539. MEDICINAL PRODUCTS ACT (ZZdr-2)

Pursuant to indent two of Paragraph 1 of Article 107 and Paragraph 1 of Article 91 of the Constitution of the Republic of Slovenia I hereby issue the following

O R D E R

on the promulgation of the Medicinal Products Act (ZZdr-2)

I hereby promulgate the Medicinal Products Act (ZZdr-2) adopted by the National Assembly of the Republic of Slovenia at its session of 24 February 2014.

Št. 003-02-2/2014-3 Ljubljana,
on this day of 4 March 2014

Borut Pahor l.r. President of the Republic of Slovenia

MEDICINAL PRODUCTS ACT (ZZdr-2)

I. GENERAL PROVISIONS

Article 1

(Scope of application and competences)

(1) (1) This Act defines the area of medicinal products for use in human and veterinary medicine, stipulates the conditions and measures for assuring their quality, safety and efficacy, the conditions and procedures for their testing, manufacture, the preparation of advanced therapy medicinal products prepared on a non-routine basis, sales and consumption, prices, official control and supervision over the implementation of this Act with the aim of protecting public health for medicinal products that are industrially manufactured or manufactured in a manner that includes and industrial procedure, including pre-mixes for the preparation of medicated feedingstuffs, active substances used as starting materials and for certain substances that can be used as veterinary medicinal products that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties, as well as the tasks and competencies of the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (hereinafter: the Agency).

(2) Unless specified otherwise herein, this Act shall also apply to homeopathic medicinal products.

Article 2

(Transposition and implementation of the EU regulations)

(1) The purpose of this Act is to transpose into the legislation of the Republic of Slovenia the contents of the following directives:

- - Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (Official Journal L 40, 11. 2. 1989, p. 8, hereinafter: Directive 89/105/EEC);

- - Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (Official Journal L 228/70, 18.8.1991 p. 70; hereinafter: Directive 91/412/EEC);

- 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 of medicinal products for human use (Official Journal L 121, 1. 5. 2001, p. 34), last amended by Council Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny – Adaptation to the regulatory procedure with scrutiny - Part Four (Official Journal L 188, 18 July 2009, p. 7; hereinafter: the Regulation (EC) No 596/2009), (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), last amended by Council Regulation (EC) No 569/2009 (hereinafter: Directive 2001/82/EC), except for the part related to the use of medicinal products and the related traceability of medicinal products, which is regulated by the act regulating veterinary conformity criteria;

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code related to medicinal products for human use (OJ L 311, 28. 11. 2001, p. 67), last amended by 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1), (hereinafter: Directive 2001/83/EC);

- Directive 2003/94/EC of the European Parliament and of the Council 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; 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, 9.4.2005, p. 13; hereinafter: Directive 2005/28/EC).

(2) This Act regulates the implementation of the following regulations:

- - No 726/2004/EC of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30. 4. 2004, p. 1), last amended by Regulation No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending the Regulation No 726/2004/EC regarding pharmacovigilance (Official Journal L 316 of 14.11.2012, p. 38), (hereinafter: Regulation 726/2004/EC);

- - Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Official Journal L 324, 10. 12. 2007, p. 121), last amended by Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (Official Journal L No 348, 31. 12. 2010, p. 1), (hereinafter: Regulation 1394/2007/EC);

- - Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (Official Journal L 334, 12. 12. 2008, p. 7), last amended by the Commission Regulation (EU) No 712/2012 of 3 August 2012 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (Official Journal L 209, 4. 8. 2012, p. 4); (hereinafter: Regulation 1234/2008/EC);

- Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (Official Journal L 152, 16. 6. 2009, p. 11; hereinafter: Regulation 470/2009/EC).

Article 3

(Authority)

(1) The competent minister for medicinal products regulated by this Act shall be the minister competent for health (hereinafter: the minister), unless otherwise stipulated herein.

(2) The implementing regulations for the area of veterinary medicinal products shall be issued by the minister in agreement with the minister competent for veterinary medicine (hereinafter: the minister competent for veterinary medicine).

(3) The authority competent for medicinal products covered by this Act shall be the Agency.

(4) The Agency shall decide on administrative matters in accordance with the act governing the general administrative procedure, unless otherwise determined by this Act.

(5) Unless otherwise determined by this Act, the Agency shall in administrative matters, within five working days of receiving an incomplete application request its supplementation and set a deadline in which the applicant must supplement such application.

(6) In matters where the Agency decides pursuant hereto, it may by means of a decision request applicants to submit additional documentation or data within a set deadline. With finality of such a decision, the deadline for deciding as set out herein is suspended and begins again once the deadline for submission of documentation or data expires or data is submitted, whichever is first.

Article 4

(Strategic council for medicinal products, committees and external experts of the Agency)

(1) Strategic Council for Medicinal Products is a consulting body of the minister dealing with strategic issues in the area of medicinal products. The minister shall appoint the members to the Strategic council for medicinal products as well as determine its tasks and work method.

(2) The Agency may include in resolution of the issues that fall within its competence external experts, if while carrying out the tasks it assesses that expert knowledge which it does not possess is required to resolve issues. External experts shall be the persons or organisations possessing expert knowledge required for clarifying the state of affairs. If an organisation is appointed an external expert, one or more authorised persons shall act on its behalf in the procedure.

(3) External experts may be included in expert committees, expert working bodies and other expert groups of the European Medicines Agency and the European Commission as well as in the activities of other authorities and institutions and other international connections dealing with expert contents in the areas covered by this Act.

(4) The minister shall draw up the list of external experts referred to in the second and third paragraph hereunder and include in it the experts in the field of pharmacy, medicine, veterinary medicine and other related fields. A list of experts for the field of veterinary medicine shall be drawn up by the Minister in coordination with the minister competent for veterinary medicine. Exceptionally and provided the minister gives consent, the Agency may use an external expert who is not included in the current list of external experts, to ensure uninterrupted work process.

(5) The minister shall appoint commissions, committees and groups into which the Agency shall include the representatives and external experts referred to in the previous paragraph for solving the issues that fall within the competence of the Agency. The commissions, committees and groups shall prepare opinions and proposals in the following areas:

- procedures for obtaining a marketing authorisation for a medicinal product;
- procedures for obtaining an authorisation for a clinical trial;
- drafting the proposed list of essential medicinal products and indispensable medicinal products;
- determining exceptionally allowed higher prices of medicinal products for human use;

pharmacopeias.

(6) The criteria for determining professional qualifications and conflict of interest of candidates for external experts, the work method of individual external experts and of the committees and commissions referred to in the previous paragraph hereunder shall be determined by the Agency based on previous approval of the minister.

(7) External experts may not be biased in their work and must respect data confidentiality. They shall not have conflicts of interest that may enable them to gain unjustified benefits or prioritise individual parties in procedures.

(8) The Agency shall appoint an expert commission for determining the fulfilment of conditions of manufacturing and marketing of medicinal products and active substances and preparation of advanced therapy medicinal products prepared on a non-routine basis.

(9) The minister competent for veterinary medicine shall appoint commissions for doctrinary solutions for medicinal products for veterinary medicine.

Article 5

(Definition of

medicinal product)

(1) Medicinal product shall mean any substance or combination of substances presented for treating or preventing disease in human beings or animals.

(2) Any substance or a combination of substances which may be used on or administered to human beings or animals with a view to restoring, improving or modifying their physiological functions by pharmacological, immunological or metabolic means, or making a medical diagnosis, shall likewise be considered a medicinal product.

