) the supply of samples of medicinal products;
- 3) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of a benefit or bonus, whether in money or in kind;
- 4) sponsorship in promotional meetings, attended by health care and pharmaceutical specialists qualified to prescribe or supply medicinal products;
- 5) sponsorship of scientific congresses attended by health care professionals and pharmaceutical specialists qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith;
- 6) the support of radio, television broadcasts and/or programmes during which information about medicinal products is supplied.

71. **Advertiser of medicines** means a legal person authorised by the marketing authorisation holder and/or his representative to carry out advertising of medicinal products.

72. **Bearer prescription medicinal product** means a medicinal product to which marketing authorisation has not been granted which is indispensable for an individual patient, supplied to the Republic of Lithuania on the prescription of the patient's doctor, submitted according to the procedure established by the Minister of Health and intended to be used under direct responsibility of the doctor.

73. **Veterinary paramedic** means a legal person who has acquired professional qualification of a veterinary paramedic or a professional qualification recognised as equivalent to it according to the procedure established by the institution authorised by the Government.

74. **Veterinary surgeon** means a person possessing a diploma certifying completion of university education according to the procedure established by an institution authorised by the Government.

75. **Veterinary pharmacy** means a legal person entitled to acquire, hold, sell/dispense, manufacture veterinary pharmaceuticals and control the quality thereof.

76. **Veterinary pharmaceutical activity** means activity of legal and/or natural persons covering the manufacture, import, supply (trade in), quality control of veterinary pharmaceutical and processing of veterinary pharmaceutical waste.

77. **Veterinary pharmaceutical company** means a legal person engaged in veterinary pharmaceutical business.

78. **Manager of veterinary pharmaceutical activity** means a natural person meeting the established requirements and appointed by a legal person holding a veterinary pharmaceutical activity licence to manage veterinary pharmaceutical activity.

79. **Veterinary pharmaceuticals** means any substance or combination of substances presented for treating or preventing diseases in animals or administered in animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals.

80. **Register of veterinary pharmaceuticals** means the system of storing, protection and management of data of the veterinary medicinal products authorised for use in the Republic of Lithuania.

81. **Immediate packaging** means the container or other form of packaging immediately in contact with the medicinal product.

82. **Labelling** means information on the immediate or outer packaging.

CHAPTER II

RECOGNITION OF QUALIFICATION OF PHARMACISTS AND PHARMACIST'S ASSISTANTS (PHARMACY TECHNICIANS), LICENSING REGISTRATION, COMPETENCE AND SUPERVISION OF QUALIFICATION

Article 3. Recognition of Qualification of Pharmacists and Pharmacist's Assistants (Pharmacy Technicians)

1. Pharmacy diplomas issued by institutions of post-secondary education and higher educational institutions of the Republic of Lithuania as well as pharmacy diplomas, certificates and other documents testifying to professional qualification recognized by an institution authorised by the Government issued in other states provided they meet the minimum requirements of pharmacy study programmes for pharmaceutical specialists valid in the European Union shall be valid in the Republic of Lithuania.

2. Professional qualification (preparedness and experience) of a pharmacist and of a pharmacist's assistant (pharmacy technician) acquired in foreign states shall be assessed and recognised by an institution authorised by the Government.

Article 4. Licensing of the Pharmacist's Practice

1. The pharmacist may carry out the duties of a pharmacist in a community pharmacy, production community pharmacy, hospital pharmacy, production hospital pharmacy, university pharmacy and charity pharmacy only holding a pharmacist's practice licence.

2. A pharmacist's practice licence shall be issued for an indefinite period.

3. A pharmacist's practice licence shall be issued, refused to be issued and revoked by the State Medicines Control Agency invoking this Law and the Rules of Licensing of Pharmacist's Practice approved by the Minister of Health. The person aspiring to obtain a licence for pharmaceutical activity must submit an application, a diploma certifying the acquired professional qualification of a pharmacist and other documents established by the Rules of Licensing of Pharmacist's Practice. If the person wishes to acquire a licence after the lapse of more than one year after graduation, he must also submit documents certifying that his qualification has been improved according to the procedure established by the Minister of Health.

5. The decision on the issuing of the licence or a justified refusal to issue the licence must be presented to the applicant not later than within 30 days from the receipt of all the documents. The time limit within which the applicant shall submit the missing data shall not be included in the period of decision making but if the applicant delays to specify the data the decision must be made not later than within 60 days from the receipt of documents.

6. The State Medicines Control Agency shall publish a notice on the issuance of the pharmacist's practice licence and the revocation of the licence in the information supplement to the official gazette "*Valstybės žinios*".

7. A state fee of the established amount shall be paid for the issuing of the licence.

8. Issuing of a pharmacist's practice licence shall be refused if:

1) not all documents have been submitted or if the submitted documents do not meet the established requirements, are not duly executed;

2) erroneous data has been given in the documents;

3) the person's legal capacity has been restricted by an effective court decision;

4) the person has been prohibited from engaging in the pharmacist's practice by an effective court decision;

5) a State fee of the established amount has not been paid.

9. The licence shall be revoked:

1) upon the request of the licence holder;

2) if the licence holder committed a violation of pharmaceutical activity resulting in heavy consequences which were determined by the institutions controlling the pharmaceutical activity;

3) if erroneous data has been submitted for the issuance of the licence;

4) if legal capacity of the licence holder has been restricted by an effective court decision;

5) if the licence holder has been prohibited by an effective court decision from engaging in the pharmaceutical activity;

6) if the licence holder failed to discharge the obligation established in Subparagraph 2 of paragraph 3 of Article 7;

7) if the licence holder dies.

10. After the revocation of the licence the pharmacist and the employer shall be within 10 days notified thereof in writing with the reasons thereof specified.

11. A new licence to engage in pharmaceutical activity may be issued on the applicant's request upon having submitted the documents specified in the rules for licensing the pharmaceutical activity only after the lapse of 6 months from the day of the licence except in cases where the licence has been revoked by an effective court decision or the person's legal capacity has been restricted by an effective court decision. In such case a new licence may be issued not earlier than after the expiry of the time limit specified in the court decision or after the lifting by the court of the restrictions of legal capacity. The 6 months time period shall not apply where the licence is revoked upon the request of the licence holder.

12. The decisions of the institutions issuing the licences shall be subject to appeal according to the procedure established by legal acts.

Article 5. Registration of the Pharmacist's Assistant (Pharmacy Technician)

1. The pharmacist's assistant (pharmacy technician) shall have the right to engage in the practice of pharmacist's assistant (pharmacy technician) in the pharmacy from the day of entry of the pharmacist's assistant (pharmacy technician) in the List of Pharmacist's Assistants (Pharmacy Technicians).

2. Entry in the List of Pharmacist's Assistants (Pharmacy technicians) shall be made on the decision of the State Medicines Control Agency. The pharmacist's assistant (pharmacy technician) shall submit to the State Medicines Control Agency an application in the established form requesting to be entered in the List of Pharmacist's Assistants (Pharmacy Technicians), a diploma certifying the acquired professional qualification of the pharmacist's assistant (pharmacy technician) and other documents specified by the Minister of Health.

3. State Medicines Control Agency shall take a decision to enter or to refuse entering the pharmacist's assistant (pharmacy technician) in the List of Pharmacist's Assistants (pharmacy technicians) no later than within 30 days from the day of receipt of the documents specified in paragraph 2 of this Article if the pharmacist's assistant (pharmacy technician) meets the requirements laid down by this Law and the Minister of Health.

4. The applicant with respect to whom a decision is take not to enter him in the List of Pharmacist's Assistants (Pharmacy technicians) shall have the right to appeal the decision according to the procedure established by legal acts

5. In case the contract of employment regarding the practice of the pharmacist's assistant (pharmacy technician) is concluded with the person who is not entered in the List of Pharmacist's Assistants (pharmacy technicians), the employer shall be held liable according to the procedure laid down by legal acts for the failure to meet the requirement set in paragraph 1 of this Article.

6. The pharmacist's assistants (pharmacy technicians) must every 5 years submit to the State Medicines Control Agency documents confirming the improvement of professional qualification of the pharmacist's assistant (pharmacy technician) according to the procedure laid down by the Minister of Health.

7. The applicant shall not be entered in the List if:

- 1) not all documents have been submitted or they do not meet the requirements, have not been duly executed;
- 2) erroneous data have been given in the documents;
- 3) the person's legal capacity has been restricted by an effective court decision;
- 4) the person has been prohibited by an effective court decision from engaging in the practice of the pharmacist's assistant (pharmacy technician).

8. The pharmacist's assistant (pharmacy technician) is removed from the List of Pharmacist's Assistants (Pharmacy Technicians):

- 1) upon his own request;
- 2) if the pharmacist's assistant (pharmacy technician) is prohibited by an effective court decision from performing the activities of the pharmacist's assistant (pharmacy technician);
- 3) if legal capacity of the pharmacist's assistant (pharmacy technician) is restricted by an effective court decision;
- 4) if it transpires that the applicant submitted erroneous data for the entry in the list;
- 5) in case of failure by the pharmacist's assistant (pharmacy technician) to discharge the duty specified in paragraph 6 of this Article; 6) in case of death of the pharmacist's assistant (pharmacy technician).

Article 6. Improvement of Qualifications of Pharmacists and Pharmacist's Assistants (Pharmacy Technicians)

1. Improvement of qualifications of pharmacists and pharmacist's assistants (pharmacy technicians) shall be carried out according to the procedure established by the Minister of Health by the higher educational establishments and related NGOs of the Republic of Lithuania.

2. The employees engaged in the improvement of qualifications shall be excused from work according to the procedure established in the Labour Code.

Article 7. Rights and Duties of Pharmacists and Pharmacist's Assistants (Pharmacy Technicians)

1. The rights, duties, professional competence and responsibility of pharmacists and pharmacist's assistants (pharmacy technicians) shall be established in this Law, the schedule of rights and duties of pharmacists and pharmacist's assistants (pharmacy technicians) approved by the Minister of Health, other legal acts, description of the posts of the pharmacist and pharmacist's assistant (pharmacy technician).

2. The pharmacists shall have the right to:

1) engage in the pharmaceutical activity according to the procedure established by this Law and other legal acts;

2) sell/dispense to the general public medicinal products and pharmacy goods;

3) engage in extemporaneous preparation of medicinal products and quality control of such preparations;

4) receive information required for the pharmaceutical activity, when necessary cooperate with health care professionals and receive information about the medicinal products intended for patients and used by them;

5) inform and consult the residents about rational use of medicinal products, propagate healthy way of living;

6) refuse to sell/dispense medicinal products if this would be contrary to the pharmacist's principles of professional ethics or may present direct danger to the person's life or cause harm to his health;

7) take part in the activities of pharmacists' professional organisations if other legal acts do not establish otherwise.

3. The pharmacist must:

1) improve his professional qualifications according to the procedure established by the Minister of Health;

2) at least once in 5 years notify the State Medicines Control Agency according to the procedure established by the rules for licensing the pharmaceutical activity of the improvement of the pharmacist's professional qualifications and the pharmaceutical activity, if the pharmacist performs pharmaceutical activities in the pharmacy;

3) respect the principles of pharmacist's professional ethics;

4) fulfil other duties established by legal acts.

4. The pharmacist's assistant (pharmacy technician) shall have the right to:

1) engage in the practice of the pharmacist's assistant (pharmacy technician) according to the procedure established in this Law and other legal acts;

- 2) sell pharmacy goods, provide information about the conditions of their use or storing, sell/dispense medicinal products under the control of the pharmacist;
 - 3) manufacture extemporaneous medicinal products;
 - 4) manage stocks of medicinal products and pharmacy goods;
 - 5) receive information necessary for the performance of practice of the pharmacist's assistant (pharmacy technician);
 - 6) take part in the activities of professional organisations of pharmacist's assistants (pharmacy technicians) if other legal acts do not establish otherwise.
5. The pharmacist's assistant (pharmacy technician) must:
- 1) improve his professional qualification according to the procedure established by the Minister of Health;
 - 2) respect the principles of pharmacist's professional ethics;
 - 3) performing the practice of the pharmacist's assistant (pharmacy technician) cooperate with pharmacists and health care professionals;
 - 4) perform other duties established by legal acts.
6. The pharmacist and the pharmacist's assistant (pharmacy technician) shall also have other rights established by other legal acts.

CHAPTER III

SUPPLY OF MEDICINAL PRODUCTS TO THE MARKET

Article 8. General Provisions

1. Medicinal products manufactured industrially or by a method involving an industrial process may be supplied to the market of the Republic of Lithuania only if registered in the Register of Medicinal Products of the Republic of Lithuania, in the Community Code of Medicinal Products or entered in the List of Parallely Imported Medicinal Products (hereinafter referred to as medicinal products granted marketing authorisation).
2. The marketing authorisation requirement shall also apply to radionuclide generators, sets of radionuclides, radiopharmaceutical products – radionuclide precursors and industrially manufactured radiopharmaceutical products.
3. The following medicinal products not granted marketing authorisation may be supplied to the market of the Republic of Lithuania and used for health care according to the procedure established by the Minister of Health:

1) the necessary medicinal products if they have been granted marketing authorisation in any EEA state;

2) bearer prescription medicinal products where the doctor prescribing them for the use of a single patient assumes direct and personal responsibility.

4. Only legal persons who have received a wholesale distribution licence according to the procedure established by this Law may bring into the Republic of Lithuania from another EEA state medicinal products not granted marketing authorisation or import from a third country bearer prescription medicinal products.

5. The Minister of Health may provisionally grant an authorisation to place on the market of the Republic of Lithuania medicinal products not granted marketing authorisation that are necessary to be used when pathogenic or chemical factors, toxins or ionising radiation posing a health hazard is suspected or established, also if a natural disaster occurs.

6. Without derogating from the requirements of the procedure of supply of bearer prescription medicinal products laid down by the Minister of Health, the holders of the marketing authorisation, the manufacturers and health care professionals shall not be held liable for the consequences of the use of medicinal products not granted marketing authorisation or medicinal products which have been granted marketing authorisation without approved indications, if recommended or instructed to use them by the Ministry of Health, having suspected or established the presence of pathogenic or chemical factors, toxins or ionising radiation which pose a danger to health or after the happening of a natural disaster. The above provision shall not apply in the cases established in the Civil Code of the Republic of Lithuania regarding the products of inferior quality.

7. The requirements of marketing authorisation, manufacturing, wholesale distribution, advertising of a medicinal product and pharmacovigilance in respect of the medicinal product established by this Law shall not be applied with respect to:

1) interim products intended for processing in the legal entities holding the manufacturing licence issued according to the procedure established by this Law;

2) radionuclides in the form of sealed sources;

3) whole blood, plasma or blood cells of human origin, except for plasma manufactured applying the method embracing industrial manufacture process.

8. The marketing authorisation requirement shall not apply with respect to radiopharmaceutical products manufactured in accordance with the manufacturer's instructions exclusively from authorised radionuclide generators, radionuclide kits or radionuclide precursors prior to its use in the health care establishment holding an authorisation to work with the sources of ionising radiation.

9. Legal persons in possession of a licence for the provision of personal health care services may acquire medicinal products only from legal persons holding a licence for manufacturing or a wholesale distribution licence, and the *Magistral Formula* – from production community pharmacy. These legal persons shall keep and enter the acquired medicinal products in the records according to the procedure established by the Minister of Health.

10. The legal persons who are not in possession of a licence for the provision of personal health care services or licence to engage in pharmaceutical activity may acquire medicinal products only from pharmacies.

11. The rules for filling prescriptions for medicinal products and for dispensing (selling) medicinal products to the general public shall be approved by the Minister of Health.

12. Medicinal products subject to medical prescription shall be dispensed (sold) to patients undergoing outpatient treatment only on the doctors' prescription.

13. A natural person shall have the right to import to the Republic of Lithuania for his own needs and to take out of the Republic of Lithuania, to receive or send by post medicinal products according to the procedure established by the Minister of Health.

14. It shall be prohibited to manufacture, import, distribute and place on the market counterfeit medicinal products. The monitoring of counterfeit medicinal products shall be coordinated by the institution authorised by the Government of the Republic of Lithuania. Products which are deliberately fraudulently mislabelled with respect to identity an/or origin shall be considered counterfeit medicinal products..

Article 9. Granting of Medicinal Product Marketing Authorisation

1. Medicinal product marketing authorisation shall be granted in a EEA state by the authorised institution of that state and in all EU Member States (hereinafter in the Community) – by the European Commission.

