The Agency for Medicinal Products and Medical Devices of the Republic of Slovenia has prepared the unofficial consolidated text for the Medicinal Products Act which includes:

- Medicinal Products Act (Official Gazette of the Republic of Slovenia, No. 31/06 – ZZdr-1);
- Act Amending the Medicinal Products and Medical Devices Act (Official Gazette of the Republic of Slovenia, No. 45/06 – ZZdr-1A).

Number:
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MEDICINAL PRODUCTS ACT

UNOFFICIAL CONSOLIDATED TEXT (ZZdr-1-NPB1)

I. GENERAL PROVISIONS

Article 1
(scope of regulation and competence)

(1) This Act regulates medicinal products for human and veterinary use, stipulates provisions and measures for ensuring their proper quality, safety and efficacy, provisions and procedures for their testing, manufacturing, pricing, marketing, official control and supervision with intent to protect public health, and stipulates the establishment and tasks of the public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia.

(2) This Act stipulates provisions and procedures for medicinal products manufactured commercially and manufactured by a method involving an industrial process, including pre-mixes for medicated feedingstuffs, active substances used as starting material, and certain substances which may be used as veterinary medicinal products and have anabolic, anti-infectious, antiparasitic, anti-inflammatory, hormonal or psychotropic properties.

(3) This Act shall transpose the following Directives, which regulate certain issues of implementing the following regulations into the legislation of the Republic of Slovenia:

- Council Directive 89/105/EEC 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 (OJ, L 40, 11. 2. 1989, p. 8).

- 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 L 121, 01.05.2001, p. 34, as amended; hereinafter: Directive 2001/20/EC);

- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1, as amended; hereinafter: Directive 2001/82/EC);

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to human medicinal products (OJ L 311, 28.11.2001, p. 67, as amended; hereinafter: Directive 2001/83/EC);

- 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 (OJ L 262, 14.10.2003, p. 22, as amended; hereinafter: Directive 2003/94/EC);

- 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 (OJ L 91, 09.04.2005, p. 13, as amended; hereinafter: Directive 2005/28/EC);

- Council Regulation (EEC) No. 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.08.1990, p. 1, as amended; hereinafter: Regulation 2377/90/EEC);

- Commission Regulation (EC) No. 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State (OJ L 159, 27.06.2003, p. 1, as amended; hereinafter: Regulation 1084/2003/EC);

- 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 inspection of medicinal products for human and veterinary use and establishing the European

Medicines Agency (OJ L 136, 30.04.2004, p. 1; hereinafter: Regulation 726/2004/EC).

Article 2
(competence)

(1) The Minister (hereinafter: Minister) competent for medicinal products shall be the Minister of Health unless stipulated otherwise by this Act.

(2) Implementing regulations for veterinary medicinal products shall be issued by the Minister in agreement with the Minister competent for the veterinary domain.

(3) The competent authority for medicinal products covered by this Act shall be the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia.

(4) A competent authority for medicinal products shall decide upon administrative matters pursuant to the law regulating the general administrative procedure, unless stipulated otherwise by this Act.

(5) Unless stipulated otherwise by this Act, the competent authority for medicinal products should, in administrative matters, within 30 days of the receipt of the application, require the applicant to supplement the application should it be incomplete and impose a period on the applicant (hereinafter: Applicant), within which the application must be supplemented.

Article 3
(committees and experts)

(1) Standing and ad-hoc committees and individual experts (hereinafter: Experts) operate at the competent authority for medicinal products. These committees and individual Experts shall have a consultative role and shall be professionally independent within the framework of their scope of operations.

(2) Standing committees operate in the field of medicinal products, clinical trials and pharmacopoeia.

(3) Standing committees shall be expert bodies on an individual field. Their composition for the scope of human medicinal products shall be determined by the Minister, who shall also appoint the members of the standing committee, and for the scope of veterinary medicine by the Minister competent for the veterinary domain, among experts (hereinafter: Experts) from the fields of pharmacy, medicine, veterinary medicine, pharmacology and other disciplines.

(4) Standing committees shall adopt the rules of procedure.

(5) Temporary committees and individual Experts shall be appointed by the competent authority for medicinal products in order to consider and give opinions in professional fields requiring special knowledge.

(6) Committee members and individual Experts shall act impartially and in accordance with the regulations when conducting their operations. Due to the conflict of interests rules they shall not enable unjustified advantage nor shall they favour individual applicants; they shall respect the confidentiality of data.

Article 4
(experts in bodies of the European Union)

(1) Experts cooperating in operations of bodies of the European Union competent for medicinal products for human use shall be appointed by the Minister following a proposal of the competent authority for medicinal products.

(2) Experts cooperating in operations of bodies of the European Union competent for veterinary medicinal products shall be appointed by the Minister for the veterinary domain following a proposal of the competent authority for medicinal products.

Article 5
(definition of a medicinal product)

(1) A medicinal product is any substance or combination of substances presented as having properties for treating or preventing disease in human beings and animals.

(2) A medicinal product shall also be any substance or combination of substances which may be used in or administered to human beings or animals with a view to restoring, correcting or modifying physiological functions by exerting pharmacological, immunological or metabolic action or to making a medical diagnosis.

(3) The substance referred to in the first paragraph hereunder may be:
1. of human origin, e.g., human blood, blood preparations, blood products;
2. of animal origin, e.g., whole animals, parts of organs, animal secretions, toxins, extracts, blood products;
3. of vegetable origin, e.g., plants, parts of plants, vegetable secretions, extracts;
4. of microbial origin, e.g., whole microorganisms, their components;
5. of chemical origin, e.g., elements, naturally occurring chemical substances, chemical products obtained by chemical change or synthesis;
6. produced by biotechnological processes.

Article 6
(definitions of other terms)

For the purposes of this Act, the terms used shall have the following meanings:

1. An analysis of a quality of a medicinal product shall be a qualitative analysis of all the ingredients, quantitative analysis of at least all the active substances and all other tests necessary for determining quality of the medicinal product in accordance with the requirements in the marketing authorisation.

2. A biological medicinal product shall be a product that, as an active substance, contains a biological substance o r a substance produced by a process involving biological systems. A biological substance shall be a substance extracted from, or obtained by means of a biological source and which requires for determining its quality, a combination of physico-chemical and biological testing, together with a production process and control over it. These are for example medicinal products obtained by a biological or biotechnological procedure, including cell cultures, and recombinant DNA technology, medicinal products derived from blood or plasma, immunological medicinal products and similar.

3. Centralised procedure shall be a procedure for obtaining a marketing authorisation for a medicinal product in the European Union as stipulated by the Regulation 726/2004/EC.

4. Decentralised procedure shall be a procedure for obtaining a marketing authorisation for a medicinal product which is concurrently initiated in the reference and concerned Member States of the European Union. It shall be obligatory for medicinal products which shall not be subjected to the centralised procedure and have not acquired the marketing authorisation in the European Union, and shall be on the market of more than one Member State of the European Union as stipulated by the Directive 2001/83/EC and Directive 2001/82/EC.

5. Good distribution practice is a quality system relating to the organisation, implementation and control of the storage conditions of products according to a specific order prior to the further application or placement on the market, and transportation of medicinal products from the manufacturer to the final consumer.

6. Good clinical practice in clinical trials in human medicine shall be an international ethical and scientific quality system of designing, conducting, recording, monitoring and reporting on clinical trials on humans, providing for the credibility of data acquired through trials and the protection of rights and the safety of trial subjects pursuant to the Declaration of Helsinki of the World Health Organisation on biomedical testing on human subjects (1964) with all the amendments as well as pursuant to this Act and any regulations arising hereof.

7. Good clinical practice in clinical trials in veterinary medicine is an international ethical and scientific quality system of designing, conducting, recording, monitoring and reporting on clinical trials on target animals, which ensures the credibility of data obtained in the trial and safety of animals in accordance with this Act and regulations issued on the basis thereof and regulations for animal protection.

8. Good control laboratory practice, which may also be a part of good manufacturing practice, is a system of performing analytical testing of medicinal products, used to control the quality of the product.

9. Good laboratory practice shall be a quality system relating to organisational processes and conditions under which non-clinical health and environmental safety studies are designed, conducted, monitored, recorded, archived and reported.

10. Good manufacturing practice shall be a quality system ensuring the consistent manufacture and control of products according to the quality criteria, and compliance with the intended purpose as required by the documentation for obtaining marketing authorisation for a medicinal product and the product's specification.

11. European pharmacopoeia is a pharmacopoeia as defined by the Convention on the Elaboration of the European Pharmacopoeia of the European Council (1964).

12. Pharmaceutical form is the form of a medicinal product into which through technological procedures an active substance (active substances) is (are) incorporated, enabling its (their) administration considering physiological conditions and physico-chemical characteristics of the active substance and excipients.

13. Pharmacopoeia is a collection of regulations for manufacturing medicinal products, identity testing, determining purity and testing other quality parameters of medicinal products and substances of which medicinal products are made.

14. Pharmacovigilance is a system for detection, collecting and assessment of adverse reactions of medicinal products and other knowledge on safety of medicinal products and actions with a view to managing and decreasing risks related to medicinal products.

15. Natural person shall be an individual sole proprietor (hereinafter: Individual) or any other natural person with permanent residence in the European Union, performing a profitable activity as his/her exclusive business activity, which complies with the relevant criteria of the Member State concerned.

16. Galenic product for human use shall be a medicinal product prepared in a galenic laboratory of a pharmacy in accordance with the prescriptions of a valid pharmacopoeia and intended for retail supply by the pharmacy in question.

17. Galenic product for veterinary use shall be a medicinal product prepared in a galenic laboratory of a pharmacy in accordance with the prescriptions of a valid pharmacopoeia and intended for retail supply.

18. Generic medicinal product shall be a medicinal product which has the same qualitative and quantitative composition of 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. 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, the applicant must submit additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an active substance in a medicinal product for which a marketing authorisation has already been obtained. The various immediate-release oral pharmaceutical forms shall be considered to be the same pharmaceutical form. Bioavailability studies need not be submitted if so stipulated by the relevant guidelines prepared in accordance with the scientific and technical findings.

19. Homeopathic medicinal product shall be a medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the EU Member States. A homeopathic medicinal product may also contain a number of principles.

20. Name of the medicinal product may be either an invented name which shall not be liable to confusion with the common name, or a common name or a scientific name, accompanied by a trade mark or the name of the marketing authorisation holder (hereinafter: Holder).

21. Medicinal product marketing authorisation holder shall be a natural person or a legal entity with its registered office in the European Union, meeting the conditions specified in this Act.

22. Immunological medicinal product shall be medicinal products which consist of vaccines, toxins, serums and allergen products, namely:
    a) Vaccines, serums and toxins shall cover in particular agents to diagnose the state of immunity :
       - agents used to produce active immunity,
       - agents used to produce passive immunity,
       - agents used to diagnose the state of immunity;
    b) Allergen products shall be any medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent;

c) Immunological veterinary medicinal product shall be a medicinal product administered to animals in order to produce active or passive immunity or to diagnose the state of immunity.

23. The retail supply of a medicinal product shall be retail sales to the end user (hereinafter: User), accompanied with adequate expert support and consultancy.

24. The manufacturer (hereinafter: Manufacturer) of a medicinal product shall be a legal entity or a natural person holding a manufacturing authorisation pursuant to this Act and any regulations arising hereof.

25. Exceptional/Off-label use shall be the use of a veterinary medicinal product which is not consistent with the summary of the product characteristics but nevertheless allowed under this Act and the act regulating veterinary conformity criteria.

26. Exit of a medicinal product shall be the wholesale thereof from the Republic of Slovenia into other EU Member States.

27. Export of a medicinal product shall be the wholesale thereof from the Republic of Slovenia into third countries.

28. The strength of a medicinal product shall be the content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the pharmaceutical form.

29. Withdrawal period shall be the period necessary between the last administration of the veterinary medicinal product to animals under normal conditions of use pursuant to this Act and any regulations arising hereof and the beginning of the production of foodstuffs from such animals, in order to ensure that such foodstuffs do not contain residues in quantities in excess of the maximum limits laid down in Regulation No. 2377/90/EEC.

30. Magistral preparation for human use shall be a medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient.

31. Magistral preparation for use in veterinary medicine shall be a medicinal product prepared in a pharmacy in accordance with a veterinary prescription for an animal or a small group of animals.

32. National procedure for obtaining a marketing authorisation for a medicinal product in the Republic of Slovenia shall be the procedure for obtaining a marketing authorisation for those medicinal products which are not subject to centralised procedure and for which marketing authorisation will only be issued in the Republic of Slovenia.

33. Maximum residue limit shall be the maximum residue limit of medicinal products for veterinary use as stipulated by the Regulation No. 2377/90/EEC.

34. Package leaflet shall be the information for the user attached in written form to the medicinal product, as a rule in the form of a leaflet

35. Unexpected adverse reaction of a medicinal product shall be an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of the product characteristics.

36. Unexpected adverse reaction in clinical trials shall be an adverse reaction, the nature, severity or outcome of which is not consistent with the applicable product information (e.g., investigator's brochure, hereinafter: Investigator, or summary of product characteristics).

37. Adverse event in clinical trials shall be any untoward medical occurrence in a patient (hereinafter: Patient) or clinical trial subject (hereinafter: Subject) administered a medicinal product and which does not necessarily have a causal relationship with this treatment.

38. Adverse reaction to a medicinal product shall be a reaction which is noxious and unintended and which occurs at doses normally used in humans or animals for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.

39. Adverse reaction in humans caused by veterinary medicinal products shall be a reaction which is noxious and unintended and which occurs in humans unintentionally exposed to a veterinary medicinal product.

40. Adverse reaction in clinical trials shall be all noxious and unintended responses to an investigational medicinal product related to any dose administered.

41. Public service obligation shall mean the obligation placed on wholesalers (hereinafter: Wholesaler) of medicinal products and holders of a marketing authorisation to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.

42. Labelling of medicinal product shall be information on the immediate or outer packaging.

43. Parallel distribution shall be the entry of a medicinal product for which a marketing authorisation was obtained in accordance with the centralised procedure from one Member State of the European Union or the European Economic Area (hereinafter: the EEA) to another, if performed by a wholesaler who is not in a business

relationship for the marketing of such medicinal product with the marketing authorisation holder, in accordance with the applicable regulations.

44. Parallel import shall be the entry of a medicinal product for which a marketing authorisation was obtained in the exporting country that is sufficiently similar to the medicinal product for which marketing authorisation was obtained in the Republic of Slovenia according to the national procedure, the mutual recognition procedure or the decentralised procedure and is entered from one Member State of the European Union or the EEA to another on the basis of the marketing authorisation for a parallel imported medicinal product issued by a competent authority for medicinal products if parallel import is performed by a wholesaler who is not in a business relationship for the marketing of such medicinal product with the marketing authorisation holder.

45. Periodic safety update report shall be a periodic report submitted in predetermined intervals or upon the request of the competent authority for medicinal products by the marketing authorisation holder, which must include all the prescribed data on the safety of the medicinal product and the evaluation of the the risk-benefit balance.

46. Excipient shall be a substance having physico-chemical characteristics which can support the action of a medicinal product and improve its tolerability.

47. Mutual recognition procedure shall be the procedure for obtaining the marketing authorisation of the medicinal product initiated after the approval in the reference Member State also in other EU Member States concerned and is mandatory for those medicinal products not subjected to the centralised or decentralised procedure for obtaining the marketing authorisation which will be marketed in more than one EU Member State, as stipulated by the Directives 2001/83/EC and 2001/82/EC.

48. Premix for medicated feedingstuffs shall be any veterinary medicinal product prepared in advance, intended for the subsequent manufacture of medicated feedingstuffs.