(3) Substances referred to in the first and second paragraph of this Article may be:

- - of human origin,
- - of animal origin,
- - of plant origin,
- - of microbial origin,
- - of chemical origin,
- chemical products obtained by chemical change or synthesis; or
- developed by means of by biotechnological procedures.

Article 6

(Definition of

terms)

The expressions used herein shall have the following meaning:

1. Quality analysis of a medicinal product shall mean a qualitative analysis of all constituents, a quantitative analysis of at least all active substances and all other tests, requisite for assessing the quality of medicinal products in compliance with the marketing authorisation requirements or testing methods consistent with Article 28 hereof or developed and validated for the purpose of assessing quality of medicinal products.

2. Biological medicinal product shall mean a medicinal product that contains biological substances or substances obtained through a process including biological systems. A biological substance is a substance obtained from, or through the use of, a biological source, the quality of which is determined by means of a combination of physico-chemical and biological testing, together with the manufacturing process and supervision. These are for example medicinal products made by means of a biological or biotechnical process, including cell cultures and similar.

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

4. Placing medicinal product on the market shall mean to supply the market in medicinal products or make the medicinal product available in the Republic of Slovenia in return for payment or free of charge.

5. Decentralised procedure shall mean the procedure for obtaining a marketing authorisation for the medicinal product initiated simultaneously in the reference Member State and the

EU Member States concerned. It is mandatory for those medicinal products not subjected to centralised procedure which have not yet obtained the marketing authorisation for the medicinal product in the European Union and which will be marketed in more than one EU Member State, as required by Directive 2001/83/EC and Directive 2001/82/EC.

6. Good distribution practice shall mean a qualitative system governing the organisation, implementation and control of product storage in accordance with a defined regime prior to their further use or putting into circulation and transportation of medicinal products from the manufacturer to the end user (hereinafter: the user) according to the principles and guidelines for medicinal products or active substances adopted and published by the European Commission.

7. Good pharmacovigilance practice shall mean the guidelines on the implementation of pharmacovigilance activities according to Article 108a of Directive 2001/83/EC.

8. Good clinical practice in clinical trials in human medicine shall mean an international ethical and scientific system of quality control, planning, implementation, recording, controlling 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 Medical Association on biomedical testing on human subjects (1964), to this Act and any regulations adopted on the basis hereof, and to the regulations adopted by the European Union.

9. Good clinical practice in clinical trials in veterinary medicine shall mean an international ethical and scientific system of quality control, planning, implementation, recording, controlling and reporting on clinical trials on target animals providing for the credibility of data acquired through trials and the safety of animals pursuant to this Act, any regulations adopted on the basis hereof and the regulations on animal protection.

10. Good control laboratory practice shall mean a qualitative system of the analytical testing of a medicinal product, which can also be part of good manufacturing practice used for controlling the quality of products.

11. Good laboratory practice shall mean a qualitative system governing organisational processes and conditions of planning, implementing, controlling, recording and archiving non-clinical medical and environmental studies and reporting thereon according to the principles and guidelines adopted and published by the European Commission.

12. Good manufacturing practice shall mean a qualitative system providing for the consistent manufacture and control of medicinal products and active substances according to quality standards relevant for their intended use in line with the principles and guidelines adopted and published by the European Commission.

13. Supposed adverse reaction to a medicinal product is a suspected adverse reaction, where the causal relationship between the medicinal product and the adverse event is at least reasonably possible.

14. European Pharmacopoeia shall mean the pharmacopoeia as defined by the Council of Europe Convention on the elaboration of a European Pharmacopoeia (1964), published at the website http://www.edqm.eu and published by the European Directorate for the Quality of Medicines (EDQM).

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

16. Pharmacopoeia shall mean a collection of monographs and other provisions for regulating the development, preparation or manufacture of medicinal products, their identification, establishing their purity and testing the other quality parameters and other characteristics of the medicinal product and other substances used for manufacturing them, as well as other data on medicinal products.

17. Pharmacovigilance shall mean a system of identifying, evaluating, understanding and preventing the adverse reactions to medicinal products and other findings about the safety of a medicinal product and measures taken with the aim of managing and reducing the risks arising from medicinal products.

18. Galenic medicinal product for human use shall mean a medicinal product prepared for stock in a pharmacy or its galenic laboratory from active substances and/or excipients according to applicable pharmacopoeia and the formulas from applicable pharmacopoeia or according to the formulas (for the purpose of hospital activity) that are at the common proposal of a wider expert collegium competent for the field of treatment and expanded expert committee for the pharmacy industry approved by the Agency and which is intended to be dispensed to end users of the services of the pharmacy in question according to the regulations governing the pharmacy activity.

19. galenic medicinal product for use in veterinary medicine shall mean a medicinal product prepared for stock in a pharmacy or its galenic laboratory from active substances and/or excipients according to applicable pharmacopoeia and the formulas from applicable pharmacopoeia.

A galenic product can also be prepared according to the formulas that are at the proposal of the expert body representing veterinary activity and wider expert collegium for pharmacy, approved by the Agency and the authority competent for veterinary medicine, and which is intended to be dispensed to end users of the services of the pharmacy in question according to the regulations governing the pharmacy activity.

20. Generic medicinal product shall mean a medicinal product with the same qualitative and quantitative composition, active substance(s) and pharmaceutical form as the reference medicinal product whose bioequivalence with the reference medicinal product has been proved by suitable bioavailability studies. Various salts, esters, ethers, isomers, mixed isomers, complexes or active substance derivatives shall be treated as equal active substance unless they differ considerably in terms of safety or efficacy or both.

21. Pharmacovigilance system master file shall mean a detailed description of the pharmacovigilance system used by marketing authorisation holders for one or more medicinal products that have been granted a marketing authorisation.

22. Homeopathic medicinal product shall mean a medicinal product prepared from substances called homeopathic stock by a homeopathic method described in the European Pharmacopoeia or the existing Pharmacopoeias of the EU Member States, if the European Pharmacopoeia does not contain such provisions. A homeopathic medicinal product may also contain a number of essential constituents.

23. The name given to a medicinal product may be either an invented name which shall not be liable to confusion with the common name or scientific name, together with a trade mark or the name of the marketing authorisation holder.

24. Immunological medicinal products consist of vaccines, toxins and serums used to:

- - produce active immunity;
- - produce passive immunity or
- - diagnose the state of immunity; and
- allergens intended to identify or induce a specific acquired alteration in the immunological response to an allergising agent.

25. Intermediate is an intermediate product of a multi-level synthesis of the active substance that is usually subjected to further molecular changes or refinement and can be isolated or not before it becomes an active substance. This definition refers to the substances manufactured following the level of synthesis which is defined by the manufacturer as the beginning of the synthesis of the active substance.

26. The issue of a medicinal product in retail sales shall mean the retail sales and delivery of a medicinal product in retail sales, delivery of a medicinal product in part or completely to the debit against public funds or delivery of a medicinal product which has been donated or provided from budgetary funds to the end user, accompanied with adequate independent expert support and consultancy.

27. Off-label use shall mean 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.

28. Exit of a medicinal product shall mean the wholesale from the Republic of Slovenia into other EU Member States. Exit of a medicinal product shall also mean the transfer of a medicinal

product from the territory of the Republic of Slovenia to the territory of other Member States of the European whenever the medicinal product is brought in by an individual for personal use or the needs of his/her household or an authorisation for personal use of a maximum of one individual who is not a member of the family, or his/her respective animal.

29. Exports of a medicinal product shall mean the wholesale from the Republic of Slovenia into third countries. Export of a medicinal product shall also mean the transfer of a medicinal product from the territory of the Republic of Slovenia to third countries whenever the medicinal product is brought in by an individual for personal use or the needs of his/her household or an authorisation for personal use of a maximum of one individual who is not a member of the family, or his/her respective animal.