2. The State Medicines Control Agency shall issue in the Republic of Lithuania medicinal product marketing authorisation and marketing authorisation licences, shall renewal of marketing authorisation of medicinal products, certify the supplements to the licences and variations to their terms, suspend thee licence, lift the suspension of the licence or revoke the licence and manage the Register of Medicinal Products of the Republic of Lithuania according to the procedure established by the Minister of Health. The variations to the terms of a marketing authorisation of medicinal products for human use and veterinary medicinal products shall be certified according to the procedure established in the Commission Regulation (EC) No 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation of medicinal

products for human use and veterinary medicinal products granted by a competent authority of a Member State

3. The marketing authorisation shall be granted to a medicinal product of a certain strength and pharmaceutical form. Other strengths, pharmaceutical forms, methods of administration, presentations (e.g. the number of dosage units in the package and the package design), supplements to and variation of the marketing certificate shall be within the scope of general marketing law. The periods of data and market exclusiveness specified in paragraphs 5 and 6 of Article 11 of this Law shall be counted from the day of granting of the initial marketing authorisation (hereinafter referred to as primary marketing authorisation).

4. Medicinal product marketing authorisation may be granted to persons who have been established in any EEA state and meet the requirements established by this Law and other legal acts.

5. Being granted a medicinal product marketing authorisation shall not exempt the manufacturer of the medicinal product and holder of the medicinal product manufacturing authorisation from liability established in legal acts.

6. Where, taking into account all its characteristics, a product may fall within the definition of “a medicinal product” and within the definition of a product covered by other legislation of the Republic of Lithuania, the requirements applicable to a medicinal product shall apply.

7. Marketing authorisation shall be ceded according to the procedure established by the Minister of Health.

8. The State Medicines Control Agency when granting the marketing authorisation shall classify the medicinal products into medicinal products subject to medicinal prescription and those not subject to medicinal prescription. To this end the criteria laid down in Article 10 of this Law shall apply. The classification group may be changed by renewing the marketing authorisation of the medicinal product or by changing the classification based on the criteria set in this Law and in the European Commission recommendations on changing the classification of medicinal products intended for human use.

9. The State Medicines Control Agency shall approve and publish the list of medicinal product which are subject to prescription and shall update the list annually and notify the European Commission and other EEA states of the amendments of the list.

Article 10. Criteria for Classification of Medicinal Products

1. Medicinal products shall be classified as those subject to medicinal prescription and those not subject to medicinal prescription.

2. Assigned to medicinal products subject to medicinal prescription shall be those medicinal products which meet the following criteria:

1) they are likely to present a danger either directly or indirectly, if utilised without medical supervision;

2) they are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health;

3) they contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation;

4) they are normally prescribed by a doctor to be administered parenterally;

5) the medicinal products, because of their pharmaceutical characteristics or novelty or in the interests of public health, are reserved for treatments which can only be followed in a hospital environment;

6) the medicinal products are used in the treatment of conditions which must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities (although administration and follow-up may be carried out elsewhere);

7) the medicinal products are intended for outpatients but their use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.

3. The sub-category of medicinal products subject to special medical prescription shall be provided for in the group of medicinal products subject to medical prescription. Attributed to the sub-category shall be medicinal products corresponding to at least one of the following criteria:

1) the medicinal product contains a substance classified as a narcotic or a psychotropic substance entered in List II of Narcotic and Psychotropic Substances certified by the Minister of Health (narcotic and psychotropic substances permitted to be used for medicinal purposes);

2) if incorrectly used, the medicinal product is likely to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes,

3) the medicinal product contains a substance which, by reason of its novelty or properties, could be considered, as a precautionary measure, as belonging to the group envisaged in subparagraph 2 of paragraph 3 of this Article .

4. Medicinal products not corresponding to the criteria laid down in paragraphs 2 and/or 3 of this Article shall be assigned to the sub-category of medicinal products not subject to subscription.

Article 11. Submitting an Application for Marketing Authorisation

1. The person who wishes to be granted marketing authorisation simultaneously in several EEA states for a medicinal product not granted marketing authorisation in EEA states, including the Republic of Lithuania, must submit to the State Medicines Control Agency an application to be granted the marketing authorisation according to the decentralised procedure and the dossier identical to that which is submitted to the competent authority/authorities of another state/other states.

2. The person who wishes to be granted marketing authorisation of a medicinal product in any EEA state, including the Republic of Lithuania, must submit an application to the State Medicines Control Agency to be granted marketing authorisation for a medicinal product according to the mutual recognition procedure and the dossier identical to that based whereon the medicinal product was granted marketing authorisation by the first state with all the subsequent supplements.

3. The person who wishes to be granted marketing authorisation of a medicinal product only in the Republic of Lithuania while in another EEA state or other EEA states this medicinal product has not been granted marketing authorisation must submit to the State Medicines Control Agency an application for granting the medicinal product marketing authorisation according to the national procedure.

4. Pharmaceutical (physical-chemical, biological or microbiological) pre-clinical (toxicological and pharmaceutical) test and clinical trial results must be submitted alongside the application in addition to other documents and information prescribed by the Minister of Health.

5. Without prejudice to the protection of industrial property and commercial secrecy, the applicant is not required to provide the results of pre-clinical tests and clinical trials if he can demonstrate that the medicinal product presented for marketing authorisation is a generic medicinal product of a reference medicinal product which is or has been authorised for not less than 8 years in a EEA state or in the Community. This period shall stand for the period of data exclusivity of the reference medicinal product.

6. Generic medicinal product granted marketing authorisation under paragraph 5 of this Article may be supplied to the market after the lapse of not less than 10 years from the day of granting the reference medicinal product initial marketing authorisation. The two-year period counted after the period of data exclusivity shall stand for the reference medicinal product market exclusivity period.

7. The 10-year exclusivity period referred to in paragraph 6 of this Article shall be extended for not longer than one more year if during the initial 8 years of the specified 10 years the marketing authorisation holder registers one or several new therapeutic indications which according to

scientific evaluation performed prior to the granting of marketing authorisation are considered as affording substantial clinical benefit compared with the present treatment.

8. In the application of paragraphs 5-7 of this Law, the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines announced by the EU institutions.

9. Paragraphs 5–7 of this Article shall not apply with respect to reference medicinal products applications for granting marketing authorisation for which were submitted before 9 January 2005. If the applications for granting marketing authorisation for reference medicinal products were submitted before the intended date, without prejudice to the protection of industrial property and commercial secrecy the results of pre-clinical tests and clinical trials need not be submitted if it is demonstrated that the medicinal product presented for granting marketing authorisation is a generic medicinal product of a reference medicinal product which is or has been granted marketing authorisation in the Community for not less than 10 years or in any EEA state for not less than 6 or 10 years taking into account the period of data exclusivity established by that state.

10. If a medicinal product does not correspond to the term “generic medicinal product” or its bioequivalence cannot be demonstrated by appropriate bioavailability studies or if active substance(s), therapeutic indications, strengths, pharmaceutical form or route of administration (compared to reference medicinal product) is subject to modification, results of appropriate pre-clinical tests or clinical trials must be presented.

11. If a biological medicinal product similar to a reference biological medicinal product does not correspond to the term of generic medicinal product because of the difference in stocks or manufacturing processes, results of appropriate pre-clinical tests or clinical trials must be presented. Additionally presented information must comply to the analytical, pharmaco-toxicological and clinical trials of medicinal products standards, protocols and appropriate guidelines in respect of the testing of proprietary medicinal products established by the Minister of Health. The results of other trials which are in the marketing authorisation dossier of reference medicinal product need not be presented.

12. An additional not summed up one year period of data exclusivity shall be granted to a new indication of active substance of recognised medical use, if substantial pre-clinical tests and clinical trials have been conducted in respect of it.

13. The performance of necessary studies and trials in order to submit an application for the marketing authorisation in the Republic of Lithuania of a medicinal product according to paragraphs 5, 10 and 11 of this Article or in the Community Code of Medicinal Products according to the requirements laid down in Regulation (EC) No 726/2004 or in other states according to legal requirements of those states and the related practical needs shall be without prejudice to the rights granted by the medicinal product patent or by a supplementary protection certificate provided for in the Patent Law of the Republic of Lithuania and in other legal acts regulating the protection of industrial property.

14. Without prejudice to the legal acts regulating the protection of industrial property and commercial secrecy, the results of pre-clinical tests or clinical trials need not be submitted if it is demonstrated that the use in the Community medical practice of the active substance(substances) of the medicinal product presented for the granting of marketing authorisation has been recognised for not less than 10 years and its efficacy and acceptable safety has been proved based on the requirements of the standards and protocols of analytical, pharmaco-toxicological and clinical trials of medicinal products established by the Minister of Health. In this case appropriate scientific literature shall be presented instead of results of pre-clinical tests and clinical trials.

15. If the active substances of the medicinal product submitted for granting marketing authorisation have been included in the composition of the medicinal products formerly granted marketing authorisation but their composition has not been used for therapeutic purposes, the results of new pre-clinical tests and clinical trials of the combination shall be presented. Reference to scientific data regarding every active substance need not be presented.

16. The holder of the marketing authorisation of a medicinal product may permit to use the pharmaceutical, pre-clinical and clinical documents presented in the marketing authorisation dossier of the product registered in his name for considering marketing authorisation applications of subsequently presented medicinal products having identical qualitative and quantitative composition and pharmaceutical form of active substances.

17. A person must submit all clinical and/or scientific literature particulars, whether favourable or unfavourable to the product. The information must be presented in such a manner as to allow to adopt a scientifically justified decision regarding the issuing of the marketing authorisation and its terms.

18. The applicant or the marketing authorisation holder shall be liable for the accuracy of the supplied information, particulars and documents.

Article 12. Examination of the Application for Marketing Authorisation of a Medicinal Product and Issuing of Marketing Authorisation Certificate

1. Upon receiving an application for the marketing authorisation of a medicinal product the State Medicines Control Agency shall:

1) evaluate the documents and information submitted together with the application, draw the conclusion whether they meet the requirements established for granting the marketing authorisation;

2) may submit a medicinal product, its starting materials and, if need be, its intermediate products or other constituent materials for testing by the Medicines Control Laboratory of the State Medicines Control Agency, in order to ensure that the control methods employed by the manufacturer and described in the particulars accompanying the application are satisfactory;

3) may require the applicant to supplement the documents and information accompanying the application;

4) ascertain that the manufacturer and/or importer can avail himself of the option to manufacture and/or control the medicinal product according to the methods described in the documents accompanying the application for marketing authorisation; after the applicant submits a justified request, the State Medicines Control Agency may allow to have certain stages of manufacture and/or controls to be carried out by the third parties which meet the requirements.

2. The marketing authorisation of a medicinal product shall be granted or a justified refusal to grant the marketing authorisation shall be given not later than within 210 days from the day of receipt of the application submitted according to the established requirements. The time within which the applicant provides additional documents, information and, as necessary, verbal and/or written explanations required by the State Medicines Control Agency shall not be included in the time of examination of the application.

3. Upon taking a decision to grant marketing authorisation of the medicinal product, the State Medicines Control Agency shall:

1) issue the applicant the certificate of marketing authorisation of the medicinal product with the following supplements: summary of the product characteristics, the terms of the marketing authorisation, labelling and packing leaflet;

2) enter the medicinal product in the Register of Medicinal Products of the Republic of Lithuania;

3) classify the medicinal product as a medicinal product not subject to medical prescription or as a medicinal product subject to medicinal prescription in accordance with medicinal products classification criteria established by this Law;

4) publish in the media a notice of the granting of marketing authorisation of the medicinal product and the summary of the product characteristics;

5) draw up the protocol of assessment of documents of pharmaceutical, pre-clinical tests and clinical trials of the medicinal product; it shall be updated whenever new information becomes available about the quality, safety or efficacy of the medicinal product concerned;

6) immediately allow public access to the contents of assessment protocol, save confidential commercial type information. A justified decision to grant marketing authorisation shall accompany the assessment protocol and each indication shall be separately discussed.

4. A State fee of the established amount shall be payable for the examination of the application to grant marketing authorisation of a medicinal product, the accompanying documents and information and also for the issuance of marketing authorisation certificate.

5. If the State Medicines Control Agency, upon having received the application for the granting of the marketing authorisation of a medicinal product, when applying the procedure established by legal acts of the Republic of Lithuania (national procedure) establishes that the application for the granting of the marketing authorisation of the same medicinal product is being examined in another EEA state, the application shall not be considered and the applicant shall be offered to submit it under decentralised procedure.

6. If the State Medicines Control Agency, upon having received the application for the granting of the marketing authorisation of a medicinal product, when applying the national procedure establishes that the marketing authorisation of the same medicinal product has been granted in another EEA state, the application shall not be considered and the applicant shall be offered to file it according to the mutual recognition procedure.

7. Information about the submitted or considered applications for granting marketing authorisation of medicinal products or varying of the terms of marketing authorisation is confidential and not subject to publication except in cases when the disclosure of the information is required by the laws of the Republic of Lithuania or the regulations of the European Union.

Article 13. Refusal to Grant Marketing Authorisation of the Medicinal Product

Marketing authorisation of a medicinal product shall not be granted if upon examining the application, documents and information submitted by the applicant at least one of the following grounds is established::

- 1) unfavourable benefit/risk balance;
- 2) the applicant failed to fully substantiate the efficacy of the medicinal product;
- 3) the quantitative and/or qualitative composition of the medicinal product does not correspond to the declared composition

- 4) information and documents accompanying the application do not correspond to the requirements set by the Minister of Health;
- 5) a State fee of the established amount have not been paid.

Article 14. Validity and Renewal of the Marketing Authorisation

1. Marketing authorisation of the medicinal product shall be granted for the period of 5 years.
2. The application for the renewal of the marketing authorisation of a medicinal product must be submitted by its holder not later than 6 months before the expiry of its validity.
3. Together with the application for the renewal of the marketing authorisation its holder must submit a consolidated dossier covering the quality, safety, efficacy of the medicinal product and all the variations approved upon granting the marketing authorisation.
4. The State Medicines Control Agency shall renew the marketing authorisation of the medicinal product if its benefit/risk balance is again assessed favourably.
5. The marketing authorisation of a medicinal product renewed according to the procedure established by this Law and other legal acts shall be valid for an indefinite period except where the State Medicines Control Agency decides based on good reasons related to pharmacovigilance that after another 5-year period it must be repeatedly renewed.
6. If having been granted the marketing authorisation the medicinal product is not placed on the market within a 3-year period or if the medicinal product which already used to be placed on the market is not on the market for 3 years in succession the marketing authorisation shall be revoked.
7. In exceptional cases, in the interest of public health the State Medicines Control Agency may refrain from revoking marketing authorisation of a medicinal product which has not been placed on the market under paragraph 6 of this Article.
8. The holder of the marketing authorisation of a medicinal product shall pay a State fee of the established amount for the examination of the application when updating the marketing authorisation, assessment of the benefit/risk balance based on the periodically updated safety protocol and other documents and information (except in cases when the protocols are submitted immediately on the request of the State Medicines Control Agency).

Article 15. Obligations and Liability of a Marketing Authorisation Holder

1. After the marketing authorisation has been granted, its holder, taking into account the scientific and technical progress, must, as necessary, introduce any changes that may be required to enable the medicinal product to be manufactured and checked by means of generally accepted scientific methods.

2. Changes in the manufacture and checking methods shall be subject to the approval by the State Medicines Control Agency according to the procedure established by the Minister of Health.

3. The holder of the marketing authorisation of a medicinal product must ensure that the information submitted in the summary of product characteristics corresponds to the approved information after the granting of the marketing authorisation.

4. If the manufacturer of the medicinal product is not the marketing authorisation holder, he must submit, at the request of the State Medicines Control Agency, proof of control of the constituents of the medicinal product and/or control tests carried out at intermediate stages of the manufacturing process carried out according to information accompanying an application for marketing authorisation;

5. The holder of the marketing authorisation of a medicinal product must immediately submit to the State Medicines Control Agency all new information that may require supplementing the summary of the product characteristics, the terms of the marketing authorisation, labelling, package leaflet or other documents and information accompanying an application for marketing authorisation, especially where restrictions or prohibitions were placed on the medicinal product by a competent authority of any other state and submit all the new information that may affect the assessment of benefit/risk balance of the medicinal product.

6. The State Medicines Control Agency may require at any time that the marketing authorisation holder submits particulars in proof that the benefit/risk balance remains favourable.

7. Upon granting the marketing authorisation of a medicinal product its holder must within 6 months notify the State Medicines Control Agency of the date of first placing of the product on the market of the Republic of Lithuania and in cooperation with the distributor ensure proper supply of required frequency in keeping with the patients' demand.

8. Not less than two months before the intended temporary or permanent termination of supply to the market of the Republic of Lithuania of a medicinal product its marketing authorisation holder must notify the State Medicines Control Agency thereof.

9. The holder of the marketing authorisation, before supplying to the market series of immunological products and/or products derived from blood, shall submit samples of each batch for testing by the State Medicines Control Agency, except in cases where the control of the batch is performed in the official medicines control laboratory of another EEA state or in the laboratory designated for that purpose which confirms that the batch is in conformity with the quality control documents submitted with the application for marketing authorisation. In this case the State Medicines Control Agency shall be submitted a copy of certificate of release into free circulation by the EEA official control authority.