49. Representative (hereinafter: Representative) of the marketing authorisation holder shall be a legal entity or natural person acting on behalf of the marketing authorisation holder as its representative in the Republic of Slovenia.

50. Manufacturer (hereinafter: Manufacturer) of a medicinal product shall be a legal entity or natural person responsible for the development, manufacture, quality control, packaging and labelling of medicinal products as well as their safety and efficacy irrespective of whether medicinal products were manufactured by itself or on its behalf by a third party.

51. Wholesale distribution of medicinal products shall be the activity of purchasing, storing, selling, entering, exiting, importing or exporting of medicinal products with the exception of supplying medicinal products to individual natural persons and legal entities for their personal use or use in the performance of a medical activity.

52. Radiopharmaceutical products shall be radiopharmaceuticals, radionuclide precursors, radionuclide generators and radionuclide kits for the preparation of radiopharmaceuticals, namely:
    a) radiopharmaceutical shall be a medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose,
    b) radionuclide generator shall be any system incorporating a fixed parent radionuclide from which a daughter radionuclide is produced which is to be obtained by elution or by any other method and used in a radiopharmaceutical,
    c) radionuclide precursor shall be any radionuclide produced for the labelling of another substance prior to administration to a patient,
    d) radionuclide kit for the preparation of a radiopharmaceutical shall be any product to be reconstituted or combined with radionuclides (radionuclide precursors) in the final radiopharmaceutical, usually prior to its administration.

53. Risk-benefit balance shall be a positive assessment of the therapeutic efficacy of a medicinal product in comparison with the risk, as defined in points 64 and 65 hereunder.

54. Reference Member State shall be the Member State which prepares, in the mutual recognition procedure or the decentralised procedure, the assessment report of the medicinal product on the basis of which the EU Member States concerned shall decide on the acceptability of the risk-benefit balance and/or the assessment of quality, safety and efficacy of a medicinal product in accordance with the Directives 2001/83/EC and 2001/82/EC.

55. Reference medicinal product shall be a medicinal product for which marketing authorisation has been issued on the basis of Article 23 hereof and to whose documentation other applicants pursuant to this Act and any regulations arising hereof shall refer.

56. Serious adverse event or serious adverse reaction in clinical trials shall be any untoward 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 is a congenital anomaly or birth defect.

57. Serious adverse reaction of a medicinal product for use in human medicine shall be any 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 or birth defect.

58. Serious adverse reaction of a medicinal product for use in veterinary medicine shall be any adverse reaction which is fatal, life-threatening, incapacitating and constant,

persistent occurrence of signs and symptoms of disease in a treated animal, or is a congenital anomaly or birth defect.

59. Risk medicinal products shall be immunological medicinal products and medicinal products derived from blood and plasma.

60. Specialised shop selling over-the-counter medicinal products shall be a retail outlet selling those medicinal products which the competent authority for medicinal products allows to be dispensed without prescription in pharmacies and specialised shops.

61. Common name of a medicinal product shall be the international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name.

62. Sponsor of a clinical trial (hereinafter: Sponsor) shall be a legal entity, natural person or individual who takes responsibility for the initiation, management and/or financing of a clinical trial.

63. Immediate packaging shall be a container or other form of packaging immediately in contact with the medicinal product.

64. Study of the safety of medicinal product after obtaining the marketing authorisation for a medicinal product for use in human medicine shall be a pharmaco-epidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying or quantifying a safety hazard relating to an authorised medicinal product.

65. Study of the safety of medicinal product after obtaining the marketing authorisation for a veterinary medicinal product shall be a pharmaco-epidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying or investigating a safety hazard relating to an authorised veterinary medicinal product.

66. Traditional herbal medicinal product shall be a herbal medicinal product whose properties can be recognised on the basis of its traditional use and which meets the conditions stipulated by this Act.

67. Third countries shall be the Non-Member States of the European Union or the EEA Agreement.

68. Risk related to the use of medicinal product shall be:
    a) any risk of the occurrence of environmentally harmful adverse reactions,
    b) any risk to the health of a patient or animal or public health, related to the quality, safety or efficacy of a medicinal product.

69. Active substance shall be a substance which is responsible for the action of a medicinal product.

70. Official Medicine Control Laboratory shall be a legal entity or a natural person holding the authorisation of the competent authority for medicinal products for analytical testing and appointed by the Minister for implementing official control over the quality of medicinal products, which is a member of the European Official Medicine Control Laboratories Network or which annually participates in the intra-laboratory verification organised by the European Directorate for the Quality of Medicines and the results obtained are in compliance with the organiser's requirements.

71. Import of a medicinal product shall be the wholesale thereof from third countries into the Republic of Slovenia.

72. Wholesaler of medicinal products shall be a legal entity or a natural person wholesaling medicinal products on the basis of the authorisation issued by the competent authority for medicinal products with the aim of generating profit or not.

73. Entry of a medicinal product shall be the wholesale thereof from other EU Member States into the Republic of Slovenia.

74. Concerned Member State shall be the Member State which shall decide, in the mutual recognition procedure or the decentralised procedure, on the acceptability of the risk/benefit ratio and/or the assessment of quality, safety and efficacy of a medicinal product on the basis of the assessment report of the medicinal product prepared by a reference EU Member State in accordance with the Directives 2001/83/EC and 2001/82/EC.

75. Medicinal products derived from blood or plasma shall be those medicinal products obtained by means of industrial procedures by specialised legal entities or natural persons from blood components obtained in accordance with the provisions of the Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2002, p. 30) which contain above all albumins, blood-coagulating factors and immunoglobulins of human origin, taking into account the self-sufficiency principle.

76. Medicated feedingstuffs shall be any mixture of a veterinary medicinal product and feed which is ready prepared for marketing and intended to be fed to animals without further processing, because of its curative or preventive properties or other properties as a medicinal product.

77. Herbal medicinal product shall be any medicinal product which exclusively contains as active ingredients one or more herbal substances, one or more herbal

preparations or one or more such herbal substances in combination with one or more herbal preparations.

78. Medical or veterinary prescription shall be a document issued in accordance with the regulations by a professional person qualified and authorised to prescribe medicinal products.

79. Abuse of medicinal product shall be persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects.

80. Outer packaging shall be the packaging into which the immediate packaging is placed.

Article 7
(relation between medicinal and other products)

(1) In the cases of doubt, where by definition and taking into account all its characteristics, a product can simultaneously be classified as medicinal product and as product subject to other legislation, the provisions of this Act shall apply.

(2) The classification referred to in the previous paragraph shall be decided in an administrative procedure on the basis of a special declaratory procedure by the competent authority for medicinal products.

(3) The costs of evaluation of the adequacy of the proposed classification shall be borne by the applicant.

Article 8
(prohibition of inappropriate presentation of products)

It is prohibited to place on the market any products presented as having properties for treating or preventing disease in human beings and animals which, pursuant to this Act, are not considered a medicinal product.

Article 9
(equal manufacturing requirements)

The provisions of this Act on manufacturing and import shall also apply to medicinal products intended for placement on the market outside the territory of the Republic of Slovenia and for intermediate products not intended for further processing.

Article 10
(exceptions to the application of this Act)

The provisions of this Act shall not apply to the following:

1. magistral formula regulated by the legislation on pharmacy activity;
2. officinal formula regulated by the legislation on pharmacy activity;
3. intermediate products intended for further processing by manufacturing authorisation holders if intermediate products are not regulated as medicinal products;
4. radioactive isotopes in the form of sealed sources regulated by the provisions on protection against ionising radiation and on nuclear safety;
5. blood, plasma or blood cells regulated by the provisions on blood supply, except for industrially processed plasma;
6. medicated feedingstuffs regulated by the provisions on feedingstuffs;
7. inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality regulated by the provisions on veterinary medicine;
8. feed additives stipulated by the provisions on feedingstuffs.

Article 11
(classification of medicinal products on the basis of prescribing)

(1) In terms of prescribing, medicinal products shall be classified into:

- medicinal products subject to medical or veterinary prescription,
- medicinal products not subject to medical or veterinary prescription.

(2) The Minister shall determine detailed definition, classification and the manner of prescribing medicinal products.

Article 12
(data protection upon the change of classification)

If a change of classification from medicinal products subject to medical or veterinary prescription to medicinal products not subject to medical or veterinary prescription has been authorised on the basis of significant non-clinical pharmaco-toxicological tests or clinical trials, the competent authority for medicinal products shall not refer to the results of those tests or trials when examining an application by another applicant for or marketing authorisation holder for a change of the classification of the same active substance for one year after the initial change was authorised.

Article 13
(traditional herbal medicinal products)

(1) Traditional herbal medicinal products must meet the following requirements:

1. they have therapeutic indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended for self-medication;
2. they are exclusively for administration in accordance with the specified strength and posology;
3. they are intended for oral or external use or for inhalation;
4. the period of their traditional use has elapsed;
5. the data on the traditional use of a medicinal product must be sufficient; in particular, it must be proven that the product is not harmful in the specified conditions of use and that the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

(2) Traditional herbal medicinal products may also contain vitamins and minerals provided that there documented evidence on their safety exists and that the action of the vitamins or minerals is ancillary to that of the herbal active ingredients regarding the specified therapeutic indications.

3) If the competent authority for medicinal products judges that a traditional herbal medicinal product fulfils the criteria for obtaining the marketing authorisation or registration of the homeopathic medicinal product, the provisions applicable to traditional herbal medicinal product shall not apply.

Article 14
(homeopathic medicinal products)

(1) A marketing authorisation for homeopathic medicinal products must be obtained pursuant to Article 23 hereof.

(2) Notwithstanding the provision of the previous paragraph, a simplified procedure for obtaining the marketing authorisation (registration procedure) shall be applied to homeopathic medicinal products for external or oral application, provided that they meet the following requirements:

1. no therapeutic effect or therapeutic indication appears on the labelling or in any information relating thereto;
2. there is a sufficient degree of dilution to guarantee the safety of the medicinal product, as stipulated by the regulations;

(3) All the provisions of this Act shall apply to all homeopathic medicinal products, unless otherwise stipulated herein.

(4) A more specific definition, labelling, advertising and conditions for the granting of a marketing authorisation and the simplified registration procedure for homeopathic medicinal products shall be determined by the Minister.

Article 15
(list of urgently needed medicinal products)

(1) The Minister may prescribe a list of urgently needed medicinal products for use in human medicine.

(2) The minister competent for veterinary medicine may prescribe a list of urgently needed medicinal products for use in veterinary medicine.

3) Urgently needed medicinal products shall be medicinal products which are necessary in the provision of human and/or animal health care on the basis of the latest findings of biomedical science and profession and the systemic definitions in the framework of the national health priorities.

Article 16
(mutually interchangeable medicinal products)

(1) Mutually interchangeable medicinal products shall be those products that the competent authority for medicinal products defines and publishes as appropriate for mutual interchanging, taking into account the fact that the probability of the occurrence of clinically significant differences in the efficiency and safety are adequately low or negligible; such decision must be supported by:

- identification of common or comparable characteristics of medicinal products or groups of medicinal products pursuant to this Act or the regulations adopted on its basis;
- consideration of provisions stipulated by the marketing authorisation;
- incorporation of the latest findings and discoveries of the biomedical science and profession;
- opinion of the Committee for Medicinal Products;
- data on pharmacovigilance.

(2) The medicinal products referred to in the previous paragraph can only be interchanged by persons authorised for prescribing medicinal products or persons authorised for issuing medicinal products, as stipulated by the relevant provisions.

(3) The Minister shall prescribe more detailed requirements and procedures for establishing the mutual interchangeability of medicinal products.

Article 17
(marketed medicinal product)

(1) A medicinal product may be marketed:

- provided that it has obtained a marketing authorisation in accordance with this Act or in the centralised procedure according to the provisions of the European Union;

- provided that it is permitted for the needs of an individual patient by the competent authority for medicinal products upon the request of the treating physician, clinic or institute, at their personal responsibility;
- provided that the competent authority for medicinal products temporarily permits the marketing of unauthorised medicinal product cases of emergency (infections, intoxications, radiation and similar) or for other reasons which are competent authority in the interest of public health protection;
- provided that the competent authority for medicinal products, on the proposal of the competent authority for veterinary medicine, temporarily permits the marketing of an immunological veterinary medicinal product without a marketing authorisation if no appropriate medicinal product is available, provided that the competent authority for veterinary medicine shall inform the European Commission in advance of the conditions of use; or
- provided that it is included in the list of urgently needed medicinal products, stipulated in Article 15 hereof, without a marketing authorisation.

(2) Notwithstanding the provision of the first indent of the previous paragraph, medicinal products without a marketing authorisation can be used for research and development purposes as well as those with appropriate authorisation for clinical trials or further processing.

(3) Notwithstanding the provision of the first indent of the previous paragraph hereunder, veterinary medicinal products without a marketing authorisation can be used for veterinary emergencies (for example prevention of foot-and-mouth disease) if their use in such conditions is approved by the competent authority for veterinary medicine and the competent institution of the European Union.

Article 18
(off-label use of veterinary medicinal products)

(1) If no appropriate veterinary medicinal product with marketing authorisation in the Republic of Slovenia is available to treat the disease conditions affecting certain animal species, a veterinarian responsible for the treatment of animals can, in order to prevent unacceptable suffering of animals, exceptionally use medicinal products not approved for the use in those species or to treat the conditions concerned.

(2) The Minister shall determine in greater detail the conditions for off-label use.

Article 19
(responsibility)

(1) The marketing authorisation holder shall be responsible for the placing of the medicinal product on the market.

(2) The manufacturer of the medicinal product shall be responsible for the damage caused by unsuitable quality of the medicinal product or the consequences of the use of such medicinal product even if it has been proven that it would not be possible for global science to discover the defect or the consequences of use, in view of the current level of technological development at the moment the medical product was placed on the market.

(3) The marketing authorisation holder, manufacturer and health professionals shall not be responsible for the consequences of treatment arising from the use of medicinal product which is not in accordance with the granted marketing authorisation or the use of medicinal product without a marketing authorisation if such use was recommended or requested by the competent authority for medicinal products in the event of the spread of pathogens, toxins, chemical substances or nuclear radiation which could be harmful to the health of humans or animals or damage the environment.

Article 20
(pharmacopoeia)

(1) Medicinal products marketed in the Republic of Slovenia must be manufactured and controlled according to the methods and requirements of the European Pharmacopoeia and the Slovenian National Formulary thereof as prescribed by the Minister.

(2) Should the European Pharmacopoeia and the Slovenian National Formulary thereof not prescribe methods of manufacture and requirements concerning quality of medicinal products, such medicinal products may be manufactured and controlled according to methods and requirements of pharmacopoeias of other EU Member States. Should the pharmacopoeias of other EU Member States not prescribe methods of manufacture and requirements concerning quality, medicinal products may be subjected to pharmacopoeias of third countries or to the methods proposed by the manufacturer.

II MARKETING AUTHORISATION

Article 21
(marketing authorisation)

(1) A medicinal product can only be placed on the market on the basis of a marketing authorisation.

(2) Notwithstanding the provisions of the previous paragraph, the marketing authorisation shall not be required for medicinal products stated in Article 10 of this Act and for the following:
1. medicinal products subject to clinical trials;

2. medicinal products intended for treatment as a continuation of a treatment started abroad;
3. intermediate products intended for further processing;
4. medicinal products intended for research and development trials;
5. medicinal products with a parallel import licence.

Article 22
(marketing authorisation holder)

(1) The procedure for granting of a marketing authorisation shall begin with the submission of an application by a natural person or legal entity with a registered office in the European Union. This can be either the manufacturer of the medicinal product or a natural person or a legal entity that has concluded a written agreement with the manufacturer and meets the requirements stipulated hereby.