30. Providers of healthcare activity shall mean public health institutes and other natural and legal persons that provide healthcare activity in accordance with the healthcare regulations, with the exception of pharmacy services.

31. Providers of veterinary activity shall mean veterinary organisations and other organisations performing veterinary activity pursuant to the veterinary regulations.

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

33. Withdrawal period shall mean 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 issued on the basis 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 (EC) No 470/2009 and Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (Official Journal L 15, 20. 1. 2010, p. 1), last amended by the Commission Implementing Regulation (EU) No 489/2013 of 27 May 2013 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance: double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of the Israel Acute Paralysis Virus (Official Journal L 141, 28. 5. 2013, p. 4), (hereinafter: Regulation 37/2010/EU).

34. End user of a medicinal product for human use shall mean an individual who was prescribed or issued the medicinal product (hereinafter: the patient) or a provider of healthcare activity using the medicinal product in performance of healthcare services.

35. End user of a medicinal product in veterinary medicine shall mean the owner or the keeper of the animal that was prescribed or issued the medicinal product or a business entity using the medicinal product in performance of veterinary activity.

36. Magistral formula for human use shall mean a medicinal product prepared in a pharmacy on prescription for an individual patient or a group of patients and issued directly after preparation when there is no industrially or galenically produced medicinal product available on the market to achieve the therapeutic effect with the same composition of active substances and excipients in adequate strength or pharmaceutical form.

37. Magistral formula for use in veterinary medicine shall mean a medicinal product prepared in a pharmacy on veterinary prescription for a specific animal or a small group of animals and issued directly after preparation.

38. Interruption in the supply of medicinal product is a market situation in which the business entities in charge of supplying the market of the Republic of Slovenia fail to provide sufficient quantities of a medicinal product in adequate time.

39. National centre for pharmacovigilance shall mean a legal person performing the tasks specified herein in the field of pharmacovigilance of medicinal products for human use and meets the conditions as regards staff, premises and equipment specified by the minister for the respective activity.

40. National identifier of a medicinal product placing the medicinal product on the market in the Republic of Slovenia is a label assigned to a medicinal product by the Agency that represents a unique identification of a medicinal product in terms of active substance, pharmaceutical form, strength, packaging and authorisation holder.

41. National procedure for obtaining a marketing authorisation for a medicinal product in the Republic of Slovenia shall mean 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 for the sales in the Republic of Slovenia.

42. Risk management plan in the field of pharmacovigilance shall mean a detailed description of the risk management system.

43. Maximum residue limit shall mean the maximum residue limit of medicinal products for use in veterinary medicine as stipulated by Regulation No 470/2009/EC.

44. Error in use of a medicinal product shall mean any unintentional incorrect prescription, issue or use of a medicinal product by a healthcare professional, patient or end user.

45. Package insert shall mean the information for the end user attached in written form to the medicinal product, as a rule in the form of an insert.

46. Non-interventional clinical trial shall mean a clinical trial of a medicinal product where the selection of patients, method of treatment, selection of a medicinal product, prescribing of a medicinal product, determining of tests and monitoring of a patient is consistent with the standard therapy that complies with the approved or prescribed dosage, form of administration or indication area.

47. Unauthorised use of a medicinal product shall mean any intentional inadequate use of the medicinal product for a medical purpose that is contrary to the marketing authorisation for the specific medicinal product.

48. Incorrect use of a medicinal product shall mean any intentional inadequate use of the medicinal product that is contrary to the marketing authorisation for the specific medicinal product.

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

50. Advanced therapy medicinal products prepared on a non-routine basis shall mean any advanced therapy medicinal product which is prepared on a non-routine basis in the Republic of Slovenia according to the quality standards specified herein and used within the Republic of Slovenia by a provider of healthcare or veterinary activity who is:

- - performing healthcare activity, subject to exclusive professional liability of the doctor in accordance with each individual order for each advanced therapy medicinal product prepared on a non-routine basis for a specific patient; or

- - performing veterinary activity, subject to exclusive professional liability of the veterinarian in accordance with each individual order for an animal or a group of animals from the same estate.

51. Adverse reaction to a medicinal product for human use shall mean a patient's reaction which is noxious and unintended.

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

53. Adverse reaction to a medicinal product in clinical trials shall mean any noxious or unexpected response to an investigational medicinal product related to any dose administered.

54. Public service obligation shall mean the obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements in the Republic of Slovenia and in its entire territory and to deliver the supplies requested in the Republic of Slovenia within a reasonably short time which is determined by the healthcare provider based on provable medical need or medical documentation.

55. Recall of a batch of a medicinal product shall mean any activity related to withdrawing a batch of a medicinal product from

the market or use due to inadequate quality of a batch of a medicinal product or a pharmacovigilance system measure.

56. Labelling of a medicinal product shall mean information on the immediate or outer packaging.

57. Parallel distribution shall mean the entry of a medicinal product for which 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 in accordance with regulations by a wholesaler who is not in a business relationship for the marketing of such medicinal product with the holder of marketing authorisation, in accordance with the applicable regulations.

58. Similar biological medicinal product is a medicinal product that is similar to the biological reference medicinal product and is authorised for marketing. The active ingredient of a similar biological medicinal product is similar to the active ingredient of the biological reference medicinal product. Similarity to the reference medicinal product must be evidenced in the sense of quality, bioactivity, safety and efficiency on the basis of comparative studies. Dosing and method of administration must be equal to those of the reference biological medicinal product. Any deviation in the design of the medicinal product or its excipients must be appropriately based on and supported by additional research.

59. Parallel import shall mean the entry of a medicinal product for which marketing authorisation was obtained in the exporting country that is similar enough 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 into the Republic of Slovenia on the basis of the marketing authorisation for parallel imported medicinal product issued by the Agency, if parallel import is performed by a wholesaler who is not in a business relationship for the marketing of such medicinal product with the holder of marketing authorisation.

60. Occupational exposure to a medicinal product shall mean exposure to a medicinal product at the place of work.

61. A semi-product is a product that went through all phases of manufacturing except for the insertion into the outer packaging.

62. Falsified medicinal product shall mean any medicinal product with a false representation of:

- - its identity, including the packaging and labelling, its name or composition as regards any of its constituents including excipients and the strength thereof;

- - its source, including its manufacturer, country of manufacturing, its country of origin or its marketing authorisation holder; or

- - its history, including the records and documents relating to the distribution channels used.

This definition shall not apply to unintended quality defects and shall not infringe intellectual property rights.

63. Excipient shall mean any constituent of a medicinal product other than the active substance and the packaging material.

64. An individual (hereinafter: Individual) shall mean an identified or identifiable natural person who may be identified directly or indirectly.

65. A manufacturing site shall mean a restricted area that in relation to the surroundings represents an integral unit within which the manufacturing authorisation holder performs the activity of medicinal product manufacturing.

66. Individual manufacturing activities shall mean the activities of medicinal product manufacturing defined as manufacturing of semi-products, manufacturing of final forms in the narrow sense, primary packaging, secondary packaging, release of final medicinal product batches, quality control and import of medicinal products. Based on the intended purpose of a medicinal product they are divided into manufacturing of medicinal products for human use and veterinary medicinal products and based on the development level they are divided into the activities of medicinal product manufacturing and the activities of medicinal product manufacturing in clinical trial. The activities of manufacturing final forms in the narrow sense are divided according to pharmaceutical forms. The activities of quality control are divided on the basis of the type of trials performed in respect of the manufacturing of medicinal products for human and veterinary use and based on the development level they are divided into the activities of medicinal product manufacturing and the activities of medicinal product manufacturing in clinical trial. The activities of manufacturing final forms in the narrow sense are divided according to pharmaceutical forms. Quality control activities are divided according to the type of tests conducted.