10. The marketing authorisation holder must ensure that the manufacturing and purifying processes used in the preparation of medicinal products derived from human blood or human plasma are properly validated, attain batch-to-batch consistency and guarantee, insofar as the state of technology permits, the absence of specific viral contamination. He must notify the State Medicines Control Agency of the methods used to reduce or eliminate pathogenic viruses liable to be transmitted by medicinal products derived from human blood or human plasma and at its request submit samples of the bulk and/or the medicinal product

11. At the request of the State Medicines Control Agency, especially when it is necessary for reasons related to pharmacovigilance, the marketing authorisation holder must submit to it all data about the amount of the medicinal product marketed and the available data about the amount of the medicinal product prescribed.

12. If the marketing authorisation of a medicinal product is suspended under Article 66 of this Law, the marketing authorisation holder must notify thereof the wholesale distribution enterprise, pharmaceutical and health care institutions which have acquired the product.

13. If the marketing authorisation of a medicinal product is revoked, the marketing authorisation holder, cooperating with wholesale distribution enterprises, must immediately withdraw the medicinal product from the market.

14. The marketing authorisation holder shall be responsible for the marketing of the medicinal product; the appointment of the representative shall not relieve the marketing authorisation holder of responsibility according to the procedure set by legal acts.

Article 16. Specifics of Supply to the Market of Homeopathic and Traditional Biological Medicinal Products

1. Homeopathic medicinal products which satisfy the criteria set by the Minister of Health shall be subject to a simplified homeopathic medicinal product registration procedure established by the Minister of Health. The pharmacovigilance requirements shall not be applied with respect to the products.

2. Taking into account the traditions of homeopathy and the health care needs of the Republic of Lithuania the Minister of Health may approve for homeopathic medicinal products, except for those referred to in paragraph 1 of this Article, a special registration procedure laying down specific requirements for pre-clinical tests and clinical trials. If the procedure is approved the European Commission shall be notified thereof.

3. Homeopathic medicinal products that are not referred to in paragraphs 1 and 2 of this Article shall be registered according to the procedure established in Article 11 of this Law,

4. A simplified registration procedure shall be applied to traditional biological medicinal products that satisfy the criteria set by the Minister of Health, unless the State Medicines Control Agency decides that the medicinal product satisfies the criteria for registration under Article 11 of this Law.

5. Where the traditional biological medicinal product meets the criteria established by the Minister of Health to homeopathic medicinal products which may be registered according to the simplified homeopathic medicinal product registration procedure, it shall be registered according to the procedure.

6. After the State Medicines Control Agency takes a decision to register the medicinal products referred to in this Article, they shall be entered in the Register of Medicinal Products of the Republic of Lithuania and the registration certificate shall be issued.

Article 17. Parallel Import of Medicinal Products

1. Parallely imported to the Republic of Lithuania may be medicinal products which are registered in the List of Parallely Imported Medicinal Products and in respect of which a permit for parallel import has been issued

2. The State Medicines Control Agency shall, according to the procedure established by this Law and the Minister of Health, administer the List of Parallely Imported Medicinal Products, marketing authorisation of the parallely imported medicinal products, approve the terms of variation of the permits for parallel import, suspend the permit validity, revoke the suspension of validity and the permit validity.

3. A permit for parallel import may be issued to a medicinal product which is identical to the medicinal product already registered in the Republic of Lithuania or sufficiently resembling it.

4. A medicinal product shall be considered sufficiently resembling a medicinal product registered in the Republic of Lithuania if it meets the following criteria:

- 1) the same active substance and the same salt of the active substance, the same ester, ether, isomer or mixtures of isomers, complexes or derivatives of an active substance of isomers;
- 2) the same strength;
- 3) the same pharmaceutical form and administration method;
- 4) the same clinical and pharmaceutical properties;
- 5) the same or related marketing authorisation holder and/or the same manufacturer.

5. Upon taking a decision to register the medicinal product the State Medicines Control Agency shall:

- 1) designate the parallely imported medicinal product to subcategories subject to medicinal prescription or those not subject to medicinal prescription;

2) issue a permit for parallel import of a medicinal product with the following supplements:
summary of the product characteristics, labelling and packing leaflet;

3) enter the medicinal product in the List of Parallely Imported Medicinal Products.

6. A permit for parallel import of a medicinal product may be issued only to a legal person who has received a wholesale distribution licence issued according to the procedure established by this Law.

7. A permit for parallel import of a medicinal product shall be issued or a justified refusal to issue one shall be taken within 45 days from the day of acceptance of the application and documents submitted according to the requirements established by the Minister of Health. The time within which the applicant provides additional documents, information and, as necessary, verbal and/or written explanations required by the State Medicines Control Agency shall not be included in the time of examination of the application.

8. A permit for parallel import shall be issued for 5 years. A medicinal product imported parallely shall be re-registered issuing a new authorisation of parallel import according to the procedure established by the Minister of Health.

9. State fee shall be paid for filing the application to register, re-register a parallely imported medicinal product or to change the terms of the permit of parallel import, for expert examination of the documents and information submitted together as well as for the issue of the permit for parallel import.

10. Only the holder of the permit for parallel import of a medicinal product shall have the right to parallely import the medicinal product into the Republic of Lithuania.

11. The holder of the permit for parallel import must not later than 30 days before the intended import notify in writing the marketing authorisation holder and the State Medicines Control Agency of his intention to parallely import the medicinal product.

12. The holder of the permit for parallel import must fulfil the obligations of the marketing authorisation holder related in this Law and other legal acts to pharmacovigilance and withdrawal of the medicinal product from the market.

13. Other requirements related to parallel import and other duties of the holder of the permit for parallel import shall be established by the Minister of Health.

CHAPTER IV

CLINICAL TRIALS OF MEDICINAL PRODUCTS

Article 18. Requirements of Clinical Trials of a Medicinal Product

1. Clinical trials of a medicinal product shall be regulated by legal acts of the Republic of Lithuania. Compliance with them shall be controlled by the State Medicines Control Agency and other institutions authorised under laws.

2. The qualification of the principal investigator must correspond to the qualification requirements established by the Minister of Health.

3. All clinical trials of medicinal products shall be designed, conducted, registered and reported according to the regulations of Good Clinical Practice approved by the Minister of Health.

4. Clinical trials of a medicinal product may be conducted only being in possession of the approval of the Lithuanian Bioethics Committee and the authorisation of the State Medicines Control Agency. The procedure for issuing certificates of approval of the conduct of a medicinal product clinical trial and of issuing authorisations for the conduct of a medicinal product clinical trial shall be established by the Minister of Health.

5. The investigational medicinal products shall be acquired and issued for clinical trials according to the procedure established by the Minister of Health.

6. The sponsor of the clinical trial or his representative and/or principal investigator, wishing to be issued a certificate of approval or authorisation of the conduct of clinical trials of medicinal products must submit documents the list whereof shall be approved by the Minister of Health. State fee of the established amount shall be paid for expert examination of the documents submitted in order to be issued a certificate of approval of the Lithuanian Bioethics Committee and the authorisation of State Medicines Control Agency and the issue of certificates of approval and authorisations.

7. The Lithuanian Bioethics Committee shall express its approval or disapproval of the conduct of clinical trials not later than within 60 days after the day of acceptance of the application. The State Medicines Control Agency shall issue an authorisation to conduct the clinical trial or shall present a justified refusal to issue one not later than within 60 days after the acceptance of the application. It may issue an authorisation of the conduct of a clinical trial only with the approval of the Lithuanian Bioethics Committee

8. The time limit specified in paragraph 7 of this Article may be extended for 30 days in the cases when it is requested to grant authorisation of trials in which the following investigational medicinal products are used.

- 1) investigational medicinal products intended for gene therapy;
- 2) investigational medicinal products intended for somatic cell therapy;
- 3) investigational medicinal products containing genetically modified organisms.

9. In case consultations with experts are held, the authorisation period to commence clinical trials with investigational medicinal products referred to in paragraph 8 of this Article may be

extended for 90 additional days with the total period amounting to 180 days. In the case of xenogenic cell therapy, there shall be no time limit to the authorisation period.

10. The State Medicines Control Agency shall enter the data about clinical trial of a medicinal product into the European Database EudraCT according to the standard operating procedure approved by the State Medicines Control Agency, prepared according to comprehensive recommendations of the European Commission.

11. If the State Medicines Control Agency or the Lithuanian Bioethics Committee have objective grounds for considering that the application for the authorisation to conduct a clinical trial of medicinal product does not meet the requirements set by the Minister of Health or has information raising doubts about the safety or scientific validity of the clinical trial, they may refuse to issue the authorisation to conduct a clinical trial of medicinal product or the certificate of approval and shall notify the sponsor thereof.

12. The sponsor must submit to the State Medicines Control Agency and Lithuanian Bioethics Committee according to the procedure established by the Minister of Health all the received important information about the occurrence in the course of a clinical trial of adverse events or the suspected adverse reaction to an investigational medicinal product.

13. The State Medicines Control Agency shall control that data about any suspected unexpected serious adverse reactions related to an investigational medicinal product observed in Lithuania in the course of clinical trial be immediately included in the report on the suspected unexpected serious adverse reactions and in the handling of the information within the EEA in the EudraVigilance clinical trials module according to the procedure established by the Minister of Health.

14. The State Medicines Control Agency may take a decision to suspend or terminate in the country clinical trials of a medicinal product when it is already being conducted, if it has reasonable grounds to decide that the conditions of the authorisation are not being met or if there are doubts about the safety or scientific validity of the clinical trial and indicate the reasons of the decision. The sponsor and the investigator must immediately analyse the causes for suspension or termination and present a report within a week's time analysing the posed question and all the exceptional circumstances contradicting further conduct of clinical trial of the medicinal product. Having received the report the State Medicines Control Agency shall take a decision regarding the suspension of the trial, revocation of suspension or termination of the trial.

15. After the Lithuanian Bioethics Committee decides to suspend or terminate the validity of the certificate of approval, the State Medicines Control Agency shall not later than within 7 days adopt a decision to suspend or terminate the trial.

CHAPTER V

LICENSING OF PHARMACEUTICAL ACTIVITY

Article 19. Licensing of Pharmaceutical Activity

1. The manufacture, import of medicinal products, investigational medicinal products, wholesale distribution of medicinal products, active substances, activities and management of pharmaceutical waste (except for its disposal) shall be pharmacy activities subject to licensing.

2. Legal persons and foreign subsidiaries of legal persons (hereinafter referred to as legal person) shall be issued the following types of licences:

- 1) manufacturing licence;
- 2) wholesale distribution licence;
- 3) licence for pharmaceutical activity;
- 4) licence for manufacturing pharmaceutical activity;
- 5) licence for pharmaceutical waste management of (except for its disposal).

3. Licences shall be issued, changed, suspended, their validity shall be suspended or the suspension of validity shall be revoked, the changed information and/or data shall be entered in the documents submitted for the issuance of a licence by the State Medicines Control Agency Rules for licensing of pharmaceutical activities shall be approved by the Government.

Article 20. Issue of Licences

1. A legal person who wishes to obtain a licence must file an application and other documents prescribed in the rules of licensing of pharmaceutical activity. The applicant shall be responsible for the accuracy of the application, submitted data and information

2. The employees of the State Medicines Control Agency, performing the actions of control, must visit the place of action referred to in the application in order to check the accuracy and correctness of the submitted data and information, to assess whether the legal person is ready according to the procedure established by legal acts to perform pharmaceutical activity.

3. The State Medicines Control Agency shall adopt a decision to issue a licence only having ascertained that the submitted data and information are in keeping with the requirements established by this Law, Rules of Licensing of Pharmaceutical Activity, Orders of the Minister of Health and other legal acts.

4. A licence shall be issued within the time limits specified in this Law. As necessary, the State Medicines Control Agency shall be entitled to ask the applicant to submit more detailed

information related to the adoption of the decision as well as the approval of the person intended to perform the duties established in Article 29 of this Law whose qualification and experience are established in Article 28 of this Law or the person whose duties, qualification and experience are established in Article 34 of this Law. The applicant must submit the information not later than within 30 days. The time period within which the applicant shall submit the information shall not be included in the time period of adoption of the decision concerning the issue of the licence within the time limits established by this Law.

5. At the request of the State Medicines Control Agency State and municipal institutions as well as other persons must forthwith submit to it the available information about the founders, shareholders and heads of the branch of a legal person or foreign legal person, the legal person's financial situation, activities, the established violations of laws and other legal acts, conclusions of conducted verifications and examinations as well as other information required by the State Medicines Control Agency for the taking of a decision on the issue of a licence.

6. The State Medicines Control Agency shall notify the Register of Legal Entities of the issue, replacement, suspension, revocation of suspension of licences or revocation of licences according to the procedure established in the Regulations of the Register of Legal Entities, shall publish a notice to the effect in the information supplement to the official gazette "*Valstybės žinios*" and in the Internet home page of the State Medicines Control Agency.,

7. A licence shall be issued for an indefinite period of time.

8. State fee of the established amount shall be payable for the assessment of the legal entity's preparedness to perform pharmaceutical activity according to the procedure established by legal acts as well as for the issuance of the licence.

Article 21. Changing of Information and Data in the Documents Submitted by the Licence Holder for the issuance of the Licence

1. If the licence holder wants to change information and/or data in the documents submitted in order to obtain his licence (hereinafter referred to as licence information and data), he must submit to the State Medicines Control Agency an application of the form established by the Minister of Health and documents certifying the licence information and data being changed.

2. The State Medicines Control Agency, having received the application, shall have the right to go to the declared place and check the preparedness of the legal person to perform pharmaceutical activity under new conditions.

3. The decision on the licence information and data being changed shall be taken not later than within 30 days of the submission of the application and documents, except in cases provided for in this Law, Article 26 paragraph 3 and Article 32 paragraph 3.

4. The State Medicines Control Agency may request the applicant to submit more detailed information related to decision making. The applicant must submit the information not later than within 30 days. The time period within which the applicant presents the information shall not be included in the period of decision making.

Article 22. Refusal to Issue a Licence, to Enter the Changed Licence Data and Information

A licence shall not be issued or the entry of the changed licence data and information shall be refused if:

- 1) the submitted application and documents are not in keeping with the requirements set by this Law and other legal acts
- 2) the applicant fails to submit additional information within the established time period;
- 3) the applicant or the pharmaceutical activity performed by him is not in keeping with the requirements established by this Law and other legal acts;
- 4) bankruptcy proceedings have been instituted against the applicant;
- 5) a State fee of the established amount have not been paid;
- 6) licence has been revoked for a legal person and 6 months have not lapsed from the revocation of the licence (the provision shall not be applied when the licence holder terminates the activity subject to licensing and submits to the State Medicines Control Agency an application to revoke the licence).

Article 23. Suspension of the Licence, Revocation of Suspension of the Licence or Revocation of the Licence

1. The licence shall be suspended if the performed activity is not in keeping with the licence information and data, the conditions of the activity subject to licensing are not satisfied.

2. The suspension of the licence shall be revoked when the State Medicines Control Agency, having received the licence holder's written report of the eliminated violations of licensed activity conditions, establishes that the applicant has actually eliminated the specified violations.

3. The licence shall be revoked if:

- 1) the licence holder terminates the licensed activity and submits to the State Medicines Control Agency an application to revoke the licence ;
- 2) the licence holder whose licence has been suspended fails to eliminate the violations of the licensed activity terms within the established time period;
- 3) the State Medicines Control Agency establishes that upon suspension of the licence the legal person or its branch continues to engage in activity subject to licensing;

- 4) the legal person is dissolved;
- 5) if erroneous data has been submitted for the issuance of the licence;
- 6) upon suspending the licence, the licence holder committed an infringement within 12 months from the lifting of suspension of the licence which would lift suspension of his licence.

4. The State Medicines Control Agency shall suspend or revoke the licence for all or part of activities if the licence holder violates the requirements of this Law, of the Rules of Licensing of Pharmaceutical Activity or those established by the Minister of Health.

5. If a criminal or administrative action is instituted for the violations of pharmaceutical activity committed by a qualified person employed for the performance of duties under Article 29 of this Law, whose qualification and experience satisfies the requirements of Article 28 of this Law (hereinafter – the qualified person responsible for the manufacture and/or import) or by the pharmaceutical activity manager or If investigation of violations of labour regulations is started, the State Medicines Control Agency shall suspend his powers for the period of the proceedings or investigation.

CHAPTER VI

MANUFACTURE AND IMPORT FROM THIRD COUNTRIES

Article 24. Principal Requirements for Manufacture and Import from Third Countries

1. 1. A legal person may engage in manufacture and/or import from third countries of medicinal product, investigational medicinal products only having received a manufacturing licence issued according to the procedure established by law.

2. 2. A legal person may engage in total and partial manufacture of medicinal products, investigational medicinal products and/or in the various processes of dividing up, packaging or presentation only subject to holding of an authorisation. He must also acquire the authorisation when manufacture and/or import of medicinal products, investigational medicinal products intended for export. A manufacturing licence shall grant the right to distribute the medicinal products manufactured by the licence holder

3. 3. The manufacturing licence shall not be required for:

- 1) manufacturing extemporaneous medicinal products;
- 2) for repackaging or changing the presentation of the medicinal products manufactured industrially or by a method involving an industrial process if the activity is performed by pharmacies or branches and the medicinal products are intended only for the natural persons provided services by the pharmacy or the pharmacy branch.