(2) The marketing authorisation holder shall have established a pharmacovigilance management system and appointed an appropriately qualified person responsible for pharmacovigilance, who must be permanently available.

(3) The person responsible for pharmacovigilance from the previous paragraph must have a permanent residence on the territory of the European Union and hold a university degree in pharmacy or medicine or hold a university degree in pharmacy or veterinary medicine specialised in veterinary medicinal products. If such person does not have appropriate qualification, then he or she must have constantly the possibility of seeking the professional assistance of a person holding a university degree in pharmacy or human medicine for medicinal products for human use or holding a university degree in pharmacy or veterinary medicine for veterinary medicinal products.

(4) If the marketing authorisation holder does not have a registered office in the Republic of Slovenia, it can appoint, besides the person responsible, also a contact person for pharmacovigilance on the territory of the Republic of Slovenia.

Article 23
(application for obtaining a marketing authorisation)

(1) The application for obtaining a marketing authorisation shall comprise documents, samples and reference standards, if necessary and if required by the competent authority for medicinal products.

(2) The documents pursuant to the preceding paragraph shall comprise:

1. general part, including data on the manufacturer, manufacturing site, applicant and future marketing authorisation holder, data on the medicinal product, data on marketing authorisations already granted or rejected, a summary of the product characteristics, package leaflet, mock-up of the draft packaging, data on the orphan

medicinal products designation, if obtained, expert reports and summaries, risk/benefit assessment, environmental risk assessment and other data necessary for public health protection, especially in the case of risk medicinal products;

2. pharmaceutical-chemical and biological part including data on qualitative and quantitative composition, description of the manufacturing process, quality control of starting materials, process controls, quality control of the finished product, stability studies and other data necessary for public health protection;
3. non-clinical pharmacological and toxicological part, including data on the pharmaco-dynamic and pharmaco-kinetic properties of the medicinal product, its toxicity and effect on the reproductive function, data on embryo-foetal toxicity, genotoxicity and carcinogenicity, data on local tolerance, excretion and other data necessary for public health protection. The pharmacological and toxicological part of the documentation related to a veterinary medicinal product should also include data on residues and proposed withdrawal periods;
4. clinical part of the documentation including general data on trials, how they have been carried out and ensuing results, clinical and pharmacological data, data on bioavailability/bioequivalence (if required), clinical safety and efficacy, documentation on exceptional circumstances in trials (if required) and data on experience with the product gained in other countries which have granted marketing authorisations and other data necessary for public health protection.

Article 24
(scientific advice)

Before application for a marketing authorisation, the competent authority for medicinal products may provide orientations and advice, if requested by the applicant, concerning the compilation of the application and the scientific maters relating the evaluation of medicinal product.

Article 25
(generic medicinal products)

(1) Notwithstanding the provisions of Article 23 of this Act, the applicant shall not be required to provide the results of non-clinical pharmacological and toxicological tests, the clinical trials and for the veterinary medicinal products he results of residue tests, if he can demonstrate that the medicinal product is a generic of a reference product which is or has been authorised in the Republic of Slovenia or the European Union for not less than eight years.

(2) A generic medicinal product referred to in the previous paragraph shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

(3) If the reference medicinal product referred to in the first paragraph hereunder was not authorised in the Republic of Slovenia, the applicant shall indicate in the application for marketing authorisation the EU Member State in which the reference medicinal product is or has been authorised.

(4) Within 30 days of receiving the complete application the competent authority for medicinal products shall request the competent authority of the selected Member State of the European Union to confirm that granting the reference medicinal product is or has been authorised together with the qualitative and quantitative composition of the reference medicinal product in terms of the active substances and excipients and, if necessary, any other relevant documents.

(5) In line with the EU regulations, the Member State in which the reference medicinal product is or has been authorised shall send the confirmation and data referred to in the previous paragraph within one month of receiving the request.

Article 26
(data protection)

(1) The ten-year period referred to in the second paragraph of the previous Article shall be extended to a maximum of eleven years if, during the first eight years of those ten-year period, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which are held to bring a significant clinical benefit in comparison with existing therapies.

(2) For veterinary medicinal products the ten-year period referred to in the second paragraph of the previous Article shall be extended to thirteen years in respect of medicinal products for fish, bees and other animal species pursuant to this Act and any regulations arising hereof.

Article 27
(additional requirements)

In case where the medicinal product does not fall within the definition of a generic medicinal product or bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substances, therapeutic indications, strength, pharmaceutical form or route of administration in respect to the reference medicinal product, the results of appropriate non-clinical, pharmacological and toxicological tests or clinical trials shall be provided and for the veterinary medicinal products as well as the results of the safety and residues tests of the medicinal product.

Article 28
(biological medicinal products)

Where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal product because of the differences related to raw materials or differences in manufacturing process compared to the reference biological medicinal product, the results of appropriate non-clinical pharmacological and toxicological tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the requirements of this Act and any regulations arising hereof.

Article 29
(well-established application)

Notwithstanding the provisions of Article 23 of this Act, the applicant shall not be required to provide the results of non-clinical pharmacological and toxicological tests or clinical trials and for the veterinary medicinal products nor the results of residue tests if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal or veterinary use within the European Union in appropriate scope for at least ten years, with recognized efficacy and an acceptable level of safety, and if enough scientific literature on the use of active substance is available. In such case, adequate data from the available scientific literature must be submitted instead of own data.

Article 30
(well-established use and data protection)

(1) If the components of the medicinal product have a well-established medicinal use, with recognized efficacy and an acceptable level of safety and such medicinal product has obtained marketing authorisation for a new indication for which significant non-clinical pharmacological and toxicological tests or clinical trials have been submitted, other applicants shall not be allowed to refer to this part of documentation for a non-cumulative period of up to one year.

(2) If the applicant has used scientific literature for obtaining marketing authorisation for a veterinary medicinal product for food producing animals and has submitted, in respect of the same medicinal product and for the needs of obtaining authorisation for another food-producing species, new residues studies in accordance with the Regulation 2377/90/EEC together with further clinical trials, then other applicants may not refer to the data of such studies or the results of trials in accordance with the provisions of Article 25 hereof for a period of three years following the granting of marketing authorisation for the purpose of which they have been carried out.

Article 31

(data protection for veterinary medicinal products)

(1) In veterinary medicinal products intended for one or more food-producing species and containing new active substances that have not been authorised in the European Union before 30 April 2004, the ten-year period stipulated by the second paragraph of Article 25 hereof shall be extended by one year for each extension to the marketing authorisation to another food-producing species, provided that such extension to the marketing authorisation is obtained within five years of granting the initial marketing authorisation.

(2) The period stipulated by the second paragraph of Article 25 hereof, together with any extensions under the previous paragraph may not be longer than 13 years which also applies to the extension to marketing authorisation related to four or more of food-producing species.

(3) The extension of the ten-year period to 11, 12 or 13 years for a veterinary medicinal product, inteded for food-producing animals, shall only be granted if the marketing authorisation holder has originally applied for determination of the maximum residue limit established for the species covered by the marketing authorisation.

Article 32
(generic medicinal products and patent rights)

Conducting the necessary studies and trials with a view to the application of Articles 25, 27, 28 and 29 hereof and other requirements related to obtaining marketing authorisation shall not be regarded as contrary to patent rights or to supplementary protection certificate for a medicinal product.

Article 33
(combination of active substances)

If the application concerns new medicinal products containing active substances used in the composition of authorised medicinal products but not hitherto used in combination for therapeutic purposes, the results of new non-clinical toxicological and pharmacological tests or new clinical trials relating to that combination shall be provided, but it shall not be necessary to provide scientific references relating to each individual active substance. The application for veterinary medicinal products shall also contain the results of safety and residue tests, if necessary or required by the competent authority for medicinal products.

Article 34
(consent use of documentation)

The marketing authorisation holder may consent the use of the pharmaceutical, chemical, biological, non-clinical pharmacological, toxicological and clinical documentation and for veterinary medicinal products as well as data from the documentation on safety and residue tests contained in the file on the medicinal product, with a view to examining the subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.

Article 35
(exceptional circumstances)

Notwithstanding the provisions of Article 23 of this Act and in exceptional circumstances related to immunological medicinal products for the use in veterinary medicine, the applicant need not submit the results of certain field trials on the target species if these trials cannot be carried out for duly substantiated reasons.

Article 36
(registration of a traditional medicinal product)

(1) The simplified procedure for obtaining the marketing authorisation shall be applied to traditional herbal medicinal products (traditional medicinal product registration procedure), in which the applicant shall enclose with the application the general part and the pharmaceutical-chemical and biological documentation in accordance with points 1 and 2 of the second paragraph of Article 23 hereof. Instead of the data referred to in points 3 and 4 of the second paragraph of Article 23 of this Act, the following shall be submitted:

1. bibliographic or expert evidence to the effect that medicinal product in question, or a corresponding product had been in medicinal use throughout a period of at least 30 years preceding the date of application, including at least 15 years in the European Union. If a medicinal product had been in use in the European Union for less than 15 years and nevertheless meets the conditions prescribed for traditional herbal medicinal products, the competent authority for medicinal products shall submit evidence of long-term use of such medicinal product or of the corresponding medicinal product for an opinion to the European Medicines Agency; and
2. bibliographic overview of safety data together with the expert report and, when required by the competent authority for medicinal products, any other data necessary for assessing of the safety of the medicinal product.

(2) The Minister shall prescribe what is the necessary evidence of medicinal use throughout a 30-year period, the requirements for the corrresponding medicinal product and the form and contents of the required documentation in the national procedure, mutual recognition procedure and decentralised procedure, as well as the way of dealing with referral proceedings, and the rules on labelling and advertising of traditional herbal medicinal products.

Article 37
(necessary measures)

(1) Notwithstanding the provisions of Articles 23 and 25 to 36 hereof, the authority may, in order to protect public health in the event of a threat to human life or health, grant *ex officio* a marketing authorisation on the basis of the facts established in the assessment report on the medicinal product and in the valid marketing authorisation for the medicinal product concerned, obtained from the competent authority for medicinal products in the selected Member State. The marketing authorisation holder in the Member State in which the medicinal product concerned is authorised shall be informed of the proposal to grant a marketing authorisation pursuant to this Article.

(2) A wholesaler marketing the medicinal product referred to in the previous paragraph shall be responsible for labelling, the package insert, summary of the product characteristics, advertising and pharmacovigilance.

Article 38
(procedure for obtaining marketing authorisation)

(1) The competent authority for medicinal products shall verify the completeness of the application for marketing authorisation within 60 days of its receipt.

(2) The applicant shall enclose with the application, if requested by the competent authority for medicinal products, samples of the medicinal product, its starting materials and, if need be, its intermediate products or other constituent materials, which will be submitted to the official control laboratory for establishing the adequacy and reproducibility of control methods used by the manufacturer.

(3) During the evidence-taking procedure prior to the issue of marketing authorisation, the competent authority for medicinal products may order analytical testing of medicinal products in the official control laboratory, assessment of adherence to good practices by persons stated in the documentation, verification of analytical methods aimed at discovering and defining residues of veterinary medicinal products, and request additional data and explanations or other relevant evidence.

(4) During the evidence-taking procedure prior to the issue of marketing authorisation, the competent authority for medicinal products must verify compliance with the principles and guidelines of good practices by persons from third countries stated in the documentation.

(5) The Committee for Medicinal Products shall prepare an opinion on the quality, safety and efficacy of a medicinal product and the risk-benefit balance which will serve as the basis for drafting the assessment report on the medicinal product.

6) The competent authority for medicinal products shall adopt a decision on the application for marketing authorisation within 210 days of the submission of a valid application.

(7) The procedure shall be suspended until the fulfilment of requirements laid down in paragraphs 2 and 3 of this Article within the prescribed deadlines.

(8) The marketing authorisation shall be granted for a period of five years, unless otherwise determined by this Act.

Article 39
(mutual recognition)

(1) Notwithstanding the provisions of the previous Article, the competent authority for medicinal products shall issue or reject the issue of marketing authorisation in the application for obtaining marketing authorisation according to the mutual recognition procedure or the decentralised procedure on the basis of the assessment report compiled by the reference Member State.

(2) The Minister shall prescribe the contents of the application, the conditions for obtaining marketing authorisation, the structure and contents of the required documentation in the national procedure, mutual recognition procedure or decentralised procedure, as well as more detailed conditions for obtaining marketing authorisation pursuant to Articles 37 and 38 and the first paragraph hereunder.

Article 40
(conditional marketing authorisation)

In exceptional circumstances and following consultation with the applicant, the competent authority for medicinal products may grant marketing authorisation subject to a requirement for the applicant to fulfil specific obligations, in particular concerning product safety, and notify the relevant authorities of any incident relating to its use, and action to be taken. Such authorisation may only be issued for objective and verifiable reasons prescribed by the Minister. Renewal of a conditional marketing authorisation shall be linked to the annual reassessment of the fulfilment of these conditions. On the basis of positive assessment of the fulfilment of these conditions, the competent authority for medicinal products shall issue a new decision, which shall be published. The list of requirements shall be made public together with the final deadlines for meeting them.

Article 41
(scope of marketing authorisation)

Notwithstanding the fact whether a separate marketing authorisation is issued for additional strengths, pharmaceutical forms, indications, administration routes as well as any variations or extensions to the initial marketing authorisation, or an authorisation which is part of the initial marketing authorisation, all such marketing authorisations resulting from the extension to the initial marketing authorisation (new indication, new strength, new pharmaceutical form and administration route, and in the case of veterinary medicinal products also addition of a new species) shall be considered as belonging the same global marketing authorisation.

Article 42
(refused issue of marketing authorisation)

(1) The marketing authorisation shall be refused if, during the examination of the particulars and documents, the competent authority for medicinal products establishes that:
- the risk-benefit balance of the medicinal product is not considered to be favourable,
- the applicant did not provide sufficient evidence in support of the quality, safety and therapeutic efficacy of the medicinal product,
- its qualitative and quantitative composition is not as declared in the documentation, or
- the labelling or the package information leaflet, submitted by the applicant, is not in accordance with this Act and the regulations issued on the basis hereof.

(2) The marketing authorisation for veterinary medicinal products shall also be refused if the competent authority establishes that:
- the efficacy of the medicinal product is insufficiently substantiated or that the medicinal product is not efficacious,
- the withdrawal period recommended by the applicant is not long enough to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer, or is insufficiently substantiated,
- the veterinary medicinal product is offered for sale for a use prohibited under other EU provisions, or
- the veterinary medicinal product is intended for use in one or more food-producing species and contains one or more active substances not included in Annexes I, II or III of the Regulation 2377/90/EEC.

Article 43
(refused issue of marketing authorisation for a traditional medicinal product)

The granting of a marketing authorisation for a traditional herbal medicinal product shall be refused if at least one of the following conditions is fulfilled:
- its qualitative and/or quantitative composition is not as declared;
- its therapeutic indications do not comply with the prescribed conditions;

- the medicinal product could be harmful under normal conditions of use;
- the data on the traditional use are insufficient; in particular, if the pharmacological effects or efficacy of the medicinal product are not plausilble on the basis of long-term use and experience;
- the pharmaceutical quality of the medicinal product is not satisfactory demonstrated.

Article 44
(data on the placement of medicinal products on the market)

(1) The marketing authorisation holder, the holder of parallel import licence for medicinal product and the wholesaler performing parallel distribution of medicinal product shall inform the competent authority for medicinal products, in writing, of the actual placing on the market of the medicinal product in the Republic of Slovenia.