67. Business entities shall mean domestic and foreign legal persons, individual sole proprietors, individual independently engaging in an activity and other natural persons engaging in a registered activity or performing such activity on the basis of a regulation or articles of association.

68. Brokering of medicinal products or active substances or both shall mean the activities in relation to the sale or purchase of medicinal products or active substances or both, except for wholesale distribution, that do not include physical handling of medicinal product or active substance and that consist of negotiating independently and on behalf of another business entity.

69. Mutual recognition procedure shall mean the procedure for obtaining marketing authorisation for 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 centralised or decentralised procedure for the issue of marketing authorisation which will be marketed in more than one EU Member State, as set out by Directive 2001/83/EC and Directive 2001/82/EC.

70. Pre-mixes for medicated feedingstuffs shall mean any medicinal product prepared in advance for use in veterinary medicine, intended for the subsequent manufacture of medicated feedingstuffs.

71. The advantage of supply with industrially made medicinal products from Slovenian plasma (i.e. fresh frozen plasma for processing, collected in the Republic of Slovenia) is the principle based on which the supply of medicinal products from the European Union made from foreign plasma is provided on the basis of marketing authorisation, if medicinal products made from Slovenian plasma are not sufficient to cover the needs for such products in the Republic of Slovenia, except in cases the import or entry of a specific medicinal product made from foreign plasma is adequately justified or if there is a strategic reason decided upon by the Strategic Council for Medicinal Products and the Expert Council for Supply of Blood and Plasma-Derived Medicinal Products.

72. Overdosing shall mean the use of such a quantity of medicinal product in a single dose or cumulatively which exceed the maximum allowed dose pursuant to the marketing authorisation and taking into account the clinical trials.

73. Placing a medicinal product on the market shall mean the first performed activity of marketing a medicinal product that enables supplying the market with such medicinal product and makes the medicinal product available to the end user.

74. Wholesale distribution of active substances and excipients shall mean the activity of purchasing, storing, selling, entering, importing, exiting or exporting of active substances.

75. Wholesale distribution of medicinal products shall mean the activity of purchasing, storing, selling, entering, exiting or exporting of medicinal products, except for the issuing of medicinal products in retail trade to end users.

76. Retail trade in medicinal products shall mean purchasing, storing and issuing of medicinal products or the use of such product while providing healthcare or veterinary services.

77. Radiopharmaceuticals shall mean radiopharmaceuticals, radionuclide precursors, radionuclide generators and radionuclide kits, namely:

- - radiopharmaceutical shall mean a medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) intended for human and veterinary use;

- - radionuclide generator shall mean any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other method and used as a radiopharmaceutical or a radionuclide precursor;

- - radionuclide precursor shall mean any radionuclide used in the process of producing a radiopharmaceutical for the labelling of another substance prior to administration to a patient;

- - radionuclide kit shall mean any preparation to be reconstituted or combined with radionuclides (radionuclide precursors) in the final radiopharmaceutical, usually prior to its administration.

78. Risk-benefit balance shall mean an assessment of the positive effects of therapy with a medicinal product in comparison with the risks, as stipulated herein.

79. Reference Member State shall mean the Member State which compiles, in the mutual recognition procedure or the decentralised procedure, the report on the assessment 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 Directives 2001/83/EC and 2001/82/EC.

80. Reference medicinal product shall mean a medicinal product for which marketing authorisation has been issued on the basis of Article 44 hereof and to whose documentation other applicants refer taking into account the provisions of Article 59 of this Act.

81. Serious adverse reaction to a medicinal product for use in human medicine shall mean 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 a congenital anomaly or a birth defect.

82. Serious adverse reaction to a medicinal product for use in veterinary medicine shall mean any adverse reaction which results in death, is life-threatening, results in significant disability or incapacity, or a congenital anomaly, birth defect, or causes a constant or prolonged occurrence of signs and symptoms of disease in a treated animal.

83. A batch of medicinal product is a specific quantity of the medicinal product with expected homogeneity manufactured in the scope of a single process or a series of processes and identified with a clearly defined combination of characters, which can be letters or numbers. It includes all units of the pharmaceutical form manufactured from the same initial quantity of the substance, which have been included in the same series of manufacturing processes or the same sterilisation process. In the case of uninterrupted manufacturing process, it includes all units manufactured within a specific time interval.

84. Pharmacovigilance system shall mean a system of monitoring and reporting, managed by marketing authorisation holders and the European Union Member States to fulfil the tasks and responsibilities on the basis of this Act, aimed at monitoring the medicinal products that have been issued a marketing authorisation, and at discovering the changes in the risk-benefit balance in the use of medicinal products.

85. Rapid alert system is a communication system for authorities competent for medicinal products of European Union Member States and of the European Union, which is established with the aim of immediate mutual and ,if required, broader notification of the appearance of a new risk for public health relating to the safety and quality of medicinal products, and with the aim to diminish such risk.

86. Risk management system shall mean a set of activities within the pharmacovigilance system and of measures intended for detecting, identifying, preventing or reducing risks related to a medicinal product, including the assessment of efficiency of the said activities and measures.

87. Compassionate use shall mean making a medicinal product containing a new active substance that constitutes a significant therapeutic, scientific or technical innovation and is in the process of being granted a marketing authorisation or in the clinical trial process available to a group of patients with a chronically or seriously debilitating disease who cannot be treated satisfactorily by authorised medicinal products, as stipulated in Article 83 of Regulation
726/2004/EC.

88. Specialised shop selling medicinal products shall mean a retail outlet selling those medicinal products which the Agency allows to be dispensed without prescription in pharmacies and specialised shops pursuant to this Act.

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

90. Sponsor shall mean a business entity or individual who takes responsibility for the initiation, management and/or financing of a clinical trial.

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

92. Study of the safety of medicinal product after obtaining the marketing authorisation for a medicinal product used in human medicine shall mean any study on such medicinal product conducted with the aim of detecting, identifying or quantifying a safety hazard, confirming the safety characteristics of a medicinal product or measuring the efficiency of risk management measures.

93. Study of the safety of medicinal product after obtaining the marketing authorisation for a medicinal product used in veterinary medicine shall mean a pharmacoepidemiological study or a clinical trial of a medicinal product carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying or investigating a safety hazard relating to a medicinal product.

94. Traditional herbal medicinal product shall mean 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 and Directive 2001/83/EC.

95. Third countries shall mean the Non-Member States of the European Union or the European Economic Area.

96. Risk related to the use of a medicinal product shall mean:

- any risk of the occurrence of environmentally harmful adverse reactions;

or

- any risk to the health of a patient or animal or public health, related to the quality, safety or efficacy of a medicinal product.

97. Active substance or medicinal substance shall mean any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.

98. Official quality control of a medicinal product shall mean the process of determining the quality of a medicinal product according to the marketing authorisation or the provisions hereof, including analytical testing or verifying of labelling and package insert or both.

99. Official control laboratory shall mean a laboratory conducting the official quality control of medicinal products, which is a member of the network of official control laboratories (GEON).

100. Import of a medicinal product shall mean marketing of a medicinal product from third countries in the territory of the Republic of Slovenia that may be performed only by manufacturing authorisation holders if the manufacturing authorisation covers the import activity. Import of a medicinal product shall also mean the transfer of a medicinal product from third countries to the territory of the Republic of Slovenia whenever the medicinal product is brought in by an individual for personal use or the needs of his/her household or an authorisation for personal use of a maximum of one individual who is not a member of the family, or his/her respective animal.