3) radiopharmaceutical products manufactured in accordance with the manufacturer's instructions from authorised radionuclide generators, radionuclide kits or radionuclide precursors prior to their use in the health care establishment holding a licence to work with the sources of ionising radiation.

4) if the investigational medicinal product requires reconstitution before administration or packaging where this is carried out in clinical trials centres by pharmaceutical specialists or other persons authorised for the purpose and these products are intended for use in the centre only;

5) import of bearer prescription medicinal products from third countries

4. 4. Medicinal products, investigational medicinal products manufactured and/or imported from third countries in accordance with the principles and guidelines of good manufacturing practice for medicinal products and investigational medicinal products, approved by the Minister of Health and taking into account the recommendations of the European Commission, the European Medicines Agency and other European Union institutions (hereinafter referred to as good manufacturing practice).

5. 5. Medicinal products, investigational medicinal products imported from third countries must be manufactured in enterprises authorised by an authorised institution of the country to engage in manufacturing medicinal products, investigational medicinal products and standards of good medicinal practice of which are at least equivalent to those laid down in the Community.

6. 6. Only those active substances which have been manufactured taking into account the EU Commission's principles and recommendations for good manufacturing practice of starting materials may be used as starting materials in the manufacture of medicinal The provision shall also be applicable with respect to the excipients the list and specific conditions of use whereof is established by the European Commission (hereinafter - the excipients entered in the list of the European Commission).

7. Total and partial manufacture as well as import of an active substance and the various processes relating to its dividing up, packaging, labelling and presentation prior to its use in manufacturing medicinal product, including its cardboard packaging and labelling, shall be assigned to the manufacture of active substances used as starting materials for the manufacture of medicinal products.

8. 8. The provisions of this Chapter shall also be applicable with respect to intermediate products.

9. Blood products may be manufactured only from human blood and plasma selected and tested according to the requirements prescribed by the Minister of Health.

Article 25. Requirements for a Legal Person Wishing to Obtain the Manufacturing Licence

A legal person wishing to obtain the manufacturing licence must:

- 1) specify in the application the medicinal products and pharmaceutical forms which are to be manufactured or imported , groups and pharmaceutical forms of investigational medicinal products and also the place where they are to be manufactured and/or controlled.
- 2) have at his disposal, for the manufacture or import of the specified medicinal products, investigational medicinal products, suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements laid down in this Law, the Rules of Licensing of Pharmaceutical activity, and the product manufacture, control and storage requirements laid down by the Minister of Health, ensure the application of methods of manufacturing and investigation specified in the documents submitted for the issuance of manufacturing authorisation;
- 3) enter into a contract of employment with a person for fulfilling the duties of a qualified person responsible for the manufacture and/or import;
- 4) comply with other requirements laid down in this Law, the Rules of Licensing of Pharmaceutical activity and the Minister of Health.

Article 26. Principles of Issuing Manufacturing Licence

1. 1) The manufacturing licence shall be issued for engaging in activities only in the premises specified in the application and with the medicinal products or their groups and pharmaceutical forms specified in the application. The duties of the qualified person responsible for manufacture and/or import may be fulfilled only by the person who is recorded in the licence.
2. 2. The manufacturing licence shall be issued or a justified decision to refuse issuing it shall be adopted within 90 days from the day of receipt of the application submitted according to the established requirements.
3. If the licence holder asks to record the changed information and data in the documents submitted for obtaining the licence, the decision or a justified refusal to record them shall be taken not later than within 30 days from the day of receipt of the application submitted according to the established requirements. The time limit may be extended up to 90 days by a justified decision of the State Medicines Control Agency

Article 27. Main Duties of the Manufacturing Licence Holder

The manufacturing licence holder must:

1) employ a sufficient number of adequately qualified personnel for the performance of pharmaceutical activity according to the established requirements;

2) perform activities with investigational medicinal products and/or medicinal products, in respect of which a marketing authorisation has been granted, in the If EEA state only according to the legal acts of the state;

3) notify the State Medicines Control Agency in advance of all the changes in the information or data he would like to make in the documents submitted for obtaining the licence;

4) forthwith notify the State Medicines Control Agency of the changing of the qualified person responsible for manufacture and/or import; If the qualified person specified in the licence who is responsible for manufacture and/or import cannot carry out his duties due to illness, vacation or for other objective reasons, his functions may be entrusted only to another qualified person responsible for manufacture and/or import. In this case the manufacturing licence holder must designate or employ another qualified person responsible for manufacture and/or import and forthwith notify the State Medicines Control Agency thereof. If another qualified person responsible for manufacture and/or import is employed for a period not exceeding 3 months per year, the licence need not be varied;

5) allow the employees of the State Medicines Control Agency, holding the powers of administration over persons subordinate and not subordinate according to their duties, upon presenting **their certificate of employment and order**, to freely and without a prior notice enter during the working hours of the manufacturing licence holder and at other time, with the assistance of officials representing the competent authority, enter all premises of activity specified in the licence in order to check compliance with the requirements of this Law and other regulatory enactments; to submit data and documents (their copies, transcripts), articles necessary to perform the functions of the State Medicines Control Agency;

6) confer on the qualified person responsible for manufacture and/or import powers to fulfil the duties prescribed to him by this Law and ensure their continuous and uninterrupted performance;

7) adhere to good manufacturing practice;

8) use as starting materials only those active substances which satisfy the requirements of paragraph 6 of Article 24 of this Law;

9) distribute medicinal products of own manufacture or imported medicinal products in compliance with all requirements binding on wholesale distribution licence holder.

10) have a plan for the recall from the market of medicines and notify the State Medicines Control Agency of the started and completed implementation of recall from the market of medicinal products and submit all relating information;

11) comply with other requirements laid down by legal acts.

Article 28. Qualification Requirements of a Qualified Person Responsible for Manufacture and Import

Qualification and experience requirements of a qualified person responsible for manufacture and/or import.

Article 29. Main Duties of a Qualified Person Responsible for Manufacture and Import

1. The qualified person responsible for manufacture and/or import must fulfil the duties established in this Law, other legal acts and administrative acts of a licence holder. He shall be responsible for the following:

1) that each batch of medicinal products has been manufactured and checked in accordance with the requirements of this Law and other legal acts and is in accordance with the documents submitted for obtaining the marketing authorisation;

2) in the case of medicinal products coming from third countries, that each production batch has undergone in Lithuania or any other EEA state a full qualitative analysis, a quantitative analysis of at least all the active constituents and all the other checks or tests necessary to ensure the quality of medicinal products in accordance with the documents submitted for obtaining the marketing authorisation;

3) that each batch of the medicinal product under investigation has been manufactured and checked according to good manufacturing practice, the product specification dossier and the sponsor's documents submitted when requesting an authorisation to conduct a clinical trial;

4) that each batch of the medicinal product under investigation imported from a third country has been manufactured and checked applying standards of good manufacturing practice at least equivalent to those laid down by the Community, the product specification dossier and that controls have been carried out of each batch of medicinal product according to the documents submitted when requesting an authorisation to conduct a clinical trial;

5) if the medicinal product under investigation is a reference product from a third country which has been granted marketing authorisation but there is no possibility to obtain documents confirming that each batch of the product has been manufactured applying standards of good manufacturing practice at least equivalent to those laid down by the Community, that all analysis, all the other tests or checks necessary to ensure the quality of the medicinal product in accordance with the documents submitted applying for the authorisation to carry out clinical trial.

2. If batches of medicinal products have undergone controls provided for in paragraph 1 of this Article in another EEA state, they shall be exempt from repeated controls if the batches are supplied to the market accompanied by the quality control documents signed by a qualified person of the state who is responsible for manufacture and/or import.

3. 3. In case of medicinal product imported from a country with which the European Community has signed a mutual recognition agreement to ensure that the manufacturer applies standards of good manufacturing practice at least equivalent to those laid down by the Community and that the controls referred to under subparagraph 2 of paragraph 1 of this Article have been carried out in the exporting country, the qualified person responsible for manufacturing and/or import may be relieved of responsibility for carrying out those controls.

4. 4. In all cases the qualified person responsible for manufacturing and/or import must certify in a register of registering batches of medicinal products, investigational medicinal products or in the documents provided for that purpose that each production batch satisfies the requirements set this Article and other legal acts. This register or equivalent document must be kept up to date as operations of manufacture and/or import from third countries are carried out and must be placed upon request at the disposal of the State Medicines Control Agency. The filled in register or the equivalent document used for registering the batches of medicinal products must be kept for the period of 5 years.

CHAPTER VII

WHOLESALE DISTRIBUTION

Article 30. Main Requirements of Wholesale Distribution

1. A legal person shall have the right to engage in wholesale distribution of medicinal products, active substances and excipients in the list of the European Commission, used in manufacturing of medicinal products or extemporaneous medicinal products, only holding a wholesale distribution licence issued according to the procedure established by this Law.

2. Wholesale distribution shall be performed in compliance with the requirements of this Law, good distribution practice regulations approved by the Minister of Health and with a view to the recommendations of the European Commission, the European Medicines Agency and other EU institutions (hereinafter referred to as Good Distribution).

3. If the holder of the wholesale distribution licence wishes to engage in the manufacture and/or import of medicinal products from third countries, he must acquire the manufacturing licence.

4. Requirements more stringent than those applied to legal persons holding a wholesale distribution licence issued according to the procedure established by this Law may not be applied with respect to persons holding a wholesale distribution licence issued by other EEA states and wishing to engage in wholesale distribution in the Republic of Lithuania.

Article 31. Requirements for a Legal Person Wishing to be Issued a Wholesale Distribution Licence

A legal person wishing to be issued a wholesale distribution licence must:

1) specify in the application groups of medicinal products distribution whereof is intended (according to the temperature regime and groups established by the Minister of Health), indicate whether or not active substances, excipients entered in the list of the European Commission which are used for the manufacture of medicinal products or extemporaneous medicinal products will be distributed;

2) taking into account the recommendations of the European Commission, the European Medicines Agency and other EU institutions, have suitable adequate premises and equipment so as to ensure proper conservation under the conditions laid by the manufacturer and distribution of the medicinal products;

3) conclude a contract of employment with the person whose qualification would meet the requirements set in Article 34 of this Law for carrying out the duties of the manager of the pharmaceutical activities;

4) comply with other requirements laid down in this Law, the Rules of Licensing of Pharmaceutical activity and the Minister of Health.

5) undertake to fulfil the obligations incumbent on them under Article 33 of this Law.

Article 32. Issue of a Wholesale Distribution Licence

1. A wholesale distribution licence shall be issued for engaging in the activities only in the premises indicated in the legal person's application and only with the groups of products specified in the application. The duties of the manager of pharmaceutical activity may be carried out only by the person recorded in the licence.

2. The wholesale distribution licence shall be issued or a justified decision to refuse issuing it shall be adopted within 90 days from the day of receipt of the application submitted according to the established requirements.

3. If the licence holder asks to record the changed licence information and data, the decision to satisfy the request or a justified refusal shall be taken not later than within 30 days from the day

of receipt of the application submitted according to the established requirements. The time limit may be extended up to 90 days by a justified decision of the State Medicines Control Agency.

Article 33. Main Duties of the Wholesale Distribution Licence Holder

The wholesale distribution licence holder must:

- 1) employ a sufficient number of adequately qualified personnel for the performance of pharmaceutical activity according to the established requirements;
- 2) allow the employees of the State Medicines Control Agency, holding the powers of administration over persons subordinate and not subordinate according to their duties, upon presenting their certificate of employment and order, to freely and without a prior notice enter during the working hours of the wholesale distribution licence holder and at other time, with the assistance of officials representing the competent law enforcement authority, enter all premises of activity specified in the licence in order to check compliance with the requirements of this Law and other regulatory enactments; to submit data and documents (their copies, transcripts), articles necessary to perform the functions of the State Medicines Control Agency;
- 3) submit to the State Medicines Control Agency information on the distribution of medicinal products being performed and intended and the introduced material changes which may affect the quality, safety and efficacy of the medicinal product;
- 4) obtain (in the cases established by legal acts - import) medicinal products only from legal persons in possession of the manufacturing or wholesale distribution licence;
- 5) distribute only those medicinal products or their groups which are stored in the premises which correspond to the storage conditions specified in the licence and licence documents;
- 6) supply to the market of the Republic of Lithuania only registered medicinal products and, in the cases specified in this Law, unregistered medicinal products;
- 7) supply medicinal products only to persons who are in possession of the wholesale distribution, pharmaceutical activity and/or health care activities licence;
- 8) cooperating with marketing authorisation holders ensure availability and frequent supply of medicinal products to pharmacies and personal health care establishments;
- 9) have an emergency plan which ensures effective implementation of any recall from the market ordered by the State Medicines Control Agency or to implement it in cooperation with the manufacturer or marketing authorisation holder for the medicinal product concerned ;
- 10) keep records giving for any transaction in medicinal products received or dispatched the following information: date, name of medicinal product, batch of the medicinal product, quantity of the medicinal product received or sold, name and address of the supplier or consignee;

11) supply medicinal products only with the following documents enclosed: the date, the name and pharmaceutical form of the medicinal product, the quantity supplied; the name and address of the supplier and consignor.

12) preserve for 5 years according to the procedure established by the Government of the Republic of Lithuania the documents specified in subparagraph 10 of this Article and when necessary submit them at the request of the State Medicines Control Agency;

13) carry out pharmaceutical activity according to the requirements of good distribution practice;

14) distribute only those active substances and excipients entered in the list of the European Commission which have been manufactured according to the principles and recommendations of good manufacturing practice of the European Commission;

15) designate persons responsible for pharmaceutical activity and ensure the required number and qualification of specialists performing and controlling pharmaceutical activity;

16) confer on the pharmaceutical activity manager sufficient powers to carry out the duties delegated to him and to ensure permanent and continuous performance of functions assigned to him;

17) notify the State Medicines Control Agency if the pharmaceutical activity manager is changed. If the pharmaceutical activity manager specified in the licence is unable to perform his duties due to illness, vacation or other objective reasons, his functions may be delegated only to another person who satisfies the requirements posed to pharmaceutical activity manager, referred to in Article 34 of this Law. If the pharmaceutical activity manager is replaced for a period exceeding one month, the wholesale distribution licence holder must notify the State Medicines Control Agency. If the pharmaceutical activity manager is replaced for a period not exceeding 3 months per one year, licence information and data need not be varied.

18) fulfil the requirements set by other legal acts.

Article 34. Qualification and Experience Requirements and Main Duties of the Pharmaceutical activity Manager Responsible for Wholesale Distribution

1. The pharmacist holding a licence for pharmaceutical activity and having a two-year work experience acquired at a wholesale distribution enterprise within last 10 years may be the pharmaceutical activity manager responsible for wholesale distribution.

2. The pharmaceutical activity manager must fulfil the duties set out in this Law, other legal acts and administrative acts of the licence holder. He shall be responsible that:

1) the pharmaceutical activity be carried out according to good distribution practice of medicinal products:

2) heads of the legal person be informed on whether the activities comply with the requirements set by this Law and other legal acts;

3) only the medicinal products, active substances satisfying the requirements set by this Law and other legal acts and the excipients entered in the list of the European Commission be distributed;

4) customers' complaints or notices about the quality of the medicinal product, active substance and the excipient entered in the list of the European Commission and/or services be responded to;

5) the system of withdrawal from the market of the medicinal products, active substances be introduced and functioned adequately.

CHAPTER VIII

ACTIVITIES OF PHARMACIES

Article 35. Types of Pharmacies and Peculiarities of Pharmacy Activities

1. Pharmacies and their branches shall be set up according to the procedure established by the Minister of Health. A legal person shall have the right to engage in pharmacy activities only being in possession of a production pharmacy licence issued according to the procedure established by this Law and to manufacture extemporaneous medicinal products only being in possession of a production pharmacy licence.

2. Pharmacies shall be divided according to the type of activity into: community pharmacies, production community pharmacies, hospital pharmacies, production hospital pharmacies, university pharmacies and charity pharmacies.

3. A community pharmacy shall be a pharmacy in which medicinal products are kept, controlled and sold (dispensed) to the residents and legal persons who do not possess a licence for the provision of personal health care services or a licence for pharmaceutical activity, the binding commitments of the Minister of Health in supplying the residents with medicinal products are fulfilled and student teaching practice and vocational practice is conducted.

4. Production community pharmacy means a community pharmacy which manufactures extemporaneous medicinal products and sells/dispenses medicinal products to the residents and may sell/dispense medicinal products prepared in a pharmacy according to the *Magistral Formula* to a legal person in possession of a licence for the provision of personal health care services. A production pharmacy may sell/dispense via its branches *Magistral Formula* medicinal products manufactured by it according to the procedure established by the Minister of Health.

5. A hospital pharmacy, production hospital pharmacy shall be a subdivision of a health care establishment which supplies the hospital with medicinal products but is not entitled to sell/dispense them to the patients undergoing outpatient treatment.