(2) The marketing authorisation holder referred to under the previous paragraph shall also notify the competent authority for medicinal products if the product ceases to be placed on the market, either temporarly or permanently. Such notification shall, otherwise than in exceptional circumstances, be made no less than 2 months before adopting a decision on the interruption in the placing on the market of the product.

(3) If requested by the competent authority for medicinal products, the marketing authorisation holder must submit data on the volume of sales and any data in his possession relating to the volume of prescriptions.

(4) The competent authority for medicinal products shall inform the Slovenian Health Insurance Institute (hereinafter: Institute) of the medicinal product for human use within three working days of the receipt of the notification referred to in the second paragraph of this Article and shall publish this information on its website.

(5) The competent authority for medicinal products shall inform the Veterinary Administration of the Republic of Slovenia of the veterinary medicinal product for use within three working days of the receipt of the notification referred to in the second paragraph of this Article and shall publish this information on its website.

Article 45
(roll-out period)

(1) If, following the issue of marketing authorisation, the medicinal product has not been marketed for three consecutive years, such authorisation shall cease to be valid.withdrawn

(2) Notwithstanding the provisions of the previous paragraph, the competent authority for medicinal products shall be entitled not to withdraw marketing authorisation in exceptional well-justified cases and for the needs of protecting public health even if

the medicinal product has not been actually marketed for three consecutive years after the issue of the marketing authorisation.

Article 46
(variations to the terms of a marketing authorisation)

(1) After a marketing authorisation has been issued, the authorisation holder must, in respect of the methods of manufacture and control, take account of scientific and technical progress and introduce any changes that may be required to enable the medicinal product to be manufactured and checked by means of generally accepted scientific methods. Before introducing any changes, the competent authority for medicinal products must be informed of any new information that could impact the change of marketing authorisation or the change of documentation on the medicinal product.

(2) The marketing authorisation holder must inform the competent authority for medicinal products of any data that could impact the assessment of the risk-benefit balance and particularly of any measures, restrictions or suspensions introduced by other countries.

(3) The competent authority for medicinal products shall accept or refuse the application for variation to the term of marketing authorisation within the deadlines and according to the procedure stipulated by the Regulation 1084/2003/EC.

(4) The Minister shall determine the documentation and the detailed conditions for evaluation of variations to the terms of the marketing authorisation.

Article 47
(renewal of marketing authorisation)

(1) The marketing authorisation holder shall submit an application for renewal, at least six months before the marketing authorisation ceases to be valid....

(2) The validity of the marketing authorisation can be extended after the expiry of the five-year period on the basis of the application for renewal of the marketing authorisation and re-evaluation of the risk-benefit balance.

(3) The competent authority for medicinal products shall adopt a decision on the renewal of marketing authorisation within 90 days of receiving a valid application.

(4) Once renewed, the marketing authorisation renewed shall be valid for an unlimited period or until the reasons stipulated hereby no longer exist. The competent authority for medicinal products shall be entitled to decide that another renewal of marketing authorisation is required in exceptional cases, for the needs of protecting public health and, providing an explanation for the marketing authorisation holder.

(5) Notwithstanding the provisions of the previous paragraphs, the competent authority for medicinal products shall accept or refuse the application for the renewal of marketing authorisation according to the mutual recognition procedure or the decentralised procedure on the basis of the assessment report compiled by the reference Member State.

(6) The Minister shall determine more specific conditions and contents of the documentation required for renewal of the marketing authorisation.

Article 48

,withdrawal, of and variations to marketing authorisations for medicinal products for human use *ex officio)*

(1) The marketing authorisation shall be suspended, suspended or varied if the competent authority for medicinal products for human use establishes that:

- the medicinal product is harmful under normal conditions of use;
- the therapeutic efficacy is lacking, i.e., when it is concluded that therapeutic results cannot be obtained from the medicinal product;
- the risk-benefit balance of the medicinal product is not favourable under the normal conditions of use;
- its qualitative and quantitative composition is not as declared;
- the medicinal product was marketed contrary to the provisions of the marketing authorisation; or
- the medicinal product was marketed contrary to this Act and the regulations issued on the basis hereof or the EU regulations on medicinal products.

(2) The marketing authorisation shall also be suspended, withdrawn or varied if it is subsequently established that the particulars supporting the application are incorrect, on the basis of regulations, or have not been submitted or supplemented in accordance with such regulations, or where the prescribed controls have not been carried out.

(3) The competent authority for medicinal products shall withdraw or suspend the marketing authorisation for a group of medicinal products or all medicinal products for use in human medicine which are produced on the basis of a certain manufacturing authorisation if any of the requirements of such manufacturing authorisation is not met and withdraw or suspend the manufacturing authorisation for such group of medicinal products or all medicinal products.

Article 49

(withdrawal of and amendments to marketing authorisations for medicinal products for veterinary use *ex officio)*

(1) The marketing authorisation shall be withdrawn, suspended or varied if the competent authority for medicinal products for veterinary use establishes that:

- the assessment of the risk-benefit ratio of such medicinal product is unfavourable under the authorised conditions of use, taking into account above all health and welfare of animals and safety of consumers in the event of marketing authorisation for use in zootechnics;
- the medicinal product does not have any therapeutic effect on the species of animal which is to be treated;
- its qualitative and quantitative composition is not as stated;
- the recommended withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer;
- the medicinal product is offered for sale or advertised for a use prohibited under other applicable regulations;
- the data in the application are incompliant, incorrect, or have not been supplemented in accordance with the regulations, or where the prescribed controls have not been carried out;
- the particulars from the documentation have not been amanded in line with the scientific and technological development in the field of medicinal product manufacturing and control;
- the competent authorities have not been submitted new information on any prohibitions or restrictions of the use of medicinal product in any country or new information on the risk-benefit balance;
- the medicinal product was marketed contrary to the provisions of the marketing authorisation; or
- the medicinal product was marketed contrary to this Act and the regulations issued on the basis hereof or the EU regulations on medicinal products.

(2) The competent authority for medicinal products shall withdraw or suspend the marketing authorisation for a group of medicinal products or all medicinal products for use in veterinary medicine which are produced on the basis of a certain manufacturing authorisation if any of the requirements of such manufacturing authorisation is not met and withdraw or suspend the manufacturing authorisation for such group of medicinal products or all medicinal products.

Article 50

(sale of medicinal products following the variation or expiry of marketing authorisation)

(1) A medicinal product which has been manufactured or imported prior to the expiry of or variation to the marketing authorisation may be marketed even after the expiry of the period for which its marketing authorisation was granted until the expiry date of such medicinal product, but for no longer than 18 months after the expiry of or variation to the marketing authorisation, with the exception of measures taken in accordance with Articles 83 or 84 hereof.

(2) It is prohibited to place on the market any medicinal product whose shelf life has expired or whose quality, safety or efficacy has been found to be deficient.

Article 51
(documentation as trade secret)

The documentation enclosed in the application for the issue of, variation to or renewal of a marketing authorisation is the property of the applicant and a trade secret, with the exception of the data stated in the marketing authorisation and including the summary of product characteristics of the medicinal product, the package leaflet and data on the labelling.

Article 52
(publication of lists)

(1) Lists of medicinal products for which a marketing authorisation has been granted and lists of medicinal products whose validity has expired or whose marketing authorisation has been varied, renewed, suspended or withdrawn shall be published by the competent authority for medicinal products in the Official Gazette of the Republic of Slovenia.

(2) The Minister shall prescribe the contents of the publication stated in the previous paragraph.

Article 53
(transfer of marketing authorisation)

(1) A marketing authorisation holder may transfer its marketing authorisation to another legal entity or natural person who meets the conditions stipulated hereunder.

(2) The Minister shall prescribe the procedure for the transfer of marketing authorisation stipulated in the previous paragraph and the necessary documentation and procedure for verifying the prescribed conditions and other necessary evidence.

III. TESTING OF MEDICINAL PRODUCTS

Article 54
(testing of medicinal products)

(1) Prior to being placed on the market, a medicinal product must undergo analytical and pre-clinical pharmacotoxicological tests as well as clinical trials in order to obtain the assessment of its quality, safety and efficacy.

(2) A medicinal product shall undergo analytical and pre-clinical pharmacotoxicological tests as well as clinical trials even if it has already been granted a marketing authorisation or has been marketed if such testing is performed with the purpose of control of medicinal products or for acquiring additional data on that product.

(3) Analytical and pre-clinical pharmacotoxicological tests as well as clinical trials may be carried out by legal entities and natural persons (hereinafter: medicinal product investigation institutions) who satisfy the requirements in terms of staff, facilities, equipment and principles of good practices, and hold the licence for performing such activities.

(4) Data on analytical and pre-clinical pharmacotoxicological tests as well as clinical trials represent a constituent part of the documentation for obtaining the marketing authorisation.

5) Analytical and pre-clinical pharmacotoxicological tests as well as clinical trials must correspond to contemporary scientific knowledge and guidelines of good practices. They must be described in sufficient detail so that the tests and trials can be repeated in order to ensure data comparability.

(6) The Minister shall determine more detailed methods and procedures of analytical and pre-clinical pharmacotoxicological tests as well as clinical trials and the requirements which the medicinal product investigation institutions must comply with as well as the verification procedure .

Article 55
(analytical testing)

Analytical testing shall be pharmaceutical, chemical and biological quality testing of a medicinal product in compliance with the principles of good control laboratory practice and in accordance with the data contained in the documentation for obtaining the marketing authorisation or medicinal product specifications.

Article 56
(non-clinical pharmacotoxicological testing)

(1) non-clinical pharmacotoxicological testing shall be the procedure for establishing the safety of a medicinal product and shall be carried out in compliance with the principles and guidelines of good laboratory practice and in accordance with the data contained in the documentation for obtaining the marketing authorisation.

(2) non-clinical pharmacotoxicological testing must define pharmacodynamic, pharmacokinetic and toxicological properties of a medicinal product demonstrated on laboratory animals and foresee any possible effects in human beings or target animal species.

(3) The pre-clinical pharmacotoxicological testing of veterinary medicinal products must provide data on metabolism, kinetics and elimination of medicinal product residues, and routine analysis methods that can be applied to determine the level of such residues.

Article 57
(clinical trials of medicinal products)

(1) Clinical trials of human medicinal products shall be trials involving healthy and sick human beings, with the purpose of demonstrating or ascertaining any clinical, pharmacological or other pharmacodynamic and pharmacokinetic effects of the investigational medicinal product, demonstrating any adverse reactions to it, or investigating its absorption, distribution, metabolism and elimination during the trial with a view to proving its safety and efficacy.

(2) Clinical trials of veterinary medicinal products shall be the organised study of the effect of a medicinal product on an animal organism with the purpose of demonstrating or ascertaining any clinical, pharmacological or other pharmacodynamic effects of the investigational veterinary medicinal product, demonstrating any adverse reactions to it, or investigating its absorption, distribution, metabolism and elimination and residues during investigation with a view to proving its safety and efficacy in target animal species.

Article 58
(prerequisites for a clinical trial)

(1) Medicinal products can be subjected to clinical trials only after the submission of the results on analytical and non-clinical pharmacotoxicological testing of a medicinal product and in the event of investigating a medicinal product that has no impact on the subject's germ line genetic identity.

(2) The procedure for the clinical testing of a medicinal product which is described in the documentation submitted for obtaining marketing authorisation must correspond to the requirements stipulated under Article 54 hereof and the principles of good clinical practice in clinical trial and principles of human medical and veterinary ethics as well as the mandatory and guaranteed protection of personal data.

Article 59
(conditions for the commencement of a clinical trial)

(1) The applicant for a clinical trial can be either the sponsor of such clinical trial or its representative if the sponsor's registered office is located outside the European Union in which case the representative's registered office must be located in the European Union.

(2) Clinical trial can commence once the conditions stipulated by this Act and any regulations arising hereof are fulfilled.

(3) Written authorisation must be issued by the competent authority for medicinal products before commencing clinical trials involving human medicinal products for gene therapy, somatic cell therapy including xenogenic cell therapy and all medicinal products containing genetically modified organisms.

(4) Prior to the commencement of a clinical trial of other medicinal products such trial must be notified and the trial can begin if the competent authority for medicinal products does not object within the foreseen deadline.

Article 60
(liability insurance)

Prior to the commencement of the clinical trial, the applicant for such trial must take up liability insurance for any possible damage resulting from the trial.

Article 61
(inspection of a clinical trial)

Clinical trials performed hereunder shall be inspected by pharmaceutical inspectors holding a university degree in pharmacy, human or veterinary medicine, having additional skills and experience with good clinical practice and meeting the conditions stipulated under the second and the third indents of the first paragraph of Article 102 hereof.

Article 62
(authorisation and registration of a clinical trial)

(1) Applications for authorisation or registration of a clinical trial shall be decided on by the competent authority for medicinal products. The Committee for Clinical Trials shall give an opinion on the proposed or registered clinical trial.

(2) For a human medicinal product, in addition to the application for a clinical trial, the applicant must also submit an opinion of the National Medical Ethics Committee at the Ministry of Health.

3) The application for authorisation of a clinical trial shall be decided on by the competent authority for medicinal products within 60 days of the receipt of the complete application In the case of medicinal products issuing from biotechnological procedures, this period may be extended extraordinarily by 30 days. If the proposal refers to human medicinal products intended for treatment of people with xenogenic cells, the period of the decision of the competent authority for medicinal products is not limited. The clinical trial may begin when the applicant receives a decision on the authorisation of the clinical trial for the medicinal product.

(4) The registration of the clinical trial shall be decided on by the competent authority for medicinal products within 60 days of receipt of the completed registration. If the competent authority does not respond, the registration is considered positive and the clinical trial may be initiated.

Article 63
(changes to a clinical trial)

(1) In the case of an ongoing clinical trial, the sponsor must notify the competent authority for medicinal products of important .changes

(2) The notified modification may be implemented if the competent authority for medicinal products does not issue a negative decision within 35 days of receipt of the completed application for modification. This period may be extended extraordinarily by 60 days.

Article 64
(discontinuation of a clinical trial)

The competent authority for medicinal products may, for the purpose of protecting public health or the health of the subjects, order that a trial be temporarily or permanently discontinued.

Article 65
(payment of expenses arising from trials)

If a clinical trial of a medicinal product with marketing authorisation or parallel import licence for medicinal product is required by a competent authority for medicinal products in order to verify the risk/benefit ratio, the costs shall only be borne by the applicant if it turns out that the safety and efficacy correspond to the requirements of the

marketing authorisation. In all other events, the costs shall be paid by the marketing authorisation holder.

IV. MANUFACTURING AUTHORISATION FOR MEDICINAL PRODUCTS

Article 66
(manufacture of medicinal products)

(1) Legal entities or natural persons may manufacture medicinal products only after they have been granted a manufacturing authorisation and in compliance with such authorisation. The authorisation shall comprise the manufacturing of medicinal products and their sales to wholesalers that have obtained appropriate wholesale distribution authorisation and shall be required in the following cases:
- individual manufacturing processes or the entire production process;
- individual manufacturing or production sites;
- individual pharmaceutical forms;
- manufacture of active substances;
- for excipients, based on the applicable regulations.

(2) The provisions laid down in the preceding paragraph shall also apply to the manufacturers of medicinal products intended exclusively for exports or clinical trials.

(3) Importers of medicinal products from third countries must also hold manufacturing authorisations.

(4) The manufacturing authorisation shall also include wholesale distribution to wholesalers and concern the medicinal products covered by that authorisation.