101. Wholesaler in medicinal products shall mean a business entity wholesaling medicinal products on the basis of the authorisation issued by the Agency with the aim of generating profit or not.

102. An intermediate product is partially processed material that needs to be processed with further procedures before it becomes a semi-product.

103. Entry of a medicinal product shall mean the wholesale from other European Union Member States to the Republic of Slovenia. Entry of a medicinal product shall also mean the transfer of a medicinal product from the territory of other Member States of the European Union to the territory of the Republic of Slovenia whenever the medicinal product is brought in by an individual for personal use or the needs of his/her household or an authorisation for personal use of a maximum of one individual who is not a member of the family, or his/her respective animal.

104. Protective element shall mean the information on the outer packaging of a medicinal product for human use enabling wholesalers and the competent persons for retailing medicinal products to the public in pharmacies and specialised stores to verify the authenticity of a medicinal product and identify packaging.

105. Member State concerned shall mean the Member State which shall decide, in the mutual recognition procedure or the decentralised procedure, on the acceptability of the risk-benefit balance and/or the assessment of quality, safety and efficacy of a medicinal product on the basis of the report on the assessment of the medicinal product compiled by a reference EU Member State.

106. Medicinal products derived from blood or plasma shall mean the medicinal products manufactured by means of industrial procedures, for instance medicinal products which contain above all albumin, coagulating factors and immunoglobulins of human origin, which are manufactured by specialised business entities from blood components obtained in accordance with the regulations governing blood supply and blood preparation supply and the regulations governing medicinal products.

107. Medicated feedingstuffs shall mean any mixture of a veterinary medicinal product or products and feed or feeds 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.

108. Herbal medicinal product shall mean a medicinal product which contains only one or more herbal substances, one or more herbal preparations or one or more herbal substances in combination with one or more herbal preparations.

109. An orphan medicinal product is a medicinal product intended for the treatment of very serious and very rare diseases for which no other approved treatment, prevention and diagnosis method is available, but whose marketing is without incentives not sufficiently profitable to justify the investment in its development and marketing, and which is defined as an orphan in accordance with the terms of the Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (Official Journal L 18, 22. 1. 2000), last amended by Regulation (EC) 596/2009.

110. Advanced therapy medicinal product is a medicinal product defined in Article 2 of Regulation No 1394/2007/EC.

111. Medical or veterinary prescription shall mean a document issued in accordance with the applicable regulations by an expert qualified and authorised to prescribe medicinal products.

112. Abuse of a medicinal product shall mean persistent or sporadic, intentional excessive use of a medicinal product which is accompanied by harmful physical or psychological effects.

113. Outer packaging of a medicinal product shall mean the packaging into which the medicinal product in the immediate packaging is placed.

II. MEDICINAL PRODUCTS ON THE MARKET

Article 7

(Relationship between medicinal and other products)

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

(2) The classification referred to in the previous paragraph shall be decided by the Agency in an administrative procedure by a special declaratory procedure based on the application or the manufacturer or the business entity which markets or intends to market the product referred to in the previous paragraph, or ex officio. In the process of deciding the following shall be considered:

- - qualitative and quantitative composition of the medicinal product;
- - purpose and method of administration;
- - whether the medicinal product or its constituents have pharmacological, immunological or metabolic action;
- - is the medicinal product ascribed direct or indirect effects of treatment, prophylaxis or diagnosis of disease;
- - presentation of the medicinal product and impression the medicinal product makes on the end user and/or customer;
- - possible adverse reactions and related risks for an individual and public health;
- - knowledge of the medicinal product by the end users and/or customers;
- the latest scientific findings, and
- the guidelines of the European Union, which are published by the Agency on its website and the national guidelines, which are prepared and published by the Agency on its website.

(3) The application referred to in the previous paragraph shall contain information about the qualitative and quantitative composition of the medicinal product, the safety of the medicinal product, the presentation of the medicinal product to the end users and/or customers on the leaflets or brochures attached to the packaging, websites, verbally or in any other manner, and about the status of the medicinal product in the EU Member States.

(4) The costs of the procedure based on the application referred to in the second paragraph hereunder shall be paid by the manufacturer or the business entity which markets or intends to market the product referred to in the first paragraph hereunder.

Article 8

(Relationship between industrially produced medicinal products and galenic medicinal products)

(1) Medicinal products, whereby starting materials are used to produce less than 50,000 packages per year in pharmacies or galenic laboratories, shall be treated as galenic medicinal products subject to the regulations governing pharmacy activity.

(2) The following are not permitted to be manufactured as galenic medicinal products:

- medicinal products with identical composition of active substances of the same or comparative form, with identical or comparable composition of excipients, pharmaceutical form or strength as those of medicinal products authorised for marketing in the Republic of Slovenia and present on the market;
- homeopathic medicinal products; or
- medicinal products which are not used in the EU Member States and third countries that have in place requirements concerning quality, safety and efficacy of medicinal products comparable to that of the European Union.

(3) A galenic medicinal product may be dispensed until the expiry of its shelf life, but no more than six months following the date of publication of entry on the market of the same or comparable industrially produced medicinal product, as published by the Agency at it website pursuant to paragraph three of Article 24 hereof.

(4) Industrially produced medicinal products, intermediates, intermediate products or semi-products may not be used for manufacturing galenic medicinal products, except in extraordinary situations in the interest of protecting public health in the event of a threat to the health of people and animals, subject to approval of the minister at the proposal of the expanded expert collegium for the pharmacy industry and opinion of the Strategic council for medicinal products.

(5) Notwithstanding the first paragraph hereunder, a pharmacy may manufacture a greater quantity of a galenic medicinal product based on previous approval of the Agency, if an industrially manufactured medicinal product classified in the list of essential medicinal products or list of indispensable medicinal products of the Republic of Slovenia has not been placed on the market.

(6) The Agency may approve a pharmacy for manufacturing a galenic medicinal product referred to in the previous paragraph in a special declaratory procedure on the basis of the pharmacy's

application in which the pharmacy proves that the increase in quantity is justified.

Article 9

(Prohibition of inappropriate presentation of products)

(1) It is prohibited to advertise and place on the market any products with an alleged healing properties or disease prevention properties for use in human or veterinary medicine which pursuant to this Act are not considered a medicinal product.

(2) The providers of healthcare, veterinary and pharmacy activity may not present to patients or customers the products which pursuant to this Act are not considered a medicinal product as products with healing properties or disease prevention properties.

Article 10

(Equal manufacturing and import requirements)

The provisions of this Act on manufacturing and import of medicinal products shall also apply to medicinal products intended for placement on the market outside the territory of the Republic of Slovenia and for intermediates, intermediate products, semi-products, active substances and excipients.