6. A university pharmacy shall be a structural subdivision of a university which trains specialists in pharmacy and fulfils the functions of a community or production community pharmacy.

7. A charity pharmacy shall acquire by way of sponsorship medicinal products and pharmacy goods and shall issue them to the recipients of charity according to the procedure established by the Minister of Health. The sale of medicinal products received by way of sponsorship shall be prohibited.

8. Pharmacies may engage in activities only with registered medicinal products or with unregistered medicinal products the use whereof for health care has been authorised according to the procedure established by this Law.

9. Medicinal products shall be sold (issued) to the residents according to the procedure established by the Minister of Health. A pharmacy service must be provided when selling (dispensing) to the residents medicinal products.

10. Pharmacies shall carry out their activities according to the Good Manufacturing Practice Regulations approved by the Minister of Health

11. Pharmacies may sell/dispense alongside medicinal products pharmacy goods established by the Minister of Health.

12. A community pharmacy, community production pharmacy, university pharmacy, hospital pharmacy, production hospital pharmacy, when being liquidated, reorganised or upon commencing its bankruptcy procedure may sell the medicinal products possessed by it only to a wholesale distribution establishment pending the validity of the legal person's licence for pharmacy activities or production pharmacy activities.

13. The requirements applied to the establishment of branches of pharmacies, activities and their fulfilment conditions shall be the same as those applied with respect to pharmacies.

14. A hospital pharmacy, production hospital pharmacy may be set up only by an in-patient health care institution for supplying the in-patient establishment.

15. The registered name of a legal person performing the activities of a community pharmacy, community production pharmacy must contain the word "pharmacy(pharmacies)". Legal persons who do not perform pharmacy activities shall have no right to use in their name the word "pharmacy" or its translation into another language.

Article 36. Production and Dispensing (Sale) to the Residents of Extemporaneous Medicinal Products, Change of Packaging of Registered Medicinal Products

1. Extemporaneous medicinal products may be manufactured only in production pharmacies.
2. Officinal formula medicinal products shall be prepared in accordance to a prescription attested to by the State Medicines Control Agency.
3. The pharmacy which manufactured the medicinal products shall be responsible for their quality.
4. A pharmacy shall have the right to repackage or change the presentation of the medicinal products manufactured industrially or by a method involving an industrial process as indicated in subparagraph 2 of paragraph 3 of Article 24.
5. Extemporaneous medicinal products and medicinal products which have been repackaged according to the provisions of paragraph 4 of this Article may be sold /dispensed only to the residents directly serviced by the pharmacy or branch and Magistral Formula medicinal products – also to legal persons in possession of a licence for the provision of personal health care services. It shall be prohibited to dispense/sell them to another pharmacy or its branch.
6. According to prescriptions presented to the production pharmacy the Magistral Formula medicinal products may be dispensed to legal persons holding a licence for the provision of personal health care services.
7. Actions specified in paragraphs 1, 4 and 5 of this Law shall be carried out according to the procedure established by the Minister of Health.

Article 37. Requirements for Obtaining a Licence for Pharmaceutical Activity

A legal person wishing to obtain a licence for pharmacy activities must:

- 1) have at his disposal suitable premises and technical equipment complying with the requirements laid down by the Minister of Health;
- 2) enter into a contract of employment for fulfilling the duties of a pharmaceutical activity manager;
- 3) comply with other requirements laid down in this Law, the Rules of Licensing of Pharmaceutical Activity and other legal acts.

Article 38. Issuing a Licence for Pharmacy Activities

1. Pharmacy activities licence shall be issued only for performing a specified type of activities and only in the premises specified in the legal person's application. The pharmacy

activities licence shall apply only to the same premises or at the same address, with the exception of health care establishments.

2. 2. The pharmacy activities licence shall be issued or a justified decision to refuse issuing it shall be adopted within 45 days from the day of receipt of the application submitted according to the established requirements. If the licence holder requests to change the conditions of activities specified in the licence, the time taken for the procedure relating to satisfying the request or the adoption of a justified decision to refuse the changing shall be not longer than 30 days.

Article 39. Duties of the Pharmacy Activities Licence Holder

The pharmacy activities licence holder must:

- 1) employ a pharmaceutical activity manager and confer on him sufficient powers enabling him to perform the duties entrusted to him.
- 2) obtain medicinal products, active and other medicinal substances only from the legal persons holding the manufacturing or wholesale distribution licence;
- 3) ensure the storage of medicinal products in the conditions indicated by the manufacturer;
- 4) adequately and expeditiously participate in withdrawing medicinal products from the market, collect from the residents medicinal products subject to destruction;
- 5) carry out the activities according to Good Pharmacy Practice regulations;
- 6) take part in implementing the system of pharmacovigilance;
- 7) keep and manage the documents of acquisition and transfer, in which the licence holder must indicate, besides the mandatory particulars, the following information: the name of the medicinal product, pharmaceutical form, batch and quantity of the medicinal product;
- 8) perform the activities only in non-residential premises according to the procedure established in this Law and by the Minister of Health.

Article 40. Qualification Requirements and Main Duties of the Pharmacy Pharmaceutical activity Manager

1. Only a pharmacist holding a pharmaceutical activity licence may be a pharmaceutical activity manager.
2. The pharmaceutical activity manager must fulfil the duties set out in this Law, other legal acts and administrative acts of the licence holder. He shall be responsible that:
 - 1) pharmaceutical activity be carried out according to the requirements established by this Law and other legal acts;

2) the pharmacy would acquire, keep and sell/dispense only registered medicinal products as well as medicinal products which are permitted to be used for health care by other legal acts;

3) the complaints or notices about the quality of the medicinal product and/or pharmacy services received from the medicinal product users be adequately and expeditiously responded to;

4) withdrawing of medicinal products from the market and collecting from the residents of medicinal products which are to be destroyed or are unwanted be adequately and expeditiously participated in;

5) provision of pharmacy service be ensured, proposals to heads of administration concerning the improvement of qualifications of pharmacists and pharmacist's assistants (pharmacy technicians) be presented;

6) control of production of extemporaneous medicinal products be ensured.

Article 41. Supply of Rural Residents with Medicines

1. Pharmacies and their branches shall be set up and function in rural localities according to the procedure established by the Minister of Health. The State and municipality may apply tax and fee reliefs, provide assistance and otherwise support pharmacies located in rural localities

2. In rural localities, where there is no pharmacy or pharmacy branch, the residents shall be supplied with medicinal products via the primary health care establishments located in rural localities according to the procedure established by the Government by the pharmacies which have concluded contracts for the provision of medicinal products with the primary health care establishments.

CHAPTER NINE

PHARMACEUTICAL WASTE MANAGEMENT

Article 42. Collection of Pharmaceutical Waste from the Residents

1. Pharmaceutical waste shall be collected from the residents and pharmaceutical waste holders, managed and paid for according to the procedure established by the Government.

2. The management of pharmaceutical waste collected from the residents shall be paid for from the State budget.

Article 43. Management of Pharmaceutical Waste and its Peculiarities

1. A legal person shall have the right to manage pharmaceutical waste only being in possession of the licence for managing pharmaceutical waste, except for waste disposal, issued according to the procedure established by this Law.

2. The requirement set in paragraph 1 of this Article shall not be applied with respect to legal persons collecting pharmaceutical waste from the residents.

Article 44. Requirements for Obtaining a Licence for Pharmaceutical Waste Management, except for its Disposal

A legal person, wishing to obtain a licence for pharmaceutical waste management, except for its disposal, must:

- 1) have at its disposal suitable premises, technical equipment which would comply with the requirements laid down by the Minister of Health and ensure proper storage and management of pharmaceutical waste;
- 2) enter into a contract of employment for fulfilling the duties of a pharmaceutical activity manager;
- 3) according to the requirements of the Law on Waste Management, be in possession of the authorisation issued following the procedure laid down by the Ministry of Environment;
- 4) comply with the requirements of this Law, the Rules of Licensing of Pharmaceutical Activity and the requirements laid down by the Minister of Health.

Article 45. Issuing of a Licence for Pharmaceutical Waste Management, except for its Disposal

1. The State Medicines Control Agency shall issue a licence for the management of pharmaceutical waste, except for its disposal, only having ascertained that the submitted data and information meet the requirements set in this Law and by Minister of Health.

2. A licence for pharmaceutical waste management, except for its disposal, shall be issued for engaging in the activities only in the premises specified the legal person's application.

3. A licence for pharmaceutical waste management, except for its disposal, shall be issued or a justified decision to refuse issuing it shall be adopted within 60 days from the day of receipt of the application submitted according to the established requirements. If the licence holder requests to change the information and conditions specified in the licence, the time taken for the procedure relating to this request or for adopting a justified decision of refusal shall not exceed 30 days.

Article 46. Duties of the Holder of a Licence for Pharmaceutical Waste Management, except for its Disposal

The holder of a licence for pharmaceutical waste management, except for its disposal, must:

1) ensure that pharmaceutical waste should be managed according to the technical regulation defining in detail the process of waste collection, sorting, storage, entry into records. The technical regulation agreed with the Ministry of Environment shall be approved by the Director of the Department of Pharmacy under the Ministry of Health;

2) employ a pharmaceutical activity manager and confer on him sufficient powers enabling him to perform the duties entrusted to him;

3) ensure that the premises of pharmaceutical waste management, except for its disposal, meet the requirements of legal acts and licence information and data.

**Article 47. Qualification Requirements and Main Duties of the Pharmaceutical activity
Manager of the Enterprise for Waste Management, except for Disposal**

1. Only a pharmacist holding a pharmaceutical activity licence may be a pharmaceutical activity manager of an enterprise for waste management, except for disposal.

2. The enterprise pharmaceutical activity manager must fulfil the duties set out in this Law, other legal acts and administrative acts of the licence holder. He shall be responsible that:

1) pharmaceutical waste is managed according to the requirements established by this Law and other legal acts;

2) pharmaceutical waste is expeditiously collected;

3) pharmaceutical waste, according to the established requirements, is sorted, divided up, packaged, labelled;

4) safe storage and transportation of pharmaceutical waste is ensured;

5) accounting of pharmaceutical waste is properly carried out.

**CHAPTER TEN
INFORMATION ABOUT MEDICINAL PRODUCTS**

Article 48. Pharmaceutical Information

1. The pharmaceutical information about medicinal products must be scientifically justified, objective, not misleading and not hazardous to human health.

2. The pharmaceutical information about the registered medicinal products must be in keeping with the summary of the medicinal product characteristics.

3. The pharmaceutical information about unregistered medicinal products must be submitted accompanied by a notice that this is an unregistered medicinal product.

4. The pharmaceutical information comparing several medicinal products, of which at least one is subject to medical prescription, may be presented only to health care professionals and pharmaceutical specialists.

5. When the pharmaceutical information about medicinal products is provided on the radio, television and in publications, only the common name of medicinal products may be used, except in cases where the pharmaceutical information is prepared and announced meeting the requirements set in paragraphs 5 and 7 of Article 66 and Article 67.

6. The provisions of paragraph 5 of this Article shall not be applied to the names of medicinal products indicated in scientific articles which are published in the publications overviewed by the Institute of Scientific Information and in other recognised international data bases the list whereof shall be drawn up by the Lithuanian Scientific Council, in monographs, textbooks, methodical and other scientific publications.

7. Only persons who have completed appropriate biomedical science studies the list whereof shall be approved by the Minister of Health may prepare pharmaceutical information about the properties of medicinal products, except in cases where the information is prepared and published in compliance with the requirements set in paragraphs 5 and 7 of Article 66 and Article 67.

8. The medicinal product marketing authorisation holder in at least one of the EEA states must set up a scientific service for accumulating information about the medicinal products supplied to the market.

9. The right to disseminate pharmaceutical information shall be vested in the marketing authorisation holder and/or his representative, a person possessing a licence for pharmaceutical activity qualifying him to work with medicinal products issued according to the procedure established by this Law, a legal person possessing a licence for the provision of personal health care services.

10. The pharmaceutical information about medicinal products publicised by the State Medicines Control Agency shall be considered official pharmaceutical information.

Article 49. General Provisions of Advertising of Medicinal Products

1. Only registered medicinal products may be advertised in the Republic of Lithuania.

2. The advertising of a medicinal product shall not be misleading and shall be objective, the information and the terms used therein shall comply with the particulars listed in the summary of product characteristics, present it objectively and without exaggerating its properties and encourage its rational use.

3. All advertising to the general public of medicinal products shall be set in such a way that it is clear that the message is an advertisement and that the product is identified as a medicinal product.

Marketing authorisation holders and/or their representatives must raise the qualification of medical sales representatives.

5. The medicinal product marketing authorisation holder and one or more legal persons authorised by him may engage in common activities of medicinal product marketing stimulation (e.g.: sales promotion, application of advertising, formation of market and/or its conditions, etc)

6. Advertising of medicinal products subject to medical prescription through publications, in radio and television broadcasts and through other electronic media shall be prohibited, except in cases specified in paragraph 2 of Article 51 of this Law.

7. The following institutions and persons shall have no right to advertise medicinal products:

1) State and municipal institutions and their employees;

2) health care and/or pharmaceutical specialists providing health care or pharmacy services

8. Other requirements relating to the advertising of medicinal products to the general public and health care, pharmaceutical specialists, the bringing in or import of free samples of medicinal products, their transfer to the marketing authorisation holder or his representative, the criteria of professional/scientific and advertising undertakings shall be established by the Minister of Health.

Article 50. Advertising of Medicinal Products to the General Public

1. Advertising intended to the general public shall be of medicinal products which are available on medical prescription only presenting the information and references prescribed by the Minister of Health.

2. It shall be prohibited to advertise to the general public:

1) medicinal products which contain psychotropic and/or narcotic substances entered in lists of controlled narcotic and psychotropic substances approved by the Minister of Health;

2) medicinal products which are subject to medical subscription except in cases where the manufacturers of the medicinal products, having obtained authorisation of the Minister of Health, carry out the vaccination campaign of the general public;

3) medicinal products (irrespective of their strength or amount in the packaging) the names whereof are recorded in the price list of medicinal products subject to reimbursement approved by the Minister of Health.

3. Only information specified in the package leaflet and on the packaging may be used advertising homeopathic products registered applying the simplified registration procedure and the references prescribed by the Minister of Health shall also be presented.

4. It shall be prohibited in the advertising to the general public:

1) to refer to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of the medicinal product;

2) to present a detailed description or representation of a case history which could lead to erroneous self-diagnosis;

3) to refer, in improper, alarming or misleading terms, to claims of recovery;

4) to use misleading terms or improper pictorial representation of changes in the human or animal body caused by disease or injury, or of the action of the advertised medicinal product

5) to present material directed exclusively or principally at children;

6) to give an impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail and by other information media;

7) to suggest that the effects of taking the medicine are guaranteed and are unaccompanied by adverse reactions;

8) to suggest that the effects of the advertised medicinal product are better than or equivalent to those of another medicinal product or treatment;

9) to suggest that the health of the subject can be enhanced by taking the advertised medicinal product;

10) to suggest that the health of the subject could be affected by not taking the medicinal product; this provision shall not apply to carrying out the vaccination campaigns;

11) to suggest that the medicinal product is a foodstuffs, cosmetic or other consumer product;

12) suggest that the safety or efficacy of the medicinal product is due to the fact that is natural;

13) to influence residents through persistent offers of medicinal products, indicating the alleged price reductions on price lists, price labels, pharmacy premises, other means or measures contrary to good morals and public order.

5. It shall be prohibited to directly distribute to the public medicinal products for promotional purposes.

6. It shall be prohibited to suggest, when selling (dispensing) medicinal products not subject to medical prescription, to additionally purchase analgesic medicinal products.

Article 51. Advertising of medicinal Products to Health Care Professionals and Pharmaceutical specialists

1. Advertising to health care pharmaceutical specialists of prescription and non-prescription medicinal products shall be permitted.

2. Medicinal products subject to medical prescription may be advertised only in publications intended to health care professionals and pharmaceutical specialists. The list of such publications and the criteria of inclusion in the list shall be approved by the Minister of Health.

3. Any advertising intended for health care professionals and pharmaceutical specialists shall include information about the medicinal product specified by the Minister of health.

4. Advertising medicinal products to health care professionals qualified to prescribe such medicinal products the advertisers may use the free samples of medicinal products. A free sample of medicinal product not for sale shall be identical with the smallest presentation on the market of the medicinal product of the same name, form and strength and each packaging shall be marked “free medical sample not for sale.” It shall be prohibited to leave free samples of medicinal products with the health care professionals, distribute them among the pharmaceutical specialists and the general public and use them for health care purposes.

5. The provision of inducements to health care professionals and pharmaceutical specialists to prescribe, supply or sell/dispense medicinal products by giving remuneration whether in money or in kind shall be prohibited and the above specialists shall be prohibited from asking or accepting the remuneration.