Article 67
(manufacturing conditions)

Legal entities and natural persons manufacturing medicinal products must meet the following conditions:
1. Given the volume and complexity of their medicinal product manufacture, they must employ an adequate number of professionals holding university degrees and with an appropriate state qualifying exam in pharmacy, chemistry, chemical technology, medicine, stomatology, veterinary medicine or other appropriate discipline with adequate skills depending on the subject of operations.
2. They must have concluded a contract with an adequately skilled person responsible for releasing the batch of medicinal products to the market who is available at all times. In the case of corporations and groups of companies, it is possible to appoint such person only in one of the members of the group, provided that adequate legal and organisational delimitation of responsibilities and competencies exist. Such qualified person must have a university education in one of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical

chemistry and technology, or biology. The programme of such studies must comprise skills defined by the second paragraph of Article 49 of the Directive 2001/83/EC or the second paragraph of Article 53 of the Directive 2001/82/EC. If the programme of studies does not comprise either of those skills, the qualified person must submit appropriate evidence of having obtained such skills. The qualified person must also have adequate work experience as defined by the third paragraph of Article 49 of the Directive 2001/83/EC or the third paragraph of Article 53 of the Directive 2001/82/EC.

3. They must be equipped with adequate facilities, devices and equipment for the manufacture, control, storage and dispatching of medicinal products in accordance with the guidelines and principles of good manufacturing practice.
4. The activity must be performed in accordance with the guidelines and principles of good manufacturing practice.
5. Only active substances produced in line with good manufacturing practice for starting materials must be used as starting materials, in accordance with the regulations.
6. They must only provide medicinal products for which a marketing authorisation has been issued or medicinal products manufactured or imported in the scope of manufacturing authorisation and in line with the applicable regulations.
7. The qualified person referred to under point 2 hereunder must have the possibility of independently performing its tasks and must have access to all necessary means.

Article 68
(procedure for obtaining authorisation)

(1) The procedure for the issue of a manufacturing authorisation shall be initiated on the basis of an application submitted by a legal entity or a natural person. The application for obtaining a manufacturing authorisation shall contain evidence on the fulfilment of conditions referred to under the previous Article.

(2) The competent authority for medicinal products shall issue or refuse to issue the manufacturing authorisation within 90 days of receiving a complete application on the basis of an opinion issued by the pharmaceutical .inspection

(3) The competent authority for medicinal products may require additional documentation or data needed for adopting the decision on the issue of manufacturing authorisation. The procedure shall be suspended until the fulfilment of requirements.

(4) The Minister shall determine in greater detail the contents of the application and specify the conditions and the procedures for establishing that such conditions for obtaining the manufacturing authorisation are met as well as the substance and form of the required documentation.

(5) The documentation from the application for obtaining the manufacturing authorisation shall be a business secret if defined as such by the applicant, in accordance with the regulations.

Article 69
(certificate of good manufacturing practice)

(1) The manufacturing authorisation holder may require that the competent authority for medicinal products issue a certificate of good manufacturing practice.

(2) The procedure for granting or withdrawing the certificate of good manufacturing practice shall be prescribed by the Minister.

Article 70
(modifications of the conditions which serve as the basis for issuing manufacturing authorisations)

(1) The manufacturing authorisation holder must inform the competent authority for medicinal products of any change in the conditions stipulated under Article 67 hereof which served as the basis for the issue of a manufacturing authorisation.

(2) The period for issuing the decision shall be 30 days except in the case a specific declaratory procedure is necessary for verifying conditions based on examination. In such cases the period for issuing the decision shall be 90 days.

(3) The Minister shall determine in greater detail the contents of the application for the change of conditions on the basis of which the manufacturing authorisation has been issued and specify the conditions and the procedures for establishing that such conditions for issuing a manufacturing authorisation are met.

Article 71
(withdrawal of the manufacturing authorisation)

A manufacturing authorisation shall be suspended or withdrawn should the competent authority for medicinal products ascertain that the manufacture of medicinal products no longer satisfies the requirements defined in Article 67 herein and regulations arising hereto.

V. LABELLING AND PACKAGE LEAFLET

Article 72

(labelling and package leaflet)

(1) each medicinal product placed on the market must be labelled in Slovenian on its outer packaging or, where there is no outer packaging, on the immediate packaging. Identical information may be given in one or more foreign languages. Data must be legible.

(2) In every packaging of medicinal product placed on the market must be inserted a package leaflet in Slovenian in line with the summary of product characteristics, unless the information required by a regulation is given on the outer packaging or, where there is no outer packaging, on the immediate packaging. Data must be legible and comprehensible for the user.

(3) Notwithstanding the provisions of the first and the second paragraph hereunder the competent authority for medicinal products may exceptionally allow the use of packaging in a foreign language with a label in Slovenian and the patient information leaflet in a foreign language, provided that the insert is enclosed with the medicinal product in Slovenian in the prescribed manner.

(4) The name of the medicinal product on the packaging must also be expressed in Braille. The marketing authorisation holder must ensure that the package leaflet is available in formats appropriate for the blind and partially-sighted if required by patient's organisations.

(5) The Minister shall prescribe a more detailed manner of labelling medicinal products, the form and contents of patient information leaflet and the manner of using the labels, special labelling conditions and package leaflet for individual medicinal products or groups of medicinal products.

VI WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS

Article 73
(conditions for wholesalers)

(1) Wholesalers of medicinal products may only buy medicinal products from legal entities and natural persons holding appropriate manufacturing or distribution authorisation.

(2) Wholesalers of medicinal products may only sell medicinal products to legal entities and natural persons holding appropriate distribution or retail authorisation and pharmacies.

(3) Notwithstanding the provision of the previous paragraph, wholesalers may sell medicinal products directly to health institutions, legal entities or natural persons holding an authorisation issued by the competent authority, for performing medical

activity, provided that they have established the system for receiving, storing and tracing medicinal products which has been appropriately verified by the competent authority , and appointed a qualified person to receive, store and ensure traceability of medicinal products who holds a diploma, degree or another university or equivalent certificate in the field of pharmaceutical science. The Minister shall determine the system of the receipt, storage and traceability of medicinal products.

(4) Notwithstanding the provision of the second paragraph hereunder, the wholesalers may sell veterinary medicinal products to veterinary and other organisations which perform veterinary activity in line with the veterinary regulations and authorised manufacturers of medicated feedingstuffs in accordance with the regulations and in the scope covered by wholesale distribution authorisation.

(5) The medicinal products referred to in the third paragraph hereunder may only be used for the provision of health services arising from the abovementioned authorisation for performing medical activity.

Article 74
(conditions for wholesalers)

(1) The wholesale of medicinal products may be undertaken by legal entities and natural persons holding an authorisation issued by the competent authority for performing that activity and satisfying the following requirements:

1. Have at their disposal the services of professionals, based on contractual relationship, holding a university degree in pharmacy and experts in other disciplines, if necessary.
2. Appoint from among the experts mentioned in the previous point a person responsible for receiving, storing, issuing and transporting medicinal products as well as examining documentation that enables traceability of medicinal products. Such responsible person must hold a university degree in pharmacy.
3. Have at their disposal adequate facilities and equipment, depending on the type of medicinal product that is the subject of wholesale trade.
4. Keep appropriate documentation so as to enable the immediate withdrawal of a medicinal product from the market and resolve complaints.
5. Organise work in accordance with the principles of good distribution practice.
6. Guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a reasonably short time over the whole of the area in question.
7. Have an established quality assurance system.
8. Meet the conditions for performing trading activity in accordance with the applicable trade regulations.

(2) If the person responsible stipulated by point 2 of the previous paragraph does not have a university degree in pharmacy, such person must have obtained additional skills defined by the second paragraph of Article 49 of the Directive

2001/83/EC or the second paragraph of Article 53 of the Directive 2001/82/EC. If the programme of studies does not comprise either of those skills, the responsible person must submit appropriate evidence of having obtained such skills. The responsible person must also have adequate work experience as defined by the third paragraph of Article 49 of the Directive 2001/83/EC or the third paragraph of Article 53 of the Directive 2001/82/EC.

(3) Legal entities or natural persons having obtained the distribution authorisation for medicinal products in another EU Member State and intending to wholesale medicinal products in the Republic of Slovenia can commence performance of such activity in the Republic of Slovenia once they have notified the competent authority for medicinal products in accordance with the procedure prescribed by the Minister.

(4) Wholesale distribution authorisation holders must obtain the manufacturing authorisation and meet the conditions stipulated by Article 67 hereof if they plan to carry out any part of manufacturing process or importation of medicinal products in addition to wholesaling

(5) The Minister shall determine in greater detail the conditions for the wholesalers of medicinal products and procedure for establishing that such conditions are met as well as the notification procedure in agreement with the minister competent for trade.

(6) In view of the type of medicinal products in wholesale, the Minister may prescribe different conditions of wholesale for certain medicinal products.

Article 75
(issue of authorisation)

(1) The procedure for the issue of a wholesale authorisation shall be initiated on the basis of an application submitted by a legal entity or a natural person. The application for obtaining a wholesale authorisation shall contain evidence on the fulfilment of conditions referred to under Article 74 hereof.

(2) The authority competent for medicinal products shall decide on the issue of a wholesale authorisation within 90 days of receiving a complete application on the basis of an expert opinion issued by the pharmaceutical inspection concerning the fulfilment of conditions.

(3) The authorisation referred to in the previous paragraph may be issued for a limited time or under certain conditions and can be suspended or withdrawn should the authority competent ascertain that the holder of the wholesale authorisation no longer satisfies the prescribed requirements.

Article 76
(Importation)

(1) Medicinal products shall be imported by the manufacturing authorisation holders and wholesalers who, besides the conditions stipulated by Article 74 hereof, also meet the conditions prescribed for the manufacturers of medicinal products in respect to the parts of manufacturing procedure they carry out.

(2) Wholesalers and manufacturing authorisation holders importing medicinal products from third countries and not having themselves the appropriate facilities, equipment and devices for controlling the quality of each imported batch of medicinal product, can enter into a contractual relationship with a legal entity or natural person for the provision of the services of analytical testing of medicinal products, provided that such entity or person holds the authorisation of the competent authority for medicinal products to perform analytical testing of medicinal products.

(3) The batches of medicinal products which have undergone such controls in another EU Member State shall be exempt from the controls prior to their marketing in the Republic of Slovenia, provided that they are accompanied by the quality control reports signed by the qualified person responsible for batch release.

(4) In the case of medicinal products imported from a country that has entered into a Mutual Recognition Agreement with the European Union for the area of medicinal products, the analysis certificate obtained in the exporting country shall be recognised.

Article 77
(entry and imports of medicinal products)

(1) Entry and imports of medicinal products with:
- marketing authorisation,
- parallel import licence fo rmedicinal product, or
- authorisation for clinical trial or adequately notified clinical trial,

are free conditions of meeting provided that the requirements stipulated by this Act are met.

(2) Notwithstanding the provisions of the previous paragraph, the entry and import of medicinal products shall only be allowed on the basis of an entry authorisation or import authorisation issued by the competent authority for medicinal products within 30 days of the receipt of a complete application in the following cases:
1. immunological serums, vaccines, blood products, radiopharmaceuticals;
2. medicinal products without marketing authorisation in cases of emergency for individual treatment proposed by a legal entity performing tertiary medical activity or a competent veterinarian of the veterinary organisation and on the basis of personal responsibility of a doctor or veterinarian in charge of individual cases of treatment;

3. medicinal products stipulated by Article 15 hereof without a marketing authorisation;
4. medicinal products intended for research and development work under the responsibility of the institution performing such research and development work.

(3) The application for obtaining the entry authorisation referred to in the previous paragraph can be submitted by a wholesaler and for obtaining the import authorisation by a person meeting the requirements for the import of medicinal products.

(4) The Minister shall determine in greater detail the requirements, methods and procedures governing the entry and imports referred to in the previous paragraph.

Article 78
(parallel import of medicinal products)

(1) The procedure for obtaining a parallel import licence for medicinal product shall be initiated on the basis of an application submitted by the importer who is a wholesaler and is not in a business relationship for the marketing of the concernedthe concernedconcernedthe concernedconcernedconcerned medicinal product with the holder of the marketing authorisation. The competent authority for medicinal products shall issue the parallel import licence for medicinal products within 60 days of receiving a complete application.

(2) The Minister shall lay down more detailed conditions, method and procedure for obtaining the parallel import licence for medicinal products.

Article 79
(retail trade)

(1) Retail trade in medicinal products for human use, accompanied by adequate expert support and advice, shall be carried out in pharmacies and specialised retail shops, while veterinary medicinal products shall also be sold in veterinary organisations, together with the service provided.

(2) Notwithstanding the provisions of the previous paragraph, only those medicinal products can be sold in specialised retail shops which are not subject to medical or veterinary prescription and are authorised by the competent authority for medicinal products.

(3) When defining medicinal products that can be sold in specialised retail shops, the competent authority for medicinal products may introduce certain restrictions concerning strengths, packaging sizes and number of units sold.

(4) The competent authority for medicinal products shall only authorise the sales of those medicinal products in specialised retail shops which have a favourable risk/benefit ratio and an acceptable pharmacovigilance and toxicovigilance profile.

(5) Medicinal products in specialised retail shops may only be sold to adult persons.

(6) The method and place of issuing medicinal products shall be defined in the relevant marketing authorisation.

(7) Homeopathic medicinal products may only be issued in pharmacies, while veterinary homeopathic medicinal products may also be sold in veterinary organisations, together with the service provided.

(8) Issue based on self-service shall only be allowed in pharmacies and specialised retail shops and shall be limited to medicinal products referred to in the second paragraph hereunder which are of herbal origin.

(9) Sales of medicinal products over the Internet, accompanied by adequate expert support and advice, shall be allowed if performed by a holder of an authorisation for performing such pharmaceutical activity who ensures quality and traceability of medicinal products. The ministry competent for health may recognise such authorisations issued by the competent bodies of the EU Member States.

(10) In addition to the responsibility of the Internet source of a medicinal product, which includes the liability of manufacturer, wholesaler and retailer, the user or buyer of such medicinal product shall also be responsible for any risks and damages incurred through the use of medicinal products obtained from non-traceable Internet sources or sources that do not correspond to the requirements of the previous paragraph.

(11) The Minister shall determine the detailed manner of issue and the related classification of the medicinal product.

Article 80
(pharmacies)

Conditions for marketing medicinal products imposed on pharmacies and Internet pharmacies shall be regulated by a separate act.

Article 81
(specialised retail shops)

(1) The retail sale of medicinal products in specialised retail stores may be undertaken by legal entities and natural persons holding an authorisation issued by the competent authority for performing that activity and satisfying, in addition to the general conditions for performing the retail sale activity, also the following requirements:

1. They must employ at least one qualified person with at least a level V pharmacy education, who has passed the qualifying examination and is put in charge of purchasing, storing and selling medicinal products and keeping documentation and must be available at all times during the store's business hours.
2. They must dispose of adequate facilities which must be physically separated from the facilities in which other products are sold, and the necessary equipment.
3. They must keep appropriate documentation so as to enable the immediate recall of a medicinal product from the market and resolve complaints.

(2) The procedure for the issue of a retail authorisation for the sale of medicinal products in specialised retail shops shall be initiated on the basis of an application submitted by a legal entity or a natural person.

(3) The competent authority for medicinal products shall issue a retail authorisation for the sale of medicinal products in specialised retail shops within 90 days of the receipt of a complete application on the basis of an expert opinion issued by the pharmaceutical inspection concerning the fulfilment of conditions.

(4) The authorisation referred to in the previous paragraph may be issued for a limited time or under certain conditions and can be suspended or withdrawn should the competent authority ascertain that the holder of marketing authorisation no longer satisfies the prescribed requirements.

(5) More detailed requirements for marketing medicinal products imposed on specialised retail shops retailing medicinal products and the procedure for ascertaining their compliance shall be determined by the Minister in agreement with the minister competent for trade.