Article 11

(Exceptions to the application of this Act)

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

1. magistral formulas regulated by the provisions on pharmacy activity;
2. galenic medicinal products regulated by the regulations on pharmacy activity, except in the part which specifies the quantity distinction between medicinal products produced industrially and medicinal products produced galenically in pharmacies and/or their galenic laboratories;
3. medicinal products intended for research and development trials, without prejudice to the implementation of the provisions on clinical trials of medicinal products;
4. intermediates, intermediate products and semi-products intended for further processing by manufacturing authorisation holders into medicinal products that shall be authorised for marketing, except for manufacturing and import of medicinal products according to the provisions of the previous Article;
5. radioactive isotopes in the form of sealed sources regulated by the provisions on protection against ionising radiation and nuclear safety;
6. blood, plasma or blood cells regulated by the provisions on blood supply, except for plasma produced in a way that includes industrial procedures and which is used for manufacturing medicinal products;
7. human tissues and cells intended for treatment of humans, regulated by the provisions on quality and safety of human tissues and cells intended for treatment;
8. medicated feedingstuffs regulated by the provisions on feedingstuffs;
9. feed additives stipulated by the provisions on feedingstuffs;
10. Medicinal products for use in veterinary medicine foreseen exclusively for aquarium fish, cage birds, terrarium animals, small rodents and ferrets, considering the provisions from Articles 5 through 8 of the Directive 2001/82/EC, provided that such products do not contain substances the use of which requires veterinary control and that all necessary measures have been taken to prevent unauthorised use of the products for other animals.

Article 12

(Classifying medicinal drugs according to their anatomic-therapeutic-chemical classification and determining of defined daily dose)

(1) Medicinal products marketed in the Republic of Slovenia shall be classified according to the anatomic-therapeutic-chemical classification (hereinafter: ATC classification of medicinal products for human use or ATCvet for veterinary medicinal products) and the methodology of determining defined daily dose (hereinafter: DDD), which is published on the website of the WHO Collaborating Centre for Drug Statistics Methodology, Oslo, Norway (http://www. whocc.no), in its applicable form.

(2) The Agency shall provide the translation of the ATC classification and uniform national naming of active substances and DDD for medicinal products for use in human medicine and translation of ATC classification of medicinal products for veterinary use, marketed in the Republic of Slovenia, and shall publish them on its website.

Article 13

(National identifier of medicinal products)

(1) The Agency shall determine the national identifier of medicinal products for human use that represents a unique identification of a medicinal product in terms of active substance, pharmaceutical form, strength, packaging and authorisation holder placing the medicinal product on the market in the Republic of Slovenia.

(2) More detailed definition, method and procedure for determining and recording the national identifier of medicinal products and mandatory users shall be determined by the Minister.

Article 14

(Classification of medicinal products on the basis of prescribing and dispensing)

(1) In terms of prescribing and dispensing practices, medicinal products shall be classified as follows:

- - medicinal products dispensed on the basis of medical or veterinary prescription,
- - medicinal products for dispensing of which medical or veterinary prescription is not required.

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

Article 15

(Changed classification of a medicinal product regarding the prescription and dispensing regime, and data protection)

(1) A marketing authorisation holder may submit to the Agency an application for a change in the classification, whereby a medicinal product which may be prescribed and dispensed only based on a medical or veterinary prescription is classified among the medicinal products which may be prescribed and dispensed without a medical or veterinary prescription. In the application it shall submit the results of non-clinical pharmacotoxicological studies or clinical trials that justify the change in the classification of a medicinal product.

(2) If the Agency issues an authorisation for marketing a medicinal product with changed classification referred to in the previous paragraph on the basis of the results of significant non-clinical pharmacotoxicological studies or clinical trials, it shall, for one year of issuing the marketing authorisation for the medicinal product with changed classification, not consider the results of the tests or trials submitted by the holder of the marketing authorisation referred to in the previous paragraph when deciding on a change in the classification of a medicinal product of another holder of a marketing authorisation for a medicinal product with the same active substance.

(3) The change in the classification of a medicinal product referred to in this Article shall be treated as an amendment to the marketing authorisation under Article 62 herein.

Article 16

(Import, export, entry and exit of medicinal products for personal use and use on their animal)

(1) Individuals are prohibited from importing or exporting medicinal products.

(2) Notwithstanding the prior paragraph, an individual may for their personal use, the personal use of members of close family or pursuant to authorisation for the personal use of at most

one individual who is not their family member, or their individual animal which is not of a food producing animal species, import or export in their personal luggage a medicinal product in the quantity consistent with the relevant therapeutic use, as follows:

- - for a maximum of three weeks for acute conditions;

- - for a maximum of three months according to prescribed dosage for chronic diseases and conditions that require long-term use of medicinal products or exceptionally for up to 12 months if an individual submits to the competent customs authority proof of permitted residence in the target country in the respective period, unless the regulations on illicit drugs specify otherwise.

(3) In the import or entry of medicinal products for personal use as set out in the paragraph above, for which a medical or veterinary prescription is required, the customs authority may demand that the individual provide proof of medical or veterinary prescriptions for such medicinal products.

Article 17

(Essential and indispensable medicinal products)

(1) Essential medicinal products are those medicinal products that have been on the basis of the latest findings of biomedical science and systemic definitions in the framework of the national health priorities, taking into account the sustainability of public funds, recognised as essential for the provision of human and/or animal healthcare and classified in the list of essential medicinal products.

(2) In the list of essential medicinal products, medicinal products shall be defined by their common name, pharmaceutical form and strength, and the manner of prescribing and dispensing.

(3) The following criteria shall be applied when classifying medicinal products in the list of essential medicinal products:

- - that the medicinal product is significant in terms of public health protection;

- - that the medicinal product is significant in terms of implementation of healthcare programme priorities;

- - that the medicinal product is significant in the implementation of priorities of treatment of humans and the prevention of conditions defined in the resolution referring to the national healthcare plan or in the document of the World Health Organisation on priority healthcare programmes in Europe, or if the medicinal product is a selected medicinal product in exceptional circumstances with the aim of managing public health threats (in the event of large-scale accidents, infections, epidemics, pandemics, poisoning, radiation, including iodine prophylaxis and similar) or for other reasons in the interest of public health protection, or

- - that the medicinal product is significant in ethical terms.

(4) The list of essential medicinal products for human use shall be determined by the minister on the proposal of the Agency, and the list of essential medicinal products for veterinary use shall be determined by the minister competent for veterinary medicine at the proposal of the Agency.

(5) Indispensable medicinal products shall be medicinal products not included in the list of essential medicinal products referred to in the first paragraph hereunder and for which the provider of tertiary healthcare services or an expanded expert committee for its area of competence justifies new healthcare needs and which the Agency, on such basis and in view of the criteria referred to in the third paragraph hereunder, classifies in the list of indispensable medicinal products.

(6) The competent ministers shall publish the lists referred to in the fourth paragraph hereunder at least once annually, by no later than 31 January of the current year taking into account the medicinal products on the list referred to in the preceding paragraph.

(7) Several medicinal products marketed in the Republic of Slovenia based on the first and second paragraph of Article 20 hereof and having the same ATC classification code on the fifth level, same composition of active substances and appropriate pharmaceutical form, may simultaneously fit the description of an essential medicinal product from the list referred to in first paragraph hereunder and the description of indispensable medicinal products referred to in the fifth paragraph hereunder.

(8) If no medicinal products referred to in the first and second paragraph of Article 20 hereof, that fit the description of an essential medicinal product from the list of essential medicinal products or the description of an indispensable medicinal product from the list of indispensable medicinal products, are marketed in the Republic of Slovenia, the Agency may issue a temporary authorisation for marketing a medicinal product in line with indent 3 of the third paragraph of Article 20 hereof.

(9) A galenic medicinal product, which may be marketed according to the provisions of this Act, may fit the description of an essential medicinal product from the list referred to in the first paragraph hereunder or the description of an indispensable medicinal product from the list referred to in the fifth paragraph hereunder.

(10) The two lists of essential medicinal products and indispensable medicinal products shall be posted on the Agency's website.

Article 18

Placement on the market and availability of orphan medicinal products)

When placing orphan medicinal products on the market and ensuring their availability, the professional doctrine in the area of serious and rare diseases in the Republic of Slovenia shall be taken into account.