6. Hospitality at professional/scientific sales promotion of medicinal products shall always be reasonable in level and must not be extended to other than the participating health care professionals and/or pharmaceutical specialists. Payment of travelling, accommodation and other expenses of the above professionals and specialists shall be prohibited.

7. Hospitality at professional/scientific congresses shall be secondary to the main purpose of the meeting. Only the payment of travelling, accommodation, catering and/or registration expenses of health care professionals and/or pharmaceutical specialists shall be authorised.

8. The marketing authorisation holder or his representative in the Republic of Lithuania must accumulate information about the expenses intended for promotional, professional/scientific events and the health care professionals and/or pharmaceutical specialists participating therein and submit the information to the State Medicines Control Agency according to the procedure established by the Minister of Health.

CHAPTER ELEVEN

PHARMACOVIGILANCE

Article 52. General Requirements of Pharmacovigilance

1. Pharmacovigilance shall be implemented in compliance with this Law, the procedure established by the Minister of Health and the recommendations of the European Commission concerning the rules governing medicinal products in the European Community. Implementing pharmacovigilance information on misuse and abuse of medicinal products shall also be taken into account as this may have an impact on the evaluation of benefits and risks of medicinal products.

2. The Minister of Health must apply measures encouraging health care professionals and pharmaceutical specialists to provide information about the observed suspected adverse reactions.

3. The implementation of pharmacovigilance shall be coordinated and the received pharmacovigilance information shall be managed by the State Medicines Control Agency.

4. Health care professionals and pharmaceutical specialists must notify the State Medicines Control Agency according to the procedure established by the Minister of Health about the serious effects of adverse reaction or unexpected adverse reactions and other cases which could affect the state of health of the patients undergoing treatment, even if the medicinal product was administered not as specified in the summary of product characteristics or abused.

5. Having received a notification of the suspected serious effect of adverse reaction determined in the Republic of Lithuania, the State Medicines Control Agency shall forthwith (not later than within 15 days of the receipt of the information) notify the European Medicines Agency, other EEA states and the holder of the medicinal product marketing authorisation through the Eudra Vigilance post-authorisation module of handling of notification in the EEA according to the procedure established by the State Medicines Control Agency.

Article 53. Duties of Marketing Authorisation Holder in Implementing Pharmacovigilance

The medicinal product marketing authorisation holder must:

1) establish measures of pharmacovigilance and implement them with respect to medicinal products the marketing authorisation whereof it possesses as well as guarantee that where necessary it will take appropriate measures agreed with the State Medicines Control Agency;

2) permanently and continuously have at his disposal in at least one EEA state an appropriately qualified person responsible for pharmacovigilance and ensure fulfilment of the duties laid down in Article 54 of this Law; The information about the qualified person must be submitted to the State Medicines Control Agency;

3) register suspected adverse reactions and submit periodical safety update reports according to the procedure established by the State Medicines Control Agency;

4) in reporting serious adverse reactions internationally recognised medical terminology shall be used.

Article 54. Qualification and Responsibility of the Qualified Person Responsible for Pharmacovigilance

1. A person possessing the doctor's or pharmacist's qualification and knowledge of pharmacovigilance may be the qualified person responsible for pharmacovigilance.

2. The marketing authorisation holder shall create conditions for the qualified person responsible for pharmacovigilance to perform the functions assigned to him and obligate him:

1) to be responsible for the establishment and maintenance of a system which ensures that information about all suspected adverse reactions which are reported to the employees of the marketing authorisation holder, including medical representatives, is collected and collated in order to be accessible at least within one point of the Community;

2) to prepare and submit to the State Medicines Control Agency periodic safety update reports;

3) to ensure that any request by the State Medicines Control Agency for the submission of additional information necessary for the evaluation of benefit and risks afforded by the medicinal product be responded to properly and quickly, including the information on the amount of the medicinal product sold or prescribed;

4) to be responsible for the submission to the State Medicines Control Agency of other information necessary for the evaluation of benefit and risks afforded by the medicinal product, including the information about the post-authorisation safety study.

Article 55. Registration of Adverse Reactions and Submission of Period Safety Update Reports

1. The medicinal product marketing authorisation holder must:

1) register all suspected adverse reactions occurring either in the Community or in a third country and report thereof to the State Medicines Control Agency and the European Medicines Agency. Reports shall be submitted electronically. In exceptional cases notice may also be given in other ways.

2) register all suspected effects of adverse reactions which have been observed in the Republic of Lithuania and of which he has been informed by the health care professional or pharmaceutical specialist and forthwith (in any case within 15 days of the receipt of the information) notify the State Medicines Control Agency thereof;

3) register all other suspected effects of adverse reactions observed in the Republic of Lithuania, which satisfy the criteria laid by the Minister of Health and of which he can be

reasonably expected to have knowledge and immediately (within 15 days of receipt of information) report to the State Medicines Control Agency thereof;

4) immediately (no later than 15 days following the receipt of information) notify the State Medicines Control Agency and the European Medicines Agency of all suspected serious unexpected effects of adverse reactions and the suspected transmission of agents of infection via a medicinal product observed in third countries.

2. If mutual recognition procedure, decentralised procedure or procedure of arbitration by European Commission has been applied with respect to a medicinal product, the marketing authorisation holder must additionally ensure that all suspected serious effects of adverse reactions observed in the Community are notified to the reference state or the institution authorised by the member state which acts in the capacity of the reference state. The reference member state shall be responsible for the analysis and monitoring of such reactions.

3. Unless other requirements have been laid down for registering the medicinal product, the marketing authorisation holder shall report to the State Medicines Control Agency all the adverse reactions in the format of periodic safety update report. The periodic safety update reports shall include a scientific evaluation of the benefit and risk afforded by the medicinal products.

4. The periodic safety update reports shall be submitted six monthly after the day of granting the marketing authorisation until the supply of the product to the market, six monthly for two years after the first supply of the product to the market, annually for the subsequent two years and thereafter at three-yearly intervals. Moreover the reports shall be submitted immediacy at the request of the State Medicines Control Agency.

5. The medicinal product marketing authorisation holder may request the State Medicines Control Agency to examine the terms of submitting periodic update reports in accordance with the Commission Regulation (EC) No 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation of medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State.

6. The marketing authorisation holder may not provide information relating to pharmacovigilance to the general public without advance notification thereof of the State Medicines Control Agency. He must ensure that such information is objective and not misleading.

Article 56. Suspension or Revocation of Marketing Authorisation for a Medicinal Product or Making Variations to the Terms of Marketing Authorisation due to Pharmacovigilance Data

1. If the State Medicines Control Agency, upon assessing the pharmacovigilance data, believes that the marketing authorisation must be suspended or revoked or variations must be made to the terms of marketing authorisation it must forthwith notify thereof the European Medicines Agency, other EEA states and the medicinal product marketing authorisation holder.

2. In case of necessity to take urgent measures to protect the health of the public the State Medicines Control Agency may suspend the marketing authorisation and not later than within one working day notify the European Medicines Agency, the European Commission and other EEA states thereof.

Article 56. Suspension or Revocation of Marketing Authorisation for a Medicinal Product or Making Variations to the Terms of Marketing Authorisation due to Pharmacovigilance Data

1. If the State Medicines Control Agency, upon assessing the pharmacovigilance data, believes that the marketing authorisation must be suspended or revoked or variations must be made to the terms of marketing authorisation, it must forthwith notify thereof the European Medicines Agency, other EEA states and the medicinal product marketing authorisation holder.

2. In case of necessity to take urgent measures to protect the health of the public the State Medicines Control Agency may suspend the marketing authorisation and not later than within one working day notify the European Medicines Agency, the European Commission and other EEA states thereof.

CHAPTER TWELVE

PRICING OF REIMBURSABLE MEDICINAL PRODUCTS AND MEDICAL AID EQUIPMENT

Article 57. General Requirements of Pricing of Reimbursable Medicinal Products and Medical Aid Equipment

1. The Minister of Health shall approve the base and highest wholesale prices of reimbursable medicinal products and medical aid equipment. Once per year they shall be published in the Reimbursable Medicinal Products Price List and Reimbursable Medical Aid Equipment Price List. When necessary the Minister of health shall supplement and/or adjust the price lists. All price lists and their supplements shall be published in “*Valstybės žinios*” and enter into force one month after their publication.

2. The highest retail prices of reimbursable medicinal products and medical aid equipment shall be calculated by adding to the price declared by the holder of manufacturing authorisation of the medicinal product or his representative or the manufacturer of medicinal aid equipment or his representative the amount of wholesale or retail mark-ups laid down by the Minister of Health and the amount of value added tax if the medicinal product or the medical aid equipment is subject to the tax.

3. Reimbursable medicinal products and reimbursable medical aid equipment shall be sold to the pharmacy and the legal person in possession of a licence for the provision of personal health care services at the price not exceeding the wholesale price which is calculated by adding to the price declared by the holder of the manufacturing authorisation of the medicinal product or his representative or the manufacturer of the medical aid equipment or his representative the retail mark-up laid down by the Minister of Health.

4. The reimbursable medicinal products shall be sold to wholesale distribution licence holder and the reimbursable medical aid equipment shall be sold to the wholesale distribution enterprises at the price not exceeding the price declared to the competent state authorities by the manufacturing authorisation holder of the medicinal product or his representative or the manufacturer of the medical aid equipment or his representative.

Article 58. Entry of Medicinal Products in the Lists of Diseases and Reimbursable Medicinal Products for their Treatment, Reimbursable Medicinal Products and Reimbursable Medical Aid Equipment

1. Medicinal products, diseases and medical aid equipment shall be entered in the Lists of Diseases and Reimbursable Medicinal Products for their Treatment, Lists of Reimbursable Medicinal Products and Reimbursable Medical Aid Equipment according to the procedure established by the Minister of Health.

2. Seeking to enter a medicinal product, a disease or medical aid equipment in the Lists specified paragraph 1 of this Article the applicant shall submit an application and documents to the Department of Pharmacy under the Ministry of Health according to the procedure established by the Minister of Health The applications shall be considered according to the procedure established by the Minister of Health.

3. The decision concerning the entry of the medicinal product, disease or medical aid equipment in the Lists specified in paragraph 1 of this Article and their prices shall be adopted not later than within 180 days from the day of registration of the application with the Department of

Pharmacy. If a decision is adopted the reasons of the decision based on objective and verifiable criteria shall be specified.

Article 59. Entry of Medicinal Products in the Price List of Reimbursable Medicinal Products and in the Price List of Reimbursable Medical Aid Equipment

1. Approved shall be retail and base prices only of those reimbursable medicinal products the common name whereof has been entered in the Lists of Diseases and Reimbursable Medicinal Products for their Treatment and Lists of Reimbursable Medicinal Products approved by the Minister of Health, of medical aid equipment the name whereof has been entered in the List of Reimbursable Medical Aid Equipment and in respect whereof an application has been received for entering them in the Price List of Reimbursable Medicinal Products or in the Price List of Reimbursable Medical Aid Equipment.

2. The application in the established form to enter the medicinal product or medical aid equipment in the Price List of Reimbursable Medicinal Products or Reimbursable Medical Aid Equipment shall be submitted to the Department of Pharmacy under the Ministry of Health according to the procedure established by the Minister of Health.

3. Decisions on the establishment and/or increasing the price of reimbursable medicinal products shall be adopted not later than within 90 days from the day of receipt of the application submitted according to the requirements established by the Minister of Health. If the information submitted for the adoption of the decision is insufficient, the applicant shall be forthwith notified what additional information is required. The decision shall be adopted not later than within 90 days from the receipt of the information.

4. In case a negative decision is adopted the applicant shall no later than within 14 days after the adoption of the decision be notified thereof in writing and the reasons of the decision based on objective and verifiable criteria shall be specified. If a decision on the determination and/or raising of the price is not adopted within the time period provided for in paragraph 3 of this Article the price of the medicinal product suggested by the applicant shall be entered in the subsequent Price List of Reimbursable Medicinal Products.

CHAPTER XIII

SUPPLY TO THE MARKET OF MEDICINAL PURPOSE PRODUCTS

Article 60. Peculiarities of Supply to the Market of Medicinal Purpose Products

1. Only registered medicinal purpose products may be supplied to the market of the Republic of Lithuania

2. Medicinal purpose products shall be registered according to the procedure established by the Minister of Health entering them in the List of Medicinal Purpose Products and issuing the certificate of authorisation of the medicinal purpose product granting marketing authorisation in the Republic of Lithuania.

3. The State Medicines Control Agency shall manage the List of Medicinal Purpose Products and issue marketing authorisation, renew the marketing authorisation of the medicinal purpose products, approve the variations in the terms of the marketing authorisation and suspend the marketing authorisation of products, lift the suspension of the marketing authorisation and/or revoke the marketing authorisation.

4. The marketing authorisation certificate shall be issued or a justified refusal to issue the marketing authorisation certificate shall be adopted not later than within 90 days from the day of receipt of the application submitted according to the established requirements. The time within which the applicant provides additional documents, information and, as necessary, verbal and/or written explanations required by the State Medicines Control Agency shall not be included in the time of examination of the application.

5. The marketing authorisation certificate shall be issued for 6 years. An application for renewal of marketing authorisation of a medicinal purpose product must be submitted not later than 4 months before the expiry of validity of the marketing authorisation certificate. Upon renewal of marketing authorisation of a medicinal purposes product its marketing authorisation in the Republic of Lithuania shall be extended for 6 years.

6. A State fee of the established amount shall be payable for the examination of the application for the issuance of marketing authorisation, renewal of authorisation of a medicinal purpose product and the accompanying documents and information as well as for the issuance of the marketing authorisation certificate.

7. Only the legal persons entered in the List of Persons Performing Activities with Medicinal Purpose Products may manufacture medicinal purpose products, the List shall be managed by the State Medicines Control Agency. The procedure of entry in and removal from the List shall be established by the Minister of Health.

8. Only the person holding a wholesale distribution licence may distribute and/or import from third countries medicinal purpose products and only the person holding a licence to engage in pharmacy activities may sell the products to the general public. In rural localities, where there is no pharmacy or pharmacy branch, the residents shall be supplied with medicinal purpose products

according to the procedure established by the Government through primary health care institutions located in rural localities.

9. The advertising of medicinal purpose product must be not misleading and objectively present its characteristics. The information and terminology must correspond to the terms of labelling and packaging leaflet approved by the State Medicines Control Agency. All advertising to the general public of a medicinal purpose product shall be set in such a way that it is clear that the message is an advertisement and that the product is identified as a medicinal purpose product .

10. It shall be prohibited, when advertising medicinal purpose products, to:

1) present information that the advertised product is a medicinal product or to indicate that the medicinal purpose product has a therapeutic effect, name the diseases or case history;

2) suggest that the effects of the advertised medicinal purpose product are better than or equivalent to those of other medicinal purpose products, medicinal product or another treatment;

3) suggest that the health of the subject could be affected by not taking the medicinal purpose product

4) suggest that the safety or efficacy of the medicinal purpose product is due to the fact that it is natural;

5) suggest that the health of the subject could be enhanced by taking the advertised medicinal purpose product ;

6) use misleading terms or improper pictorial representation of changes in the human or animal body caused by disease or injury, or the advertised medicinal purpose product ;

7) present material directed exclusively or principally at children;

8) suggest that the effects of the medicinal purpose product are guaranteed and unaccompanied by adverse reactions;

9) to refer to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of the medicinal purpose product;

10) compare the medicinal purpose product to a medicinal product.

11. The advertising of medicinal purpose products to state or municipal institutions shall be prohibited.

12. Other requirements to activities related to medicinal purpose products shall be established by the Minister of health.

CHAPTER XIV

STATE CONTROL OF ACTIVITIES WITH PHARMACEUTICAL PRODUCTS

Article 61. Executive Body and Regulation of State Control of Activities with Pharmaceutical Products

1. The State control of activities with pharmaceutical products prescribed by this Law shall be executed by the State Medicines Control Agency. State fee of the established amount shall be paid for the valuation, examination and issue of confirming documents performed by the State Medicines Control Agency.

2. The State Medicines Control Agency shall protect the rights of consumers.

3. Control shall be exercised in compliance with this Law and other legal acts and also having regard to the Compilation of Community Procedures on Inspections and Exchange of Information adopted on behalf of the European Commission by the European Medicines Agency.

4. State control of veterinary pharmacy shall be exercised by the State Food and Veterinary Agency and the institution authorised by it – the Lithuanian State Inspectorate on Veterinary Preparations.

Article 62. Main Principles of Control of State Activities with Pharmaceutical Products

1. The State Medicines Control Agency performing repeated inspections and samples control tests without prior notice must ensure compliance of activities involving pharmaceutical products with the requirements established by this Law and other legal acts.

2. The State Medicines Control Agency may, without a prior notice, on its own initiative or at the request of another EEA state, the European Commission or the European Medicines Agency, perform an inspection of active substances used as starting materials within the premises of manufacturers or the medicinal product marketing authorisation holder if it is reasonable to assume that GMP is not complied with. Manufacturers of starting materials may be inspected at their own request.