VII. PHARMACOVIGILANCE

Article 82
(pharmacovigilance system)

(1) Reports on adverse reactions to medicinal products for human use shall be collected and assessed by a legal entity meeting the conditions concerning personnel, facilities and equipment and authorised for performing such activity by the Minister.

(2) A doctor or another health care professional who identifies or suspects any adverse reactions to medicinal products for human use shall inform the legal entity

referred to in the previous paragraph hereof in accordance with the applicable regulations.

(3) A veterinarian who identifies or suspects any adverse reactions to veterinary medicinal products shall inform the marketing authorisation holder thereof in accordance with this Act and the regulations issued on the basis hereof. In the case of unexpected serious adverse reactions in animals and in human beings related to the use of veterinary medicinal products the competent authority for medicinal products shall also be informed, in addition to the marketing authorisation holder in accordance with this Act and the regulations issued on the basis hereof.

(4) Marketing authorisation rholder must setup and maintain their own pharmacovigilance system which ensures collection, evaluation and exchange of data with the legal entity referred to in the first paragraph hereunder and with the competent authorities for medicinal products in the Republic of Slovenia and the European Union as well as other sources, such as the publications of the World Health Organisation and other professional publications. They must compile reports and perform other tasks within the deadlines and in the way stipulated by Articles 103 and 104 of the Directive 2001/83/EC and Articles 74 and 75 of the Directive 2001/82/EC.

(5) The legal entity referred to in the first paragraph hereunder must regularly submit the collected data on adverse reactions and any other significant data concerning safety and efficacy and use of medicinal products as well as the functioning of the pharmacovigilance system to the competent authority for medicinal products.

(6) The competent authority for medicinal products shall identify and evaluate the adverse reactions to medicinal products and other safety findings of medicinal products and take measures with the aim of managing and reducing the risks arising from medicinal products, with expert assistance provided by the legal entity stipulated by the first paragraph hereunder, verify the implementation of the pharmacovigilance system by the marketing authorisation holders and perform tasks in accordance with the provisions of Articles 105, 106 and 107 of the Directive 2001/83/EC and Articles 76, 77 and 78 of the Directive 2001/82/EC.

(7) The provisions of this Article shall not apply to the homeopathic medicinal products specified in the second paragraph of Article 14 of this Act. The Minister may prescribe the pharmacovigilance management system for such homeopathic medicinal products.

(8) The Minister shall determine in greater detail the conditions for the functioning of the pharmacovigilance system.

Article 83

(measures taken in case of quality defect of medicinal products)

(1) Legal entities or natural persons, manufacturing or marketing medicinal products must report all events or suspected events regarding quality defects of medicinal products, which could affect the safety or efficacy of the medicinal product, to the tcompetent authority for medicinal products, the marketing authorisation holder and the legal entity or natural person marketing the medicinal products.

(2) The marketing authorisation holder shall be obliged to recall the defective medicinal product from the market or take any other necessary measures as well as inform, regularly and without delay, the competent authority for medicinal products of any activities taken.

(3) The marketing authorisation holder shall be obliged to notify the competent authorities of the EU Member States in which the medicinal product is marketed forthwith of any action taken by the holder to recall a medicinal product from the market or to suspend or withdraw the marketing authorisation, together with the reasons for such action if the latter concerns the efficacy of the medicinal product or the protection of public health.

(4) The competent authority for medicinal products shall monitor and, if necessary, direct the activities of the marketing authorisation holder in relation to the measures taken in the event of the quality defect of medicinal products and report to the international rapid alert system.

(5) The competent authority for medicinal products shall immediately inform the European Medicines Agency in the case of taking any measures that could influence the protection of public health in the EU Member States and, if necessary, also the World Health Organisation.

(7) The Minister shall determine in greater detail the measures to be taken in the case of quality defects.

Article 84
(measures taken in pharmacovigilance cases)

(1) The provisions of the previous Article shall also apply in the cases of increased risk arising from adverse reactions that could be harmful for the health of people or animals or impact on the risk-benefit balance of the medicinal product and should be reported to the international rapid alert system.

(2) The Minister shall determine in greater detail thethethethe measures to be taken in the cases stated in the previous paragraph.

VII. ADVERTISING OF MEDICINAL PRODUCTS

Article 85
(advertising of medicinal products)

Advertising of medicinal products shall mean any form of information, including door-to-door information, publication or inducement designed to promote the prescription, issue, sale or consumption of medicinal products.

Article 86
(terms and conditions of advertising)

(1) The marketing authorisation holders may advertise medicinal products only in accordance with the provisions of this Act and the regulations issued on the basis of this Act.

(2) It is prohibited to advertise medicinal products which have not been granted a marketing authorisation.

(3) All elements of the advertising of a medicinal product must comply with the summary of product characteristics.

(4) Advertising of medicinal products must encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties, and may not be misleading.

Article 87
(advertising of medicinal products to the general public)

(1) Only medicinal products not subject to prescription may be advertised in the mass media.

(2) It is prohibited to advertise to the general public the following:
- medicinal products that are subject to prescription;
- medicinal products containing psychotropic or narcotic substances within the meaning of international conventions, such as the United Nations Convention on narcotic drugs of 1961 and the United Nations Convention on psychotropic substances of 1971.

(3) The advertising of a medicinal product to the general public shall not contain any material which:
- gives the impression that a medical or veterinary consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;

- suggests that the effects of taking the medicine are absolutely guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;
- suggests that the health of the person or animal can be enhanced by taking the advertised medicine;
- suggests that the health of the person or animal could deteriorate by not taking the advertised medicine; this prohibition shall not apply to vaccination programmes;
- is directed exclusively or principally at children;
- refers 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 medicinal products;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refers, in improper, alarming or misleading terms, to claims of recovery; or
- uses improper, alarming or misleading terms, pictorial representations of changes in the human or animal body caused by disease or injury, or action of a medicinal product on the human or animal body or parts thereof.

(4) Direct distribution of medicinal products to end users for promotional purposes shall be prohibited.

Article 88
(advertising of medicinal products to the expert community)

(1) Holders of marketing authorisations may advertise medicinal products with marketing authorisation in scientific literature, professional journals and other professional publications, as well as directly inform persons authorised for prescribing or dispensing of medicinal products.

(2) Where medicinal products are being promoted to the expert community, i.e. persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine, veterinary medicine or pharmacy. The value of gifts, pecuniary advantages or small benefits in kind may not exceed the value prescribed for civil servants.

(3) Organisation and implementation of promotional meetings must be strictly limited to the professional purpose of the meeting which includes the obtaining of new skills and knowledge on new medicinal products and may only be provided to persons authorised to prescribe and issue medicinal products.

(4) Marketing authorisation holders, manufacturers of medicinal products, legal entities and natural persons acting on behalf of manufacturers and legal entities and natural persons marketing medicinal products, as well as subsidiaries of foreign manufacturers may enable persons who prescribe or issue medicinal products to acquire knowledge on new medicinal products in scientific and expert meetings, however, only in the scope of restrictions referred to in the second and the third paragraph hereunder.

(5) Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under the second and the third paragraph hereunder.

(6) The marketing authorisation holder shall be obliged to establish a scientific service for advertising medicinal products with medical experts to advertise medical experts to persons prescribing and issuing medicinal products. Such experts for human medicinal products must hold a university degree in pharmacy or human medicine or a university degree in natural sciences or biomedicine with additional skills in medicinal products. Such experts for veterinary medicinal products must hold a university degree in pharmacy or veterinary medicine or a university degree in natural sciences or biomedicine with additional skills in medicinal products.

(7) The Minister shall determine in greater detail the conditions and method of advertising.

Article 89
(advertising in extraordinary cases)

(1) The Minister may, by way of exception and in the interest of the general public, with a view to preventing an epidemic, an epizootic, or in case of a natural disaster or in other similar emergencies, allow or approve information about the use of certain medicinal products to be distributed to the mass media.

(2) In the cases referred to in the previous paragraph concerning veterinary medicinal products, the Minister shall allow or authorise informing on the use of certain medicinal products in public media in agreement with the minister competent for veterinary medicine.

(3) The competent authority for medicinal products may allow advertising of medicinal products used in vaccination programmes to the general public.

Article 90
(official records of the competent authority for medicinal products)

(1) The competent authority for medicinal products shall keep official records of:

1. data on medicinal products arising from marketing authorisation based on the type and classification of medicinal products (name, pharmaceutical form, strength, packaging, marketing authorisation holder, manufacturer, the maximum allowed price and extraordinary maximum price);
2. data on medicinal products arising parallel import licence for medicinal products (name, pharmaceutical form, strength, packaging, holder of parallel import licence for medicinal products, manufacturer, the maximum allowed price and extraordinary maximum price);
3. data on medicinal products arising from entry or import authorisation (name, pharmaceutical form, strength, packaging, entry authorisation holder, manufacturer);
4. data on the marketing authorisation holder (name and legal form of organisation, registered office, name and surname of qualified person responsible for pharmacovigilance);
5. data on the manufacturing authorisation holder (name, registered office and legal form of organisation, name and surname of qualified person in charge of releasing the batch of medicinal products to the market);
6. data on the distribution authorisation holder (name and legal form of organisation, registered office, name and surname of qualified person in charge of receiving, storing and transporting medicinal products as well as examining documentation);
7. data on notified foreign wholesalers (name and legal form of organisation, registered office, name and surname of qualified person in charge of receiving, storing and transporting medicinal products as well as examining documentation);

8. data on the retail authorisation holder (name and legal form of organisation, registered office, name and surname of qualified person in charge of purchasing, storing and selling medicinal products as well as keeping documentation);
9. data on the holders of parallel import licence for medicinal products (name and legal form of organisation, registered office, name and surname of qualified person responsible for pharmacovigilance).

(2) The competent authority for medicinal products shall publish professional and general informative publications in its areas of competence.

IX. OFFICIAL QUALITY CONTROL OF MEDICINAL PRODUCTS

Article 91
(official medicines control laboratory)

(1) The official medicines control laboratory shall be a legal entity or a natural person complying with the requirements set in the third paragraph of Article 54 hereof, appointed by the Minister for verifying the official quality of medicinal products, which is a member of the European network of official control laboratories or which annually participates in the intra-laboratory verification organised by the European Directorate for the Quality of Medicines and the results achieved are in compliance with the organiser's requirements.

(2) The Minister shall prescribe more detailed conditions regarding personnel, facilities, equipment and fulfilment of standards prescribed for quality control of medicinal products, compliance with the principles and guidelines of good laboratory practice and management of the quality system.

Article 92
(types of official controls)

(1) Official quality control of a medicinal product shall be the process in which the official medicines control laboratory establishes the quality of medicinal product on the basis of analytical testing, verification of certificates of analysis, packaging, patient information leaflet or other documents.

(2) This Act stipulates the following types of official quality controls of a medicinal product:
- regular quality controls of all medicinal products, performed in respect to each medicinal product *ex officio* at least once in five years for each of its pharmaceutical forms and strengths;
- extraordinary quality controls of medicinal products i.e. quality controls upon the request of the competent authority for medicinal products or pharmaceutical ;inspector

- special quality controls performed prior to the placing on the market of each batch of risk medicinal products, i.e. immunal serums and vaccines, immunoglobulins and blood products on the basis of the proposal submitted by the marketing authorisation holder or the applicant stipulated under the third paragraph of Article 77 hereof, if no marketing authorisation has been issued for the medicinal product;
- quality controls of each first batch of medicinal product prior to the placing on the market, carried out on the basis of the proposal submitted by the marketing authorisation holder, in the case of medicinal products imported from third countries which have not entered into a Mutual Recognition Agreement with the EU;
- quality controls of medicinal products required by the competent authority for medicinal products in the framework of the procedure for obtaining marketing authorisation;
- quality controls of each first batch of medicinal product with parallel import licence for medicinal products.

Article 93

(test report)

(1) The official medicines control laboratory shall issue a test report on the performed quality control of a medicinal product with assessed quality of the medicinal product which shall be submitted to the competent authority for medicinal products, the pharmaceutical ,inspection and the marketing authorisation holder or the applicant requesting control.

(2) The samples and costs of the official quality control specified in the second paragraph of the previous Article shall be borne by:
- in the case of regular quality control, the marketing authorisation holder or the holder of parallel import licence for medicinal product;
- in the case of extraordinary quality control, the marketing authorisation holder for the medicinal products with such authorisation and the wholesaler for the medicinal products without such authorisation, if it turns out that the quality of a medicinal product is deficient. If it turns out that the quality of a medicinal product is adequate, the costs will be borne by the applicant for such extraordinary quality control;
- in the case of special quality control, the marketing authorisation holder for the medicinal products with such authorisation and the applicant stipulated under the third paragraph of Article 77 hereof for the medicinal products without such authorisation;
- in the case of quality controls of each first batch of medicinal products imported from third countries, prior to the placing on the market, the marketing authorisation holder;
- in the case of quality controls of medicinal products required in the framework of the procedure for obtaining marketing authorisation, the applicant specified in Article 22 hereof;

- in the case of quality controls of each first batch of medicinal product with parallel import licence for medicinal product, the holder of marketing authorisation for a parallel imported medicinal product.

(3) The Minister shall determine the contents and the deadlines of official quality controls of medicinal products, the sampling method and the price of services noted in Article 92.

X. FEES

Article 94
(fees)

(1) The applicant shall pay the fees for the procedures stipulated hereunder, unless otherwise stipulated.

(2) The holders of parallel import licence for medicinal products and the holders of authorisation to perform activities issued by the competent authority for medicinal products, shall also pay the annual fees for the monitoring of medicinal products on the market concerning individual medicinal products depending on the number of pharmaceutical forms.

(3) Legal entities and natural persons who submitted the applications for expert advice with the competent authority for medicinal products in accordance with Article 24 hereof, shall be obliged to pay the prescribed fees.

(4) The Minister shall determine the amount of such fees.

XI. PRICES OF MEDICINAL PRODUCTS

Article 95
(pricing)

The prices of medicinal products shall be formed freely according to the market conditions except for the cases stipulated herein.

Article 96
(price monitoring)

In the interest of protecting public health, the Minister or the minister competent for veterinary medicine may designate certain medicinal products or groups of medicinal products the prices of which shall be determined by the competent authority for medicinal products.

Article 97
(price determination)

(1) The maximum allowed price of medicinal products for human use with marketing authorisation, parallel import licence, or that for medicinal products with import licence as well as that for medicinal products without marketing authorisation but with entry or import authorisation which are included in the list stipulated by Article 15 hereof and are financed from public funds or are intended for financing from public funds, shall be determined by the competent authority for medicinal products.

(2) On the basis of the application for the increase of the maximum allowed price referred to in the preceding paragraph, the opinion of the Committee for Medicinal Products and established public interest in the field of health and economic findings on the risk arising from the disrupted supply of medicinal products, the extraordinary maximum price of medicinal products may be determined by the competent authority for medicinal products.

(3) The criteria for the determination of the maximum allowed price and extraordinary maximum price of medicinal products, method and procedure and compulsory components of the application for the determination of the maximum allowed price of medicinal products and extraordinary maximum price of medicinal products, level of marketing at which the price is regulated, and period for which the maximum allowed price or extraordinary maximum price of medicinal products is determined, as well as method, criteria and procedure for amending the maximum allowed prices of medicinal products shall be determined by the Minister.

(4) The prices of veterinary medicinal products with marketing authorisation or entry or import authorisation, the level of which could impact animal health care or endanger the health of human beings, may in exceptional cases be formed or determined according at any level of marketing of the medicinal product according to the method that may be specified by the minister competent for veterinary medicine.