Article 19

(Interchangeable medicinal products)

(1) Interchangeable medicinal products for human use are those medicinal products that the Agency defines and publishes as suitable for interchanging, taking into account the fact that the probability of the occurrence of clinically significant differences in the efficacy and safety of such medicinal products is 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 issued on its basis;

- consideration of marketing authorisation;

- incorporation of the latest findings and discoveries of biomedical science and profession;

- data on pharmacovigilance.

(2) Medicinal products shall be interchanged by the persons authorised to prescribe medicinal products or issue medicinal products according to special regulations.

(3) The Agency shall initiate the procedure for establishing interchangeability of medicinal products:

- ex officio based on its own initiative; or

- - at the initiative of the competent ministry, expanded expert committee for medicinal products or the holder of rights arising from compulsory health insurance (hereinafter: the OZZ provider); or

- - based on the application of the marketing authorisation holder from the first paragraph of Article 20 hereof.

(4) The procedure referred to in the indent 1 of the previous paragraph shall commence:

- on the day the authorisation referred to in the first paragraph of Article 20 hereof becomes applicable; or

- - on the day the data referred to in the second paragraph of Article 20 hereof become applicable; or

- - on the day the Agency discovers new facts and circumstances that provide the basis for re-establishing interchangeability of medicinal products.

(5) The Agency shall decide on interchangeability by a decision issued in three months of receiving a complete application or from the commencement of the procedure that had been initiated ex officio. An appeal shall not stay the execution of such decision.

(6) The Agency may require the marketing authorisation holder referred to in the first paragraph of Article 20 hereof to provide additional documentation or data pursuant to paragraph six of Article 3 hereof. The procedure shall be suspended until the requirements have been fulfilled.

(7) The minister shall determine more detailed requirements and procedures for establishing interchangeability of medicinal products.

Article 20 (Marketed medicinal product)

(1) A medicinal product can be marketed in the Republic of Slovenia provided that it has been granted a marketing authorisation, a parallel import authorisation or a parallel distribution certificate or a compassionate use certificate.

(2) Notwithstanding the previous paragraph, a medicinal product that has been granted a marketing authorisation under centralised procedure, may be marketed in the Republic of Slovenia if on the basis of the marketing authorisation holder's application the Agency determines the national identifier of medicinal products and data from Article 13 hereof for the product.

(3) Notwithstanding the first paragraph hereunder, the Agency may in exceptional cases temporarily allow marketing of a medicinal product without a marketing authorisation:

- - for the needs of one or more patients or an animal or a group animals, on the basis of a request of the treating physician and the opinion of the responsible person of the clinic or institute, or in the event of a veterinary medicinal product, on the basis of a request of the treating veterinary, at their personal responsibility;
- - in exceptional cases (infections, epidemics, pandemics, poisoning, radiation and similar) for the purpose of implementing protective measures or for other reasons in the interest of public health protection;
- - for a medicinal product whose active substance, pharmaceutical form and strength are classified in the list of essential medicinal products or indispensable medicinal products referred to in Article 17 hereof, provided the same medicinal product has not been placed on the market with a marketing authorisation or is not present on the market of the Republic of Slovenia in accordance with this Act;
- - for medicinal products covered from the budget of the Republic of Slovenia pursuant to Article 141 of this Act, if there is no other medicinal product with the same composition and a marketing authorisation available in the Republic of Slovenia; or
- - in the event of epizootic diseases, on the proposal of the authority competent for veterinary medicine, for an immunological veterinary medicinal product without marketing authorisation, if no appropriate medicinal product is available, in which case the authority competent for veterinary medicine shall inform the European Commission in advance of the detailed conditions of use.

(4) The Agency may within 30 days of receiving a complete application exceptionally temporarily allow the marketing of a medicinal product referred to in the previous paragraph, except in the cases referred to in indents 2 and 5 of the previous paragraph, where it shall decide in no later than seven days. The Agency shall request that the application for temporary marketing of a medicinal product referred to in indent 2 and 5 of the previous paragraph be supplemented in five days at the latest.

(5) The Agency shall once a month submit to the minister or the minister competent for veterinary medicine the data on medicinal products authorised for temporary marketing.

(6) The applicant for obtaining a temporary marketing authorisation referred to in the third paragraph hereunder can be a wholesaler in medicinal products.

(7) The minister shall determine more specific conditions and the procedure for the issue of a temporary marketing authorisation in cases referred to in the third paragraph hereunder.

Article 21

(Prohibition to place medicinal product on the market)

It is prohibited to place on the market a medicinal product:

- - that does not have a marketing authorisation referred to in the first, second or third paragraph of the previous Article;
- - that does not have the approval referred to in the fifth and sixth paragraph of Article 8 herein;
- - that has not been manufactured according to the documentation for the marketing authorisation or good manufacturing practice;
- - that is past its shelf life, or
- - whose quality, safety and efficacy has been found to be deficient.

Article 22

(Approval of specific deviation)

(1) Notwithstanding the indent 3 of the previous Article, after the issue of a marketing authorisation, the Agency may, on the proposal of the marketing authorisation holder, approve in exceptional cases, when such approval is in the interest of public health protection, specific deviation from the terms of the marketing authorisation if such refers to a single batch or few batches of a medicinal product. The marketing authorisation holder shall submit in the application the data about the proposed scope of approval of specific deviation and provide evidence that the deviation does not affect the quality, safety and efficacy of a medicinal product as well as propose preventive and corrective measures which it shall implement to establish supply of the medicinal product in respect of the terms of the marketing authorisation.

(2) The minister shall determine more specific conditions and the procedure for approval of the specific deviation referred to in the previous paragraph as well as the contents of the application.

Article 23

(Measures upon quality deviations and suspected falsification of medicinal product)

(1) Business entities involved in marketing of a medicinal product shall inform the Agency about inadequate quality of a medicinal product or suspected falsification of a medicinal product. The Agency shall assess the data, require and monitor a recall of a medicinal product as well as decide on the manner of informing the public thereof.

(2) The minister shall decide on the manner and contents to be observed by business entities involved in marketing of a medicinal product when informing about quality deviations and suspected falsification of medicinal product.

Article 24

(Informing about placement of a medicinal product on the market and submission of data about the volume of sales, purchase, issue and consumption of medicinal products)

(1) A marketing authorisation holder, a marketing authorisation holder for parallel imported medicinal product, a holder of parallel distribution certificate and a holder of temporary marketing authorisation for a medicinal product referred to in the indent 3 of the third paragraph of Article 20 hereof shall inform the Agency about the date of the actual beginning of distribution of the medicinal product in the Republic of Slovenia or the date of placement of the medicinal product on the market no later than on the day of the first placement of the medicinal product on the market of the Republic of Slovenia.

(2) The holder referred to in the previous paragraph shall notify the Agency on any temporary or permanent suspension of such marketing or interrupted supply of such medicinal product at least two months prior to the suspension of such marketing, except in the case of force majeure. In the notification the marketing authorisation holder shall provide the reasons for temporary or permanent suspension of marketing the medicinal product, its assessment of the risk to public health protection in the Republic of Slovenia as well as its measures for reducing potential risk.

(3) In the case of medicinal products for human use the Agency shall inform the OZZ provider within five business days of receiving the notification from the first and second paragraph of the present Article, as well as publish such data on its website.

(4) In the case of medicinal products for veterinary use, the Agency shall inform, the authority competent for veterinary medicine within five business days of receiving the notification from the second paragraph hereunder and publish such data on its website.