3. The State Medicines Control Agency shall inspect and evaluate:

1) the manufacturing or commercial establishments of the manufacturers, importers of medicinal products, investigational medicinal products or active substances used as starting materials, as well as laboratories entrusted by the manufacturing licence holder with the task of carrying out checks;

2) whether the manufacturing processes used in the manufacture of immunological products are properly validated and whether the batch-to-batch consistency is attained. As necessary, require the manufacturer and/or importer to submit copies of the control reports signed by the qualified person.

- 3) whether the manufacturing and purifying processes used in the preparation of medicinal products derived from human blood or human plasma are properly validated, batch-to-batch consistency is ensured and the absence of specific viral contamination is guaranteed;
- 4) performance of clinical tests or trials;
- 5) the establishments, reports and documents relating to the carrying out of pharmacovigilance of the medicinal product marketing authorisation holder or another person entrusted by him to implement pharmacovigilance;
- 6) third country manufacturers where there are grounds for that and the agreements of the European Community with third countries are not violated;
- 7) legal persons upon submitting the application for the issuance of a licence for pharmaceutical activity;
- 8) carrying out the advertising of medicinal products, medicinal purpose products according to the requirements laid down in this Law and the Law on Advertising;
- 9) other activities involving medicinal products and the entities related to the activities within the competence established by the Regulations of State Medicines Control Agency.

Article 63. Rights of State Medicines Control Agency Employees Performing Actions of control

1. The State Medicines Control Agency employees performing actions of control shall have the right to:
 - 1) to receive all information and documents related to the object inspection required in order to assess compliance with the established requirements;
 - 2) upon presenting the certificate of employment and the order, freely and without a prior notice during the working hours of the licence holder and at other hours – having enlisted, according to the procedure established by law, the assistance of competent law enforcement authority officers, enter all establishments in the places of activities specified in the licence, inspect, according to their competence, the establishments, equipment, installations, resources, the actions performed, the staff composition, their qualification etc., seeking to establish compliance with the requirements set by this Law and other regulations;
 - 3) issue mandatory instructions according to their competence;
 - 4) use technical means necessary for implementing effective control;
 - 5) enlist the assistance of necessary experts to participate in the inspection of the activities and the assessment of their compliance with the established requirements;
 - 6) to carry out control verifications and control purchases of medicinal products;

7) exercise other rights according to the procedure established by this Law and other legal acts and apply other methods of inspection;

8) take free samples for investigation.

2. In the cases when it is necessary to enter the legal person's establishment not in the working hours or when the inspected legal person fails to comply with the lawful instructions of the State Medicines Control Agency employees performing control activities or when it is necessary to perform in the course of the inspection certain actions which the employees of the State Medicines Control Agency have no right to perform under the effective laws the State Medicines Control Agency must apply to the competent law enforcement authority according to the procedure established by laws with a request to assist it to implement its rights or to duly perform its functions.

3. The employees who perform the actions of control must, when inspecting, verify the effect and risk to public health of the established shortcomings and infringements and, as necessary, take all the appropriate actions or perform other necessary actions according to the procedure established by the Minister of Health. The State Medicines Control Agency employees, having established when performing control actions, the presence of a criminal act or any other violations of law, the investigation of which falls outside the sphere of their competence, shall inform law enforcement or the relevant controlling authority or institution thereof.

4. The actions of employees specified in this Law may be appealed against according to the procedure established by legal acts.

Article 64. Documents of Control

1. The results of every inspection shall be recorded in the certificate of inspection, in which, in addition to other information, conclusions regarding the compliance of the activities with the established requirements shall be presented. The inspected persons shall have the right to present in the course of inspection their explanations in respect of the object of inspection and other circumstances related to inspection. Written explanations and proofs shall be presented to the State Medicines Control Agency employees performing control actions and a notice to the effect shall be made in the certificate of inspection.

2. It shall be indicated when filling up a certificate for the legal person seeking to be issued a licence to engage in pharmaceutical activity or for the licence holder whether the activities performed by him are in compliance with the good manufacturing practice or good distribution practice or the good pharmacy practice regulations. Inspecting the conduct of clinical trial their compliance with good clinical practice shall be assessed. The contents of the certificate shall be

made known to the legal person or, as necessary, the medicinal product marketing authorisation holder who has been inspected.

3. If, after the completion of the investigation, it is established that the medicinal product manufacturing or wholesale distribution licence holder complies with the requirements of good manufacturing practice or distribution practice, he must be within 90 days after the investigation issued a good manufacturing practice or good distribution practice certificate according to the procedure established by the Minister of Health.

Article 65. Validity of Inspections Carried out by other EEA States

1. The conclusions of investigations by other authorised institutions of the EEA states adopted with respect to manufacturing, import, clinical investigation, wholesale distribution, pharmacovigilance shall be valid in the Republic of Lithuania.

2. In exceptional cases, if for reasons connected with public health the State Medicines Control Agency cannot agree to the conclusions indicated in paragraph 1 of this Article, it shall notify the European Commission and the European Medicines Agency thereof.

CHAPTER XV

SANCTIONS FOR MARKETING OF A MEDICINAL PRODUCT OR MEDICINAL PURPOSE PRODUCTS

Article 66. Suspension, Revocation, Change in the Terms of Marketing and Marketing Authorisation of a Medicinal Product

1. The State Medicines Control Agency shall suspend or revoke the marketing or marketing authorisation certificate of a medicinal product or approve the varying of its terms upon establishing at least one of the following grounds:

- 1) the medicinal product is harmful under normal conditions of use;
- 2) the medicinal product lacks in efficacy ;
- 3) under normal conditions of use the benefit/risk balance of the medicinal product is unfavourable;
- 4) the quantitative and/or qualitative composition of the medicinal product does not correspond to the declared composition;
- 5) the information and documents submitted together with the application for the medicinal product marketing authorisation are erroneous or not supplemented according to the procedure established in paragraph 1 of Article 15;

6) control of the medicinal product and/or its constituents or control at intermediate stages of the manufacturing process specified in the documents submitted together with the application for the marketing authorisation is not carried out.

2. Having suspended the marketing or marketing authorisation certificate of the medicinal product the State Medicines Control Agency shall set a period not exceeding 12 months during which the medicinal product marketing or marketing authorisation certificate holder shall submit to the State Medicines Control Agency supplementary evidence required for eliminating the grounds established in paragraph 1 of this Article . If the medicinal product marketing or marketing authorisation certificate holder presents the evidence within the established time period, the State Medicines Control Agency shall adopt a decision to lift the suspension of marketing or marketing authorisation certificate for the medicinal product. Otherwise the marketing or marketing authorisation certificate for the medicinal product shall be revoked.

3. The efficacy of a medicinal product shall be considered to be lacking when it is established that the therapeutic results for which it is used cannot be obtained with the medicinal product.

4. The State Medicines Control Agency must suspend or revoke manufacturing authorisation of a group of medicinal products or all products the manufacturing whereof does not comply with the manufacturing conditions approved when granting marketing or marketing authorisation certificate.

5. Having adopted a decision to suspend or revoke the marketing or marketing authorisation certificate, the State Medicines Control Agency shall accordingly update the Register of Medicinal Products of the Republic of Lithuania and forthwith publish a notice in the media of the suspension or revocation of the marketing or marketing authorisation certificate.

6. Upon suspending the marketing or marketing authorisation certificate of a medicinal product its marketing or supply of the medicinal product to the market shall be prohibited.

7. Upon the revocation under this Article of the medicinal product marketing or marketing authorisation certificate the product must be withdrawn from the market.

8. The medicinal product marketing authorisation holder shall ensure the implementation of provisions of paragraphs 6 and 7 of this Law.

Article 67. Prohibition of Supply to the Market of a Medicinal Product and Withdrawal from the Market

1. The State Medicines Control Agency shall, without prejudice to Article 66 of this Law, prohibit to supply a medicinal product to the market and withdraw it from the market upon establishing at least one of the following circumstances:

- 1) the medicinal product is harmful under normal conditions of use;
- 2) the medicinal product is lacking in efficacy;
- 3) under normal conditions of use the benefit/risk balance of the medicinal product is unfavourable;
- 4) the quantitative and/or qualitative composition of the medicinal product is not consistent with the declared composition;
- 5) control of the medicinal product and/or its constituents or control at the intermediate stages of the manufacturing process, specified in the documents presented together with the application for the marketing authorisation is not carried out or requirements and obligations connected with the granting of marketing authorisation are not complied with.

2. The State Medicines Control Agency shall have the right to prohibit by a justified decision to supply to the market only those batches of the medicinal product which give rise to doubts according to the circumstances specified in paragraph 1 of this Article or to apply their full or partial removal.

3. The State Medicines Control Agency may suspend the manufacture or imports of medicinal products coming from third countries where the Articles of this Law are not complied with.

Article 68. Suspension and Revocation of Marketing Authorisation Certificate of Medicinal Purpose Products

1. The State Medicines Control Agency shall suspend or revoke the marketing authorisation certificate of the medicinal purpose products if at least one of the following grounds is established:

- 1) the medicinal purpose product does not meet the recognised modern quality or safety requirements;
- 2) it transpires that the documents accompanying the application for marketing authorisation of the medicinal purpose product are unlawful, erroneous or misleading;
- 3) the medicinal purpose product is harmful;
- 4) the qualitative and/or quantitative composition of the medicinal purpose product is not consistent with the declared composition;
- 5) the marketing authorisation certificate holder of the medicinal purpose product violates the terms of the marketing authorisation certificate;
- 6) this is required by the marketing authorisation certificate holder of the medicinal purpose product.

2. Having suspended the marketing authorisation certificate of the medicinal purpose product the State Medicines Control Agency shall set a period not exceeding 12 months during

which the holder of the marketing authorisation certificate of the medicinal purpose product shall submit to the State Medicines Control Agency supplementary evidence required for eliminating the grounds established in paragraph 1 of this Article. If the holder of the marketing authorisation certificate of the medicinal purpose product submits the evidence within the established time period, the State Medicines Control Agency shall adopt a decision to lift the suspension of the marketing authorisation certificate of the medicinal purpose product. Otherwise the marketing authorisation certificate of the medicinal purpose product shall be revoked.

3. The State Medicines Control Agency having adopted the decision to suspend or revoke the marketing authorisation certificate shall forthwith publish a notice in the media of the suspension or revocation of the marketing authorisation certificate.

4. After variations under this Article have been made to the terms of the marketing authorisation certificate of the medicinal purpose product, its marketing shall be conducted in compliance with the variations to the terms of the certificate.

5. Upon suspending under this Article marketing authorisation certificate of a medicinal product, its marketing and supply to the market shall be prohibited.

6. Upon the revocation under this Article of the marketing authorisation of a medicinal purpose product, the product must be withdrawn from the market.

CHAPTER XVI

INTERNATIONAL CO-OPERATION

Article 69. Cooperation with the EU Institutions and the Competent Authorities of other EEA States

1. The State Medicines Control Agency must cooperate and exchange information with the institutions of the European Union, competent authorities of other EEA states and the World Health Organisation For that purpose the Agency must:

1) submit copies of manufacturing licences and GMP certificates (except for GMP certificate for traditional herbal medicinal products) to the European Medicines Agency; it shall enter the data in the Community Data Base. If it is established during the inspection that the manufacturer, importer does not comply with the GMP requirements, the corresponding information shall be forthwith submitted to the European Medicines Agency and published in the Community data base;

2) at the request of the European Commission or any EEA state, present all the required information concerning the wholesale distribution licences issued according to this Law and other legal acts;

3) forthwith inform the European Commission and other EEA states of the suspension of the medicinal products wholesale distribution licence, lifting the suspension and revocation of the licence.;

4) if the holder of the medicinal products wholesale distribution licence of another EEA state does not comply with the terms of licensed activity, engages in activities not corresponding to the licence information and data, notify thereof the European Commission and the EEA state which issued the wholesale distribution licence to the licence holder;

5) exchange information with the competent authorities of other EEA states and participate in the common information systems necessary to ensure compliance with the terms of manufacturing, wholesale distribution licences, good manufacturing practice certificates and authorisation documentation;

6) upon reasoned request forthwith submit to the authorised authorities of another EEA state a document of inspection of compliance of the manufacturer, importer with the good manufacturing practice requirements and/or pharmacovigilance requirements; as necessary the State Medicines Control Agency must request the authorities to present to it such information;

7) forthwith notify the European Medicines Agency of the decisions to issue a medicinal product marketing or marketing authorisation certificate, to refuse to issue it or to revoke it, to change the decision to refuse to issue the medicinal product marketing or marketing authorisation certificate or to revoke it, to prohibit to supply medicinal products to the public or to withdraw them from the market, stating the reasons for such actions;

8) make known to other Member States all information necessary to ensure the quality and safety of homeopathic products manufactured and supplied to the Community;

9) forward to the European Medicines Agency the information it received from the medicinal products manufacturing authorisation holder regarding the suspension of supply to the public of the medicinal product or its withdrawal from the market;

10) forthwith bring to the attention of the World Health Organisation the information relating to the actions specified in subparagraphs 7 and 9 of this Article, if they may affect the protection of public health in third countries and forward a copy of the information to the European Medicines Agency.

2. The State Medicines Control Agency, at the request of the manufacturer, the exporter or the competent authority of an importing third country, shall issue a document certifying that a manufacturer of medicinal products is in possession of the manufacturing authorisation. When the manufacturer is not in possession of a marketing authorisation, he shall provide the State Medicines Control Agency with a declaration explaining no marketing authorisation is available.

3. The certificate specified in paragraph 2 of this Article shall be issued taking into account the administrative agreements adopted by the World Health Organisation. If the medicinal product intended for export has been granted marketing authorisation in the Republic of Lithuania, the summary of the product characteristics shall also be submitted.

CHAPTER XVII

VETERINARY PHARMACEUTICAL ACTIVITY

Article 70. Granting Marketing Authorisation of Veterinary Pharmaceuticals

1. Only veterinary pharmaceuticals registered in the Register of Veterinary Pharmaceuticals of Lithuania may be supplied to the market of the Republic of Lithuania.

2. The Register of Veterinary Pharmaceuticals shall be set up by the Government of the Republic of Lithuania. The leading management body of the Register shall be the State Food and Veterinary Service, the management body shall be the Lithuanian State Inspection of Veterinary Preparations.

3. Veterinary pharmaceuticals shall be granted marketing authorisation according to the procedure established by the State Food and Veterinary Service in compliance with the national, mutual recognition or decentralised procedures.

4. In order to be granted marketing authorisation of a veterinary pharmaceutical, the applicant must present the following documents:

- 1) an application in the form established by the State Food and Veterinary Service;
- 2) administrative information and scientific documents required to evidence the quality, safety and effectiveness of veterinary pharmaceutical.

5. A state fee of the established amount shall be paid for granting marketing authorisation of a veterinary pharmaceutical.

6. The decision on the granting of marketing authorisation of the veterinary pharmaceutical in the Register of Veterinary Pharmaceuticals shall be adopted not later than within 210 days from the receipt of the application. The time within which the applicant provides additional documents, information and, as necessary, verbal and/or written explanations shall not be included in the time of examination of the application.

7. A veterinary pharmaceutical shall not be registered in the Register of Veterinary pharmaceutical, its marketing authorisation shall be suspended or revoked, if:

- 1) under normal conditions of use the benefit/risk balance of the veterinary pharmaceutical is unfavourable;

2) the efficacy of the veterinary pharmaceutical is not sufficiently substantiated by the applicant or the veterinary pharmaceutical has no therapeutic effect on the animal species to which it is intended.

3) quantitative and qualitative composition of the veterinary pharmaceutical is not in compliance with the declared composition;

4) the withdrawal period recommended by the applicant is not sufficiently long to ensure that the foodstuffs obtained from the treated animal have no residues that may endanger the consumer's health or is not sufficiently justified;

5) labelling or package leaflet does not meet the established requirements;

6) the veterinary pharmaceutical is offered for sale for a use prohibited under other provision of EEA states;

7) it turns out that erroneous data has been submitted about the veterinary pharmaceutical.

8. The marketing authorisation holder shall be responsible for the quality, safety and efficacy of the registered veterinary pharmaceutical.

9. The State Food and Veterinary Service shall establish:

1) the procedure of temporary import and use of veterinary pharmaceuticals not registered in the Republic of Lithuania;

2) the procedure of temporary import and use of veterinary pharmaceuticals intended for scientific and clinical trial purposes that are not authorised for use in the Republic of Lithuania

Article 71. Manufacture, Import and Supply to the Market of Veterinary pharmaceuticals

1. Legal persons and branches in EU member states or EEA states of enterprises established in the Republic of Lithuania (hereinafter referred to as legal persons) who wish to manufacture or import veterinary pharmaceuticals, must:

1) have at its disposal premises, technical equipment and control facilities complying with the requirements set by the State Food and Veterinary Service;

2) employ at least one qualified person responsible for manufacture and/or import whose qualification would meet the requirements set by the State Food and Veterinary Service;

3) meet other requirements set by this Law and other legal acts.