Article 97a

(1) Pursuant to the agreement between the Health Insurance Institute of Slovenia or legal entities and natural persons who perform health services financed by public funds, and marketing authorisation holders, holders of parallel import licence for medicinal products, holders of the entry or import authorisation, and wholesalers, prices of medicinal products may also be lower than their maximum allowed prices.

(2) The preceding paragraph shall not apply to medicinal products whose extraordinary maximum price has been determined.

Article 98

(application for the pricing or determination of the prices of medicinal products)

(1) The application for the determination of the maximum allowed price of the medicinal product referred to in the first paragraph of Article 97 hereof and application for the determination of the extraordinary maximum price referred to in the second paragraph of Article 97 hereof must be submitted to the competent authority for medicinal products by the marketing authorisation holders, holders of parallel import licence and entry and import authorisation holders.

(2) The completed application for the determination of the maximum allowed price of medicinal products should be resolved by the competent authority for medicinal products within 90 days of its receipt by issuing a decision.

(3) The completed application for the determination of the extraordinary maximum price of medicinal products should be resolved by the competent authority for medicinal products within 90 days of its receipt by issuing a decision. This period may be prolonged once by 60 days due to the excessive amount of applications for the determination of the extraordinary maximum price.

(4) In this decision, the competent authority for medicinal products should specifically substantiate the reasons which should be based on the criteria of the third paragraph of Article 97 hereof.

(5) If the decision is not issued within the period referred to in the second and third paragraphs of this Article, the application shall be considered granted and the applicant is allowed to market the medicinal product at the price submitted in the application.

(6) An appeal against the decision referred to in the second and third paragraphs of this Article may be submitted by the applicant within 30 days of the receipt of the decision. The appeal shall not prevent the execution of the decision. The decision on the appeal shall be reached by the Minister within 60 days of the receipt of the appeal. The applicant may bring an action against the decision of the Minister within 30 days of the receipt of the decision by means of administrative dispute at the Administrative Court of the Republic of Slovenia.

(7) If cases where the Government adopts a measure of price control by determining the fixed prices of all medicinal products or specific groups of medicinal products, the marketing authorisation holder may address to the ministry competent for price control an application, together with the reasoned explanation, for the assessment of the introduced price regulation measure. The ministry competent for price control shall be obliged to resolve the application within 90 days of receiving the completed application.

(8) Should the ministry competent for price control establish that the application for assessment of the introduced price control measure is not grounded, the marketing authorisation holder may submit an application to the Government .

Article 99
(obligation to use the applicable price)

(1) The participants in the marketing of the medicinal product shall use the valid price of the medicinal product.

(2) Pursuant to this Act, the valid price for the medicinal product for human use may be:

- the maximum allowed price of the medicinal product;
- the price of the medicinal product determined pursuant to the first paragraph of Article 97a of this Act not superseeding the highest allowed price of the medicinal product;
- the extraordinary maximum price.

(3) The records on the prices and time of their enforcement referred to in the second indent of the preceding paragraph shall be kept by the Institute of Health Insurance Institute of Slovenia.

Article 100
(obligation to report other data)

Legal entities and natural persons authorised to market medicinal products or holding an appropriate evidence, specified in the third paragraph of Article 74 hereof must submit to the competent authority for medicinal products all data on the prices of medicinal products in the manner stipulated hereby, while data on veterinary medicinal products must also be submitted to the competent authority for veterinary medicine.

XII. INSPECTIONINSPECTION

Article 101
(competences in inspectionprofessional inspection)

(1) Professional inspection in the field of medicinal products shall be carried out by the competent authority for medicinal products in the framework of pharmaceutical inspection. The tasks of pharmaceutical inspection shall be performed by the pharmaceutical .inspectors

(2) Official veterinarians shall inspect the implementation of the provisions of this Act and regulations issued on the basis of this Act relating to the use of medicinal products and the related traceability of veterinary medicinal products.

(3) Market inspectors shall tinspect the implementation of the provisions of this Act and regulations issued on the basis of this Act relating to the prices of medicinal products.

Article 102
(pharmaceutical inspectors)

(1) In order to be appointed a pharmaceutical inspector a person must satisfy the following criteria:
- hold a university degree in pharmacy or other natural sciences with additional skills in good practices;
- at least two years of adequate working experience in the field of medicinal products;
- have passed a professional examination for a pharmaceutical .inspector

(2) The inspectors shall be designated by the authority competent for medicinal products in accordance with the Civil Servants Act.

(3) When performing their tasks in accordance with their authorities, the inspectors shall be independent and shall perform such tasks in the scope and on the basis of the Constitution and the law and always obliged to use their professional skills, educate further and participate in training and examinations.

(4) The minister competent for health shall prescribe the contents and procedures of the expert examination for a pharmaceutical inspector as well as the contents and method of examining the skills and qualification of pharmaceutical inspectors

Article 103
(customs inspection)

The import of medicinal products shall be inspected by the customs authorities with expert support provided by the competent authority for medicinal products and the official veterinarians.

Article 104
(competences of pharmaceutical inspectors)

(1) Pursuant to this Act, the pharmaceutical inspectors shall have the following competences and tasks:
- conduct the violations procedure and impose sanctions for such violations;
- order a legal entity or natural person to bring their operations in line with the requirements previously set out in this Act and the regulations arising hereof within a

period of no more than six months since the receipt of the order calling for this measure;
- ban the manufacture, testing or marketing of medicinal products on the grounds of non-conformity with prescribed conditions;
- withhold marketing of a medicinal product or a particular batch which does not satisfy the prescribed conditions, is harmful if used in the prescribed way, has no therapeutic effect or its risk/benefit balance is not favourable if used in the prescribed way;
- order destruction of a deficient medicinal product;
- ban the entry or import of a medicinal product which has not been granted a marketing authorisation by the competent authority for medicinal products or has been transported against the manufacturer's instructions;
- order the removal or destruction of the material used for illegal advertising of medicinal products;
- prohibit the advertising of medicinal products that is not in compliance with the provisions of this Act;
- order other measures necessary for the implementation of this Act and the regulations arising hereto.

(2) The pharmaceutical inspector shall be independent in performing the inspection tasks, and conducting and deciding in administrative and violation procedures and shall identify in the performance of such tasks with the certificate issued by the director of the competent authority for medicinal products on the allocation to the post of pharmaceutical .inspector

(3) In the scope of the tasks of inspecting legal entities and natural persons, the pharmaceutical inspectors be entitled to do the following:
- inspect the premises, facilities, machinery, plants, means of work, fittings, objects, goods, substances, ledgers, contracts, documents, and operations and documentation of state bodies, companies, institutes, other organisations and communities, and private undertakings;
- view ledgers, contracts, documents, and operations and documentation when such are administered and stored on an electronic medium, and to request the production of hard copies that authenticate the electronic form;
- examine documents with which persons' identities may be established;
- obtain and use, free-of-charge, personal data and other data from official records and other databases relating to the subject that is required for conducting pharmaceutical ;inspection
- take samples of goods, materials and equipment free-of-charge and to conduct investigations on the samples taken;
- photograph persons, premises, facilities, machinery, fittings and other objects specified in the first indent or record them on any other medium for visual data;
- reproduce documents, audiovisual records and other documentation;
- seize objects, documents and samples for the perpetuation of evidence;
- perform other actions in accordance with the purpose of the pharmaceutical .inspection

(4) Pharmaceutical inspectors shall have the right to enter the premises, facilities, appliances and equipment specified in the previous Article, without prior notice and without the permission of the subject or the responsible officer thereof, unless stipulated otherwise by law.

(5) If, for no grounded reason, the person who is the subject of inspection refuses access to the premises or facilities in which the activity is performed, the pharmaceutical inspector shall be entitled to enter the premises in spite of refused access. The costs of entry and any damage unavoidably incurred in so doing shall be borne by the subject.

(6) An appeal against the measures stipulated under previous paragraphs, ordered by the pharmaceutical inspector shall not prevent their implementation.

(7) Should a pharmaceutical inspector establish any violations in the area of the use of veterinary medicinal products, the authority for veterinary medicine shall be informed thereof immediately.

(8) Should the pharmaceutical inspector encounter any physical resistance during the pharmaceutical ,inspection or if such resistance is expected, police assistance may be requested. The police shall provide assistance to pharmaceutical inspectors in accordance with the regulations on police.

Article 105
(competences of market inspectors)

(1) If the persons marketing medicinal products failed to comply with the applicable prices, the market inspector shall be entitled to issue a decision and demand the following:
- that they use the applicable price,
- that they refund the undue amounts resulting from the difference in the price, with accrued interest.

(2) If the persons marketing the medicinal product failed to comply with the price stipulated on the basis of the secondary legislation stipulated under Article 97 hereof and charged too high prices to the payers, such persons shall be obliged to refund such unduly charged amounts to the payers within 15 days of the issue of a final decision by the market inspection authority, together with the accrued interest, without a specific request.

(3) Interest stipulated hereunder shall equal the default interest in economic transactions based on the law of obligations.

(4) The market inspection authority shall inform the competent authority for medicinal products of its decision or, in the case of veterinary medicinal products, also the minister or competent authority for veterinary medicine.

Article 106
(competences of official veterinarians)

The official veterinarian shall, in addition to rights and tasks set out in other regulations on inspection, also have the following competence to:

1. conduct the violations procedure and impose sanctions for such violations;
2. impose on the legal entity or natural person that they harmonise their operations with the provisions of this Act and the regulations adopted on its basis.

Article 107
(obligation to supply the market in accordance with the decision issued by a market inspector)

(1) If the persons marketing the medicinal product fail to start or stop selling a medicinal product on the basis of secondary legislation stipulated by Article 97 hereof upon their own initiative and if such action could seriously jeopardise the supply of medicinal products to the population, the market inspector may issue a decision specified in the first paragraph of the previous Article imposing on them to immediately start or continue selling such medicinal product, applying the prices stipulated on the basis of the secondary legislation defined under Article 97 hereof.

(2) In such decision, the market inspector shall lay down a deadline by which the persons marketing medicinal products must meet the obligation stipulated under the previous paragraph; nevertheless, such obligation may not last more than three months after the issue of the final decision by the market inspection authority.

Article 108
(execution of decisions)

An appeal against the decision stipulated in Article 105 hereof shall not prevent its execution with the exception of refunding the unduly charged amounts in accordance with the second paragraph of the same Article.

XIII. PUBLIC AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

Article 109
(establishment of the Public Agency)

(1) For the performance of the tasks stipulated by this Act and the act regulating medical devices the Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (hereinafter: the Public Agency) shall be founded as a public law entity.

(2) The founder of the Public Agency shall be the Republic of Slovenia. The Government exercises the rights of founder.

(3) The Ministry of Health shall exercise supervision over the work of the Public Agency.

(4) The provisions of the act regulating public agencies shall apply to the Public Agency, unless otherwise provided by this Act.

(5) The Public Agency shall take over the tasks and competences of the Agency for medicinal products and medical devices of the Republic of Slovenia as a body within the Ministry of Health and the tasks of the official control laboratory stipulated under Article 91 hereof.

Article 110
(tasks of the Public Agency)

The Public Agency shall perform the following tasks:

- administrative, professional and development activities in the area of medicinal products and medical devices for human and veterinary use with the exception of defining doctrinal solutions in terms of safe use of medicinal products in veterinary medicine;
- inspection in the area of medicinal products and medical devices for human and veterinary use with the exception of inspection of the marketing of medicinal products used in veterinary medicine;
- the tasks of official control laboratory;
- execution and adoption of decisions in national and European harmonised administrative and professional procedures of assessing the quality, safety and efficiency of medicinal products and medical devices;
- the tasks of establishing, upgrading and modernising the regulatory information system and keeping official records on the basis of this Act;
- the tasks of pharmacovigilance and materiovigilance systems;
- the tasks of establishing an internationally recognised quality system in the framework of good regulatory practice;
- the tasks in the area of determining, monitoring and analysing the prices of medicinal products and their impact on the functioning of the market;
- expert support in the implementation of system orientations in the area of medicinal products and medical devices;
- tasks that involve co-operation with other management, expert and scientific institutions.

Article 111
(sources for the functioning of the Public Agency)

(1) The sources needed for the functioning of the Public Agency are:
- fees;
- income from the provision of official quality control services as stipulated under Article 93 hereof;
- income from the provision of other expert services; and
- funds from the budget of the Republic of Slovenia.

(2) The funds from the budget of the Republic of Slovenia shall only be granted for the provision of those services of the Public Agency, the financing of which is not covered by the funds obtained from other sources on the basis of the Action Plan of the Public Agency, approved by the Government.

Article 112
(bodies of the Public Agency)

(1) The bodies of the Public Agency shall be its Director and the Council of the Public Agency.

(2) The composition and the number of council members shall be determined by the founder in the Articles of Association.

(3) The Director and the council members may not be employed by, or perform any form of work in any organisation engaged in any form of for-profit activities in the area of medicinal products and medical devices, and may not hold any function whatsoever in such organisations.

(4) In addition to the reasons, stipulated by the act regulating public agencies, the Government shall dismiss the Director or a council member of the Public Agency also in the following cases:
- if the Director is declared unfit to conduct business or becomes incapable of performing the function for health reasons,
- if the grounds from the third paragraph of this Article arise,
- in the event of final judgement sentencing the Director to imprisonment for a criminal offence or for causing economic losses.

Article 113
(reporting on the work of the Public Agency)

(1) At least once a year and no later than by 30 June, for the previous year, the Public Agency shall submit to the Government a report on its work and the situation in the field of medicinal products and medical devices.

(2) The Public Agency shall make the report from the first paragraph hereunder available to the public. Before the publication, personal data and any data constituting a business secret shall be removed from the report.

Article 114
(administrative decisions of the Public Agency)

(1) Pursuant to this Act, the Public Agency shall adopt administrative decisions in the administrative procedure at the first instance.

(2) The Public Agency shall perform all the tasks of the competent authority for medicinal products, stipulated hereby and any secondary legislation adopted on its basis or other applicable laws or regulations.

(3) Appeals against the decisions adopted by the Public Agency shall be decided on by the ministry competent for health, with the exception of the decisions falling within the competence of the market inspector, as stipulated herein, which shall be decided on by the ministry competent for the market.

(4) The Public Agency shall be the authority responsible for violations in the area of medicinal products and medical devices.

(5) A violations procedure shall be conducted and decided upon by an authorised official of the Public Agency, who fulfils the conditions laid down in the act regulating violations, and regulations adopted on the basis thereof.

XIV. PUNITIVE PROVISIONS

Article 115
(sanctions for violations)

(1) A fine of between EUR 400 and 2,000 shall be imposed on a legal entity or a natural person for committing a violation, as specified in point 15 of Article 6 hereunder for:

1. an act contrary to the fourth or the fifth paragraphs of Article 82 hereof;
2. an act contrary to Article 100 hereof;
3. an act contrary to the second paragraph of Article 16, point (d) of the second paragraph of Article 23, the fifth paragraph of Article 24 or Article 26 of the Regulation 726/2004/EC.

(2) A fine of between EUR 40 and 200 shall be imposed on the responsible person of the legal entity or natural person specified in the previous paragraph for committing a violation, as specified in point 15 of Article 6 hereunder.

Article 116
(sanctions for violations)

(1) A fine of between EUR 4,000 and 100,000,000 shall be imposed on a legal entity or a natural person for committing a violation, as specified in point 15 of Article 6 hereunder for:
1. an act contrary to Article 8 hereof;
2. an act contrary to Article 44 hereof;
3. performing the wholesale of medicinal products contrary to Article 73 hereof;
4. for performing the retail of medicinal products contrary to Article 79 hereof;

(2) A fine of between EUR 200 and 2,000 shall be imposed on the responsible person of the legal entity or natural person specified in the previous paragraph for committing a violation, as specified in point 15 of Article 6 hereunder.

Article 117
(sanctions for violations)

(1) A fine of between EUR 8,000 and 120,000 shall be imposed on a legal entity or a natural person for committing a violation, as specified in point 15 of Article 6 hereunder for:
1. an act contrary to Articles 17 or 18 hereof;
2. an act contrary to Articles 11 or 12 hereof;
3. an act contrary to the second paragraph of Article 37 hereof;
4. an act contrary to the first paragraph of Article 46 hereof;
5. an act contrary to Article 50 hereof;
6. an act contrary to Article 54 hereof;
7. an act contrary to the second, third or fourth paragraph of Article 59 hereof;
8. an act contrary to Articles 66 or 67 hereof;
9. an act contrary to Article 72 hereof;
10. an act contrary to Article 74 hereof;
11. an act contrary to Article 76 hereof;
12. an act contrary to Articles 77 or 78 hereof;
13. an act contrary to Articles 79 or 81 hereof;
14. an act contrary to the first, second or third paragraphs of Article 83 hereof;
15. an act contrary to Articles 86, 87 or 88 hereof;
16. an act contrary to Article 99 hereof;
17. an act contrary to Article 13 hereof;
18. an act contrary to Article 14 hereof.

(2) A fine of between EUR 400 and 4,000 shall be imposed on the responsible person of the legal entity or natural person specified in the previous paragraph for committing a violation, as specified in point 15 of Article 6 hereunder.

Article 118
(sanctions for violations)

(1) The official control laboratory shall be punished by a fine of between EUR 4,000 and 40,000 for acting contrary to Article 93 of this Act.

(2) The person responsible for the Official Control Laboratory shall be punished by a fine of between EUR 200 and 2,000 for an offence from the preceding paragraph.

Article 119
(sanctions for violations)

A legal entity or a natural person specified in point 15 of Article 6 hereunder who has been fined for committing violations listed in Articles 115, 116, 117 and 118 and who failed to pay the fine after the issue of a final decision, shall not be issued or extended an authorisation under the administrative procedure or a certificate regulated by this Act.

XV. TRANSITORY AND FINAL PROVISIONS

Article 120
(deadline for the establishment of the Public Agency)

(1) The Government of the Republic of Slovenia shall establish the Public Agency for medicinal products and medical devices stated in the third paragraph of Article 2 of this Act not later than one year after the enforcement of this Act.

(2) Until the establishment of the Public Agency for medicinal products and medical devices, the tasks of the competent authority for medicinal products shall be performed by the authority within the ministry competent for health.

(3) Until the establishment of the Public Agency, the tasks of the official control laboratory shall be performed by the Institute of Pharmacy and Drug research – Ljubljana.

(4) The personnel, premises and equipment needed for commencing the operations of the Public Agency shall be provided by merging the resources of the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia

established within the Ministry of Health and the Institute of Pharmacy and Drug research –- Ljubljana. Funds required for the initiation of the operations of the Public Agency shall be granted from the budget of the Republic of Slovenia.

(5) The Public Agency shall take over all the employees who, at the day the Public Agency is founded, are employed by the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia established within the Ministry of Health and the Institute of Pharmacy and Drug research – Ljubljana, including the equipment and assets, unfinished business, archives and records.

(6) The pharmaceutical inspectors working in the framework of the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia established within the ministry competent for health shall, as of the day of the establishment of the Public Agency, start performing the tasks of pharmaceutical inspectors in accordance with this Act.

Article 121
(issue of implementing regulations)

(1) The deadline for the issue of implementing regulations hereunder shall be two years of the enforcement hereof, with the exception of regulations related to the implementation of the provisions stipulated by the Directive 2001/83/EC and the Directive 2001/82/EC which must be issued within one month of the enforcement hereof.

(2) Until the implementation of the implementing regulations issued on the basis of this Act, the following implementing regulations shall be used, issued on the basis of the Medicinal Products and Medicinal Devices Act (Official Gazette of the Republic of Slovenia, Nos. 101/99, 70/00, 7/02, 13/02 – ZKrmi, 67/02 and 47/04 – ZdZPZ), provided that they are not contrary to this Act or if not otherwise stipulated hereby:

- Rules on the Classification, Prescribing and Dispensing of Medicinal Products for Human Use (Official Gazette of the Republic of Slovenia, Nos. 59/03 and 114/03);
- Rules on the conditions to be met by investigators for carrying out studies of medicinal products and the procedure of their checking (Official Gazette of the Republic of Slovenia, No. 43/00);
- Rules on pharmacological and toxicological testing of medicinal products (Official Gazette of the Republic of Slovenia, No. 44/00);
- Rules on clinical testing of medicinal products (Official Gazette of the Republic of Slovenia, No. 67/00),
- Rules on procedures relevant to the marketing authorisation of medicinal products (Official Gazette of the RS, Nos. 60/04 and 77/04);
- Rules on the conditions and the procedure for obtaining a special authorisation for the import of medicinal products and devices (Official Gazette of the Republic of Slovenia, No. 72/00);

- Rules on analytical testing of medicinal products (Official Gazette of the Republic of Slovenia, No. 73/00),
- Rules concerning the requirements to be met by specialized shops for retail trade in medicinal products and on the procedure for ascertaining their compliance (Official Gazette of the Republic of Slovenia, Nos. 73/00 and 54/03);
- Rules on labelling of medicinal products and on patient information leaflet (Official Gazette of the Republic of Slovenia, No. 82/00);
- Rules on the detailed conditions to be met by the manufacturer of medicinal products for human use and on the procedure for the verification of the manufacturer (Official Gazette of the Republic of Slovenia, No. 51/04);
- Rules on pharmacovigilance (Official Gazette of the Republic of Slovenia, No. 94/00);
- Rules on the methodology of pricing and quality control of medicinal products (Official Gazette of the Republic of Slovenia, No. 113/00);
- Rules on immunological medicinal products (Official Gazette of the Republic of Slovenia, No. 2/01);
- Rules on therapeutic substances of human origin (Official Gazette of the Republic of Slovenia, No. 2/01);
- Rules on radiopharmacological products (Official Gazette of the Republic of Slovenia, No. 7/01);
- Rules on the criteria for the formation of wholesale prices of medicinal products and the method of advising wholesale prices of medicinal products (Official Gazette of the Republic of Slovenia, No. 69/05);
- Rules on the advertising of medicinal products and medical devices (Official Gazette of the Republic of Slovenia, No. 76/01);
- Rules on homeopathic products (Official Gazette of the Republic of Slovenia, No. 90/04);
- Rules on analytical testing of medicinal products for human use to perform state control of their quality (Official Gazette of the Republic of Slovenia, No. 74/04);
- Rules on detailed conditions of wholesale of medicinal products (Official Gazette of the Republic of Slovenia, No. 75/03);
- Rules classifying vitamin and mineral products for oral use that are in a pharmaceutical form as medicinal products (Official Gazette of the Republic of Slovenia, No. 83/03);
- Rules on costs (Official Gazette of the Republic of Slovenia, No. 74/05);
- Rules determining good manufacturing practice (Official Gazette of the Republic of Slovenia, No. 10/05);
- Rules on the principles of good laboratory practice (Official Gazette of the Republic of Slovenia, nos. 38/00 and 2/04);
- Rules on the assessment and procedures for compliance monitoring of the principles of good laboratory practice (Official Gazette of the Republic of Slovenia, No. 38/00);
- Rules on the classification of medical plants (Official Gazette of the Republic of Slovenia, No. 133/03);
- Rules on the specific part of the examination for pharmaceutical inspectors (Official Gazette of the Republic of Slovenia, No. 52/05);

- Order on the determination of medicinal products issued with or without prescription (Official Gazette of the Republic of Slovenia, No. 110/99);
- Order on permitted colouring agents (Official Gazette of the Republic of Slovenia, No. 72/00);
- Order appointing a legal person for pharmacovigilance and medical devices vigilance (Official Gazette of the Republic of Slovenia, No. 100/00);
- Order setting out a uniform national nomenclature of therapeutic agents and the system classifying medicinal drugs according to their anatomic-therapeutic-chemical classification (Official Gazette of the Republic of Slovenia, No. 72/00);
- Decision on the publication of the third supplement edition of the Anatomic-Therapeutic-Chemical Classification (ATC) of Medicinal Products 2003 (Official Gazette of the Republic of Slovenia, No. 114/03);
- List of indispensable medicinal products for human use (Official Gazette of the RS, nos. 16/04, 38/05 and 81/05);
- Rules determining national formulary addition to the European Pharmacopoeia (Official Gazette of the Republic of Slovenia, No. 86/05);
- Rules on the parallel import and parallel distribution of medicinal products (Official Gazette of the Republic of Slovenia, No. 73/05);
- Decision on the implementation of the European Pharmacopoeia 5th edition (Official Gazette of the Republic of Slovenia, No. 130/04);
- Decision on the implementation of the first, second and third supplement to the European Pharmacopoeia Fifth Edition (Official Gazette of the Republic of Slovenia, No. 31/05);
- Decision designating the official control laboratory for analytical testing of medicinal products for human use (Official Gazette of the Republic of Slovenia No. 51/04);
- Decision specifying the list of inter-exchangeable medicinal products (Official Gazette of the Republic of Slovenia, nos. 6/05 and 17/05);
- Rules on the authorisation for trade in veterinary medicinal products (Official Gazette of the Republic of Slovenia nos. 3/02 and 16/04);
- Rules on the conditions for the wholesale trade in the veterinary medicinal products (Official Gazette of the Republic of Slovenia nos. 75/00 and 1/04);
- Rules on the identification and use instructions of veterinary medicinal products (Official Gazette of the Republic of Slovenia nos. 86/00, 104/00, 86/01 and 4/02);
- Rules on the pharmacovigilance of veterinary medicinal products (Official Gazette of the Republic of Slovenia, No. 70/03);
- Rules on the retailers specialised in veterinary medicinal products (Official Gazette of the Republic of Slovenia No. 55/03);
- Rules determining good manufacturing practice for veterinary medicinal products (Official Gazette of the Republic of Slovenia, No. 75/05);
- Rules on the detailed conditions to be met by the manufacturer of medicinal products for veterinary use and on the procedure for the verification of the manufacturer (Official Gazette of the Republic of Slovenia, No. 28/04);
- Rules on electro-medicinal equipment for use in veterinary medicine (Official Gazette of the Republic of Slovenia, No. 28/04);
- Rules on conditions to be met by experts issuing expert opinions on veterinary medicinal products (Official Gazette of the Republic of Slovenia, No. 28/04);

- Rules on the nature, extent and method of the analytical, pharmacotoxicological and clinical testing of veterinary medicinal products (Official Gazette of the Republic of Slovenia, No. 28/04);
- Rules on the level of expenses for testing of medicinal products, granting of authorisation for the trade in veterinary medicinal products, and for professional inspectionprofessional inspection (Official Gazette of the Republic of Slovenia No. 28/04);
- Rules on the pharmacovigilance of veterinary medicinal products (Official Gazette of the Republic of Slovenia, No. 67/01);
- Rules on the committee for medicinal products to be used in veterinary medicine (Official Gazette of the Republic of Slovenia, No. 69/2000);
- Rules on the conditions to be met by analysts in analytical testing of veterinary medicinal products and procedure for the verification of these conditions (Official Gazette of the Republic of Slovenia, nos. 1/01 and 13/01);
- Rules on the classification, prescription and administering of veterinary medicinal products (Official Gazette of the Republic of Slovenia, No. 86/00);
- Rules on the exceptional use of medicinal products for the treatment of animals and on animal treatment records (Official Gazette of the Republic of Slovenia, No. 77/00);
- Rules banning the use of certain substances having a hormonal or thyrostatic action and beta-agonists in stock farming (Official Gazette of the Republic of Slovenia, No. 16/04).

(3) With the enforcement of this Act, the Resolution on Determining Good Practices (Official Gazette of the Republic of Slovenia No. 41/97) shall cease to be valid.

Article 122
(procedures following the enforcement of this Act)

(1) All ongoing procedures until the implementation of this Act, or, in relation to which a claim or a legal remedy has been filed at the time of the entry into effect of this Act, shall be terminated according to the provisions of the Medicinal Products and Medicinal Devices Act (Official Gazette of the Republic of Slovenia, Nos. 101/99, 70/00, 7/02, 13/02 – ZKrmi, 67/02 and 47/04 – ZdZPZ), and the implementing regulations issued on the basis of this Act, unless the provisions of this Act are more favourable for the client.

(2) Notwithstanding the provisions of the previous paragraph, the competent authority for medicinal products may request from the applicant who filed the application prior to the enforcement of this Act and until the end of the procedure to submit additional or different documentation or comply with additional evidence in accordance herewith, should this be necessary for the protection of public health.

(3) The provisions on the periods of protection provided for in the first and the second paragraphs of Article 25 hereof shall not apply to reference medicinal products

for which an application for authorisation has been submitted before the enforcement hereof.

(4) The provision of the fourth paragraph of Article 72 hereof shall apply for those medicinal products which obtained the marketing authorisation prior to the enforcement hereof no later than within five years after the enforcement hereof.

Article 123
(updating of documentation)

By no later than 31 December 2007, marketing authorisation holders who obtained such authorisations before the enforcement of the Medicinal Products and Medicinal Devices Act (Official Gazette of the Republic of Slovenia, Nos. 101/99, 70/00, 7/02, 13/02 – ZKrmi, 67/02 and 47/04 – ZdZPZ), and the regulations issued on the basis of this Act must submit the data and documentation referred to in Articles 23 and 25 hereof, if such data and documentation have not yet been submitted in the previous procedures related to the marketing authorisation.

Article 124
(repealed provisions)

(1) On the day this Act enters into force, the Medicinal Products and Medicinal Devices Act (Official Gazette of the Republic of Slovenia, Nos. 101/99, 70/00, 7/02, 13/02 – ZKrmi, 67/02 and 47/04 – ZdZPZ), shall cease to be valid in the parts relating to medicinal products, namely:

- in full: Article 3, Articles 5 through and including 82, Articles 113, 119 and 124,
- the parts relating to the prices of medicinal products and dietetic products used for the treatment of metabolic disorders: Article 126,
- the part relating to medicinal products: Articles 1, 2, 4, 114, 117 and 118.

(2) On the day this Act enters into force, the title of the Medicinal Products and Medicinal Devices Act (Official Gazette of the Republic of Slovenia, Nos. 101/99, 70/00, 7/02, 13/02 – ZKrmi, 67/02 and 47/04 – ZdZPZ), shall be changed to “Medicinal Products” and “Medicinal Devices” will be stricken out.

(3) The marketing authorisations for wholesaling medicinal products, relating to the imports of medicinal products, shall cease to be valid as of the day of enforcement of this Act.

Article 125
(entry into force of the Act)

This Act shall enter into force on the fifteenth day of its publication in the Official Gazette of the Republic of Slovenia.

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Transitional and final provisions of the Act Amending the Medicinal Products and Medical Devices Act (Official Gazette of the Republic of Slovenia, No. 45/2008 of 9 May 2008 – ZZdr-1A).

TRANSITORY AND FINAL PROVISIONS

Article 14

(1) Until the new prices of medicinal products that are determined pursuant to this Act are determined, the prices of medicinal products valid on the day of the enforcement of this Act shall apply.

(2) The Minister shall issue regulations referred to in the third paragraph of Article 73 and the third article of Article 97 of this Act within two months of the enforcement of this Act.

Article 15

This Act shall enter into force on the fifteenth day of its publication in the Official Gazette of the Republic of Slovenia.

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