2. Legal persons who wish to supply to the market veterinary pharmaceuticals must:

have at their disposal premises, technical equipment that would meet the requirements established by the State Food and Veterinary Service;

2) employ at least one person – manager of veterinary pharmaceutical activity , responsible for the performed veterinary pharmaceutical activity whose qualification would meet the requirements set by the State Food and Veterinary Service;

3) meet other requirements set by this Law and other legal acts.

3. The State Food and Veterinary Service shall set the procedure for prohibiting the supply to the market and withdrawal from the market of veterinary pharmaceuticals.

Article 72. Veterinary Pharmacovigilance

1. The State Food and Veterinary Service shall implement veterinary pharmacovigilance.

2. Persons authorising and manufacturing veterinary pharmaceuticals, veterinary pharmaceutical enterprises, veterinary surgeons, health professionals must notify, according to the procedure established by the State Food and Veterinary Service, of the animal's adverse reaction to the veterinary pharmaceutical administered, detrimental effect of veterinary pharmaceuticals to human, animal health and environment.

Article 73. Licensing of Veterinary Pharmaceutical Activity

1. In the Republic of Lithuania legal and natural persons may engage in veterinary pharmaceutical activity only being in possession of a licence issued by the State Food and Veterinary Service (hereinafter referred to as the licence of veterinary pharmaceutical activity)

2. A veterinary pharmaceutical activity licence shall authorise a person to engage in activities connected only with veterinary pharmaceuticals and the types of licensed activities specified in the licence.

3. Rules for the licensing of veterinary pharmaceutical activity of legal persons, rules for the licensing of veterinary pharmaceutical activity of natural persons shall be approved by the Government.

4. Legal persons and branches established in the Republic of Lithuania of enterprises established in EU member states and other EEA states (hereinafter referred to as legal persons) shall be issued licences of veterinary pharmaceutical activity of the following types:

- 1) licence for the manufacture of veterinary pharmaceuticals;
- 2) licence for wholesale distribution of veterinary pharmaceuticals;
- 3) veterinary pharmaceutical activity licence;
- 4) licence for the import of veterinary pharmaceuticals;

5. Legal persons carrying out partial manufacture, dividing up or repacking shall also be required to possess a licence for the manufacture of veterinary pharmaceuticals.

6. In order to be issued a veterinary pharmaceutical activity licence a natural or a legal person must submit an application and other documents prescribed by the Rules of Licensing of Legal Persons Veterinary Pharmaceutical activity and of Licensing of Natural Persons Veterinary Pharmaceutical activity. The applicant shall be responsible for the correctness of the data and information submitted in the application.

7. The State Food and Veterinary Service shall adopt a decision to issue a veterinary pharmaceutical activity licence only having ascertained that the submitted data and information comply with the requirements set in this Law and other legal acts.

8. A licence shall be issued only to those natural persons who have acquired professional qualification of a veterinary surgeon or veterinary pharmacist. The activities of a veterinary paramedic and pharmacist's assistant (pharmacy technician) in veterinary pharmaceutical enterprises shall not be subject to licences. Veterinary paramedics and pharmacist's assistants (pharmacy technicians) shall work in veterinary pharmaceutical enterprises under the control exercised, according to the procedure established by the State Food and Veterinary Service, by the veterinary surgeon or a pharmacist in possession of a licence for veterinary pharmaceutical activity.

9. A veterinary pharmaceutical activity licence shall be issued only to those legal entities which employ a natural person(s) in possession of a veterinary pharmaceutical activity licence and one of them has been appointed manager of the veterinary pharmaceutical activity of the enterprise, while the enterprise for the manufacture or import of veterinary pharmaceuticals employs a qualified person in possession of a natural person's licence for veterinary pharmaceutical activity.

10. Licences for veterinary pharmaceutical activity shall be issued to legal and natural persons for an indefinite time period.

11. A state fee of the established amount shall be paid for the issuing of the veterinary pharmaceutical activity licence.

12. A veterinary pharmaceutical activity licence shall not be issued to legal and natural persons (shall not be updated or supplemented) if:

1) not all the required documents specified in the Rules for the Licensing of Veterinary Pharmaceutical activity of Legal Persons and Rules for the Licensing of Veterinary Pharmaceutical activity of Natural Persons have been submitted and the applicant has not complied with the demand of the State Food and Veterinary Service to submit the lacking documents;

2) not fully or incorrectly filled in documents have been submitted and the applicant has not complied with the demand of the State Food and Veterinary Service to eliminate the shortcomings;

3) incorrect data, lacking and inaccurate information has been submitted, and the applicant has not complied with the demand of the State Food and Veterinary Service to make good the shortcomings;

4) the veterinary pharmaceutical activity licence of the legal or natural person has been revoked and less than one year has lapsed from the revocation of the veterinary pharmaceutical activity licence; the provision shall not apply if the legal person terminates its activities of its own free will or the natural person submits an application to revoke the licence;

5) a State fees of the established amount have not been paid;

6) the natural person has not acquired the qualifications of a veterinary surgeon or a pharmacist

7) the person is prohibited from engaging in the veterinary pharmaceutical activity by the effective court decision;

8) legal capacity of the legal person has been restricted by an effective court decision;

13. Duties of the legal person holding a veterinary pharmaceutical activity licence:

1) to comply with the provisions and the requirements of this Law, the Law on Veterinary pharmaceutical, the Rules for the Licensing of Veterinary Pharmaceutical activity of Legal Persons and other legal acts regulating veterinary pharmaceutical activity;

2) to provide conditions for the improvement of employees' qualifications;

3) to provide conditions for the manager of veterinary pharmaceutical activity or the qualified person to carry out veterinary pharmaceutical activity in compliance with the requirements of this Law;

4) to notify the State Food and Veterinary Service of the replacement of the manager of veterinary pharmaceutical activity or the qualified person, suspension of the licensed activity, refusal of one's own volition to engage in the licensed activity or of the changes in the licensed activity;

5) allow the controlling state institution to inspect the licensed activity carried out.

14. Duties of the natural person holding a veterinary pharmaceutical activity licence:

1) to comply with the provisions and the requirements of this Law, the Law on Veterinary pharmaceutical, the Rules for the Licensing of Veterinary Pharmaceutical activity of Natural Persons and other legal acts regulating veterinary pharmaceutical activity;

2) to improve one's qualification according to the procedure established by the State Food and Veterinary Service;

3) to notify the State Food and Veterinary Service of the suspension of the licensed activity or the refusal of one's own volition to engage in licensed activity.

15. Rights of legal and natural persons holding the veterinary pharmaceutical activities licence:

1) to engage in licensed activity;

2) to receive explanation in the case of veterinary pharmaceutical licence suspension, licence revocation;

3) take part in considering the suspension of the veterinary pharmaceutical activity licence or revocation of the veterinary pharmaceutical activity licence issued in their name;

4) to appeal to the court against the decisions of the State Food and Veterinary Service concerning the suspension, revocation of the veterinary pharmaceutical activity licence according to the procedure established by the legal acts of the Republic of Lithuania.

16. The holder of the veterinary pharmaceutical activity licence shall have no right to authorise another person to carry out on his behalf the activity specified in the veterinary pharmaceutical activity licence or to give over under contract to another person the right to carry out the activity.

17. The State Food and Veterinary Service shall suspend the veterinary pharmaceutical activity licence: 1) if the legal or natural person does not comply with the terms of licensed activity and duties of the veterinary pharmaceutical activity licence holder;

2) to a legal person if criminal or administrative proceedings have been instituted following the infringements of veterinary pharmaceutical activity committed by the qualified person or the manager of veterinary pharmaceutical activity for the period pending the hearing or investigation of the case, except where another person is appointed to act for the qualified person or manager of veterinary pharmaceutical activity; 3) to a legal person if the qualified person or the manager of veterinary pharmaceutical activity of the legal person is prohibited by an effective court decision to engage in the licensed activity pending the appointment to the duties of another person meeting the requirements of this Law and other legal acts;

4) if the natural persons holding a veterinary pharmaceutical activity licence after a written warning fail to improve their qualification according to the qualification improvement procedure established by the State Food and Veterinary Service;

5) at the request of the legal or natural person holding a veterinary pharmaceutical activity licence.

18. After the causes for suspension of the veterinary pharmaceutical activity licence have been eliminated, the suspension of the veterinary pharmaceutical activity licence shall be lifted.

19. The State Food and Veterinary Service shall revoke the licence for veterinary pharmaceutical activity if:

1) the holder of the veterinary pharmaceutical activity licence terminates the licensed activity and submits to the State Food and Veterinary Service an application to revoke the veterinary pharmaceutical activity licence;

2) upon suspension of the veterinary pharmaceutical activity licence the holder of the veterinary pharmaceutical activity licence fails to eliminate within the established time period the violations of the licensed activity;

3) the authorised body establishes that upon the suspension of the veterinary pharmaceutical activity licence the legal person or its establishment further engages in veterinary pharmaceutical activity;

4) the legal person is in liquidation, a bankruptcy proceedings have been instituted against it or out-of court bankruptcy procedure is applied with respect to the legal person or the legal person is being reorganised, ceases to exist as an independent economic entity;

5) it transpires that erroneous data has been submitted seeking the issuance of the veterinary pharmaceutical activity licence;

6) the veterinary pharmaceutical activity licence holder, upon the suspension of its veterinary pharmaceutical activity licence and upon the lifting of the suspension of the veterinary pharmaceutical activity licence, for the second time within 12 months committed a violation related to the licensed activity;

7) the veterinary pharmaceutical activity licence holder infringes the requirements of legal acts regulating veterinary pharmaceutical activity within the time period set for the elimination of shortcomings, when the veterinary pharmaceutical activity licence is suspended, or infringes the requirements of legal acts regulating veterinary pharmaceutical activity, when irreparable damage is caused by the activity to human, animal and the environment.

8) the legal or natural person has been prohibited from engaging in licensed activity by an effective court decision;

9) the veterinary pharmaceutical activity licence holder – a natural person - does not improve his qualification after the warning or suspension of the veterinary pharmaceutical activity licence because of the qualification improvement according to the procedure established by the State Food and veterinary Service.

CHAPTER XVIII

ENSURING THE IMPARTIALITY OF PERSONS AND LIABILITY FOR LEGAL VIOLATIONS

Article 74. Ensuring the Impartiality of Decision Making Persons

1. Persons taking part in the making of decisions connected with the granting of marketing authorisation for medicinal products, issuance of permit for parallel import, granting of clinical trials authorisation, issuance of medicinal purpose registration certificate, issuance of licences for

pharmaceutical activity, who are exercising control over the activity with pharmaceutical products should not have any financial or other interests related to the matter under consideration, pharmaceutical industry or other persons who can affect their impartiality. Persons having such interests must declare them according to the procedure established by legal acts.

2. The State Medicines Control Agency shall grant the public access to its rules of procedure or those of the commissions formed at the State Medicines Control Agency, the agendas of the meetings, the adopted decisions and motives for their adoption. The adopted decisions and their motives shall be published in the webpage of the State Medicines Control Agency.

Article 75. Liability for Violations

For violations of activity involving pharmaceutical products and for veterinary pharmaceutical activity violations as well as for illegal activity natural and legal persons shall be held liable according to the procedure established by legal acts of the Republic of Lithuania

CHAPTER IXX FINAL PROVISIONS

Article 76. Entry into Force of the Law

1. The provisions of paragraph 4 of Article 12, paragraph 8 of Article 14, paragraph 9 of Article 17, paragraph 5 of Article 18, paragraph 8 of Article 20, paragraph 6 of Article 60 and paragraph 1 of Article 61 on the introduction of State fees shall enter into force on 1 July 2006. Until the entry into force of this part a remuneration in the amount approved by the Minister of Health shall be payable for the services provided by state establishments and for the issuance of documents specified in paragraph 4 of Article 12, in paragraph 8 of Article 14, in paragraph 9 of Article 17, in paragraph 5 of Article 18, in paragraph 8 of Article 20, in paragraph 6 of Article 60, and in paragraph 1 of Article 61.

2. Paragraph 1 of Article 42 of this Law shall come into force on 1 January 2007.

3. The provisions of paragraph 2 of Article 5 of this Law shall not be applicable to pharmacy technicians holding a licence for pharmaceutical activity. The State Medicines Control Agency shall enter them into the List of Pharmacist's Assistants (Pharmacy technicians) based on the information on the issued and valid licences of pharmaceutical activity.

4. The provisions of paragraph 5 of Article 5 of the Law shall enter into force a year after the date of entry into force of the Law.

5. The pharmacy technicians who have been issued a licence for pharmaceutical activity prior to the entry into force of this Law or persons who started their pharmacy technician studies prior to the entry into force of this Law, who will acquire the professional qualification of the pharmacist's assistant (pharmacy technician) after the entry into force of this Law may provide the pharmacy service according to the procedure established by the Minister of Health but for not longer than until 31 December 2015. From 1 January 2016 the persons specified in this part shall have the right to sell/dispense medicinal products under the control of the pharmacist. The pharmacist shall be liable for the activity.

6. Legal persons who are in possession of the pharmaceutical activity licence (except if they have a licence of the production community pharmacy to sell/dispense the *Magistral Formula* medicinal products), who until the entry into force of this Law supplied medicinal products to legal persons having a licence for the provision of personal health care services may supply medicinal products not longer than until 31 December 2006.

7. Pharmacy branches established prior to the entry into force of this Law which do not meet the set requirements may engage in the activities for no longer than until 31 December 2015.

8. The relations which emerged prior to the entry into force of this Law shall be continues and the provisions of this Law shall be applied with respect to them. The laws and other legal acts which used to regulate the relations attributed within the sphere of regulation of this Law shall be valid to the extent not contrary to this Law except in cases when this Law gives precedence to the provisions of other laws or legal acts.

9. The provisions of other laws of the Republic of Lithuania shall be applied to legal relations regulated by this Law to the extent they are not regulated by this Law.

Article 77. Proposals to the Government and other State Institutions Indicated in the Law

The Government of the Republic of Lithuania and other State institutions indicated in this Law shall review the legal acts related to the implementation of the provisions of this Law and, as necessary, draw up appropriate drafts for the amendment thereof or adopt new legal acts.

Article 78. Invalidation of Legal Acts

Upon the entry into force of this Law, the following laws shall be repealed:

Law Republic of Lithuania on Pharmaceutical Activities;

2) Law “on the Amending and Supplementing the Law of the Republic of Lithuania on Pharmaceutical Activities;

- 3) Law of the Republic of Lithuania on Amending Articles 1, 5, 7, 10, 12, 14, 16, 17, 19, 21, 22, 23, 24 of the Law on Pharmaceutical Activities and Supplementing the Law with Article 25;
- 4) Law on Amending Articles 10, 14 of Law Republic of Lithuania on Pharmaceutical Activities;
- 5) Law on Amending Articles 17, 21, 22, 23 24 of the Law of the Republic of Lithuania on Pharmaceutical Activities;
- 6) Law on Amending Articles 1, 4, 5, 10, 11, 15, 17, 19, 20 of Law Republic of Lithuania on Pharmaceutical Activities and adding Articles 10¹, 17¹;
- 7) Law on amending the introduction, articles 1, 2, 4, 5, 6, 7, 8, 10¹, 13, 14, 16, 19, 20, 21, 22, 24, 25 of the Law Republic of Lithuania on Pharmaceutical Activities and adding articles 10², 19¹, 20¹, 20², 20³ and Annex to the Law;
- 8) Law of the Republic of Lithuania on Medicines;
- 9) Law on Amending Article 11 of the Law of the Republic of Lithuania on Medicines;
- 10) Law on Amending Articles 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14 of the Law of the Republic of Lithuania on Medicines;
- 11) Law on Amending Articles 2, 3, 11 of the Law of the Republic of Lithuania on Medicines and supplementing the Law with Annex.

I promulgate this Law passed by the Seimas of the Republic of Lithuania

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PRESIDENT OF THE REPUBLIC

VALDAS ADAMKUS

IMPLEMENTED LEGAL ACTS OF THE EUROPEAN UNION

1. Council Directive of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (89/105/EEC) (OJ 2004 special edition, Chapter 5, Volume 1, p. 345).

2. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. (OJ 2004 special edition, Chapter 13, Volume 26, p. 299).

3. 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 (OJ 2004 special edition, Chapter 13, Volume 27, p. 69)(as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 special edition , Chapter 13 Volume 34, p. 262) and by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 special edition, Chapter 13 Volume 34 p. 262) and Directive 2004/24/EC of the European Parliament and of the Council (OJ 2004 special edition, Chapter 13, Volume 34, p. 313).

4. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (text with EEA relevance). (OJ 2004 special edition, Chapter 13, Volume 32, p. 424).

5. Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use. (OJ 2004 special edition, Chapter 13, Volume 34, p. 313).

6. Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (text with EEA relevance) (OJ 2004 special edition, Chapter 13, Volume 34, p. 262).

7. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and of supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (text with EEA relevance) (OJ 2004 special edition, Chapter 13, Volume 34, p. 229).

8. 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 (text with EEA relevance) (OJ 2005 L 091, p. 13).