(5) For the purpose of monitoring the use of medicinal products for treatment of animals, the Agency must, upon a request of the authority competent for veterinary medicine, forward to and provide the latter with the necessary data from the

marketing authorisation or import or entry authorisation and the marketing authorisation for parallel imported medicinal product or the certificate of the receipt of notification on parallel distribution of medicinal product.

(6) If requested by the Agency, the holders of authorization referred to in the first paragraph hereunder and the wholesalers shall submit data on the volume of sales in the Republic of Slovenia.

(7) The manager of databases on the consumption of medicinal products and the OZZ provider shall submit to the Agency and the ministry competent for health the data on the consumption of medicinal products received from the providers of healthcare programmes based on regulations governing the healthcare databases.

(8) Business entities providing the pharmacy activity shall submit to the Agency and the ministry competent for health the data on the purchasing and issue of medicinal products.

(9) Business entities providing the pharmacy activity and business entities retailing medicinal products in specialised stores shall submit to the Agency and the ministry competent for health the data on the purchasing and issue of medicinal products for which no prescription is required.

(10) Healthcare providers shall submit to the Agency and the ministry competent for health the data on the purchasing and consumption of medicinal products.

(11) Wholesalers shall report to the authority competent for veterinary medicine on the volume of sale of medicinal products for use in veterinary medicine and medicinal products for human use sold for exceptional use in veterinary medicine in the Republic of Slovenia.

(12) Veterinarian organisations and other organisations performing veterinary activity pursuant to the regulations on the veterinary activity and the authorised manufacturers of medicated feedingstuffs must report on the marketing of medicinal products upon the request of the authority competent for veterinary medicine.

(13) The authority competent for veterinary medicine shall submit to the Agency the data from the eleventh and twelfth paragraph hereunder once a year.

(14) The data about the volume of sale, purchase, issue and consumption of medicinal products shall include the quantity of individual medicinal product and the selling and purchase value for the respective period. The detailed requirements, methods, frequency and periods of reporting data and data models for the communication and submission of data shall be determined by the Minister. In the field of medicinal products for veterinary medicine, these shall be determined by the minister competent for veterinary medicine.

Article 25

(Notification of data on the volume of prescribing and consumption of medicinal products)

(1) Healthcare providers shall on the request of the Agency notify the data about the volume of prescribing medicinal products and their consumption.

(2) Providers of veterinary activity and authorised manufacturers of medicated feedingstuffs shall report to the authority competent for veterinary medicine on the volume of prescribing and use of medicinal products.

(3) The minister shall prescribe the detailed method of notifying data referred to in this Article.

Article 26

(Off-label use of veterinary medicinal products)

(1) If no suitable veterinary medicinal product authorised for marketing in the Republic of Slovenia is available to treat the disease state of certain animal species, the veterinary responsible for the treatment of animals may, especially in order to prevent unacceptable suffering of animals, exceptionally use medicinal products without marketing authorisation for the use in such species or to treat the disease state concerned, namely:

- a medicinal product for human use or treat by another medicinal product for veterinary use authorised for marketing in another EU Member State;
- if none of the medicinal products referred to in the previous indent is available, the medicinal product shall be prepared by the authorised persons according to the conditions of the veterinary prescription.

(2) More detailed conditions of use and off-label use of veterinary medicinal products, and the tasks related to off-label use carried out by the authority competent for veterinary medicine shall be determined by the minister competent for veterinary medicine.

Article 27

(Responsibiliti
es)

(1) Marketing authorisation holder for the Republic of Slovenia shall be responsible for the development and placing of the medicinal product on the market according to the marketing authorisation and any damage arising in this relation, including the damage resulting from inadequate quality of the medicinal product which is the responsibility of the manufacturer.

(2) If the marketing authorisation holder is not the manufacturer of the medicinal product, it shall have concluded an agreement with the manufacturer in order to provide that the medicinal product is manufactured according to the applicable regulations and the manufacturing processes stated in the documentation for acquiring and maintaining a medicinal product marketing authorisation.

(3) The manufacturer of a medicinal product, putting it on the market, shall be responsible for the manufacture, quality control, packaging and labelling of a medicinal product irrespective of whether medicinal product was manufactured by itself or on its behalf by a third party.

(4) The manufacturer of the medicinal product shall be responsible for the damage caused by inadequate quality of the medicinal product even if it is proved that it would not be possible to discover the defect, in view of the current level of global science and technological development in the moment the medical product was placed on the market.

(5) The manufacturer who removed or covered the safety feature on the medicinal product and replaced with a new one shall be responsible for the damage caused by falsification if it is established that the safety feature was removed or covered on a falsified medicinal product.

(6) A marketing authorisation holder, manufacturer, healthcare provider and healthcare professional shall not be responsible for the consequences of treatment arising from the use of medicinal product which is not in accordance with the issued marketing authorisation or the use of medicinal product without a marketing authorisation, if such use was recommended or requested by the Agency or the ministry competent for health or the ministry competent for veterinary medicine in the event of the spread of pathogenic substances, toxins, chemical substances or nuclear radiation which could be harmful to the health of humans or animals or damage the environment.

Article 28

(Pharmacopo
eia)

(1) Medicinal products marketed in the Republic of Slovenia must be manufactured and controlled according to the requirements of the European Pharmacopoeia and the Slovenian national supplement thereof.

(2) The notification of the validity of the European Pharmacopoeia and the Slovenian national supplement thereof shall be published by the Agency in the Official Gazette of the Republic of Slovenia.

(3) Should the European Pharmacopoeia and the Slovenian national supplement thereof not prescribe the methods of manufacture and requirements concerning quality of medicinal products concerned, such medicinal products may be manufactured and controlled according to the methods and requirements of pharmacopoeias of other EU Member States.

Should the pharmacopoeias of other EU Member States not prescribe the methods of manufacture and requirements concerning quality of medicinal products concerned, such medicinal products may subjected to the methods and requirements of the pharmacopoeias of third countries or to the methods proposed by the manufacturer of the medicinal product.

Article 29

(Expert advice)

The Agency may provide to the party or interested business entity, on its proposal, consultancy about the professional preparation of documentation within the relevant field of the Agency's competence, taking into account the absence of the conflict of interest which may not have bearing on any subsequent different decision in the procedure, should the facts, circumstances or technical and scientific findings change in the meantime.

III. TESTING OF MEDICINAL PRODUCTS AND COMPASSIONATE USE OF MEDICINAL PRODUCTS

Article 30

(Testing of medicinal products)

(1) Prior to being placed on the market, a medicinal product must undergo analytical and non-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 pharmacotoxicological tests as well as clinical trials even after it has already been granted a marketing authorisation or has been marketed, if such testing is performed with the purpose of regular quality control of medicinal products or for acquiring additional data on that product.

(3) Analyses of medicinal products shall be conducted by business entities holding the relevant authorisation of the Agency for manufacture of medicinal products and analytical testing.

(4) Non-clinical pharmacotoxicological testing of medicinal products is performed by those business entities that meet the conditions regarding personnel, premises, equipment and documentation keeping in compliance with the principles and guidelines of good laboratory practice.

(5) Medicinal products are clinically tested by providers of healthcare or veterinary activity, having the required personnel authorised to prescribe medicinal products in accordance with the provisions and principles of good clinical practice.

(6) Data on analytical and non-clinical pharmacotoxicological tests as well as clinical trials represent a constituent part of the documentation for obtaining a marketing authorisation and, according to requirements, also for maintaining a marketing authorisation.

(7) Analytical and non-clinical pharmacotoxicological tests of medicinal products as well as clinical trials must correspond to contemporary scientific knowledge and principles of good practices. They must be described in such a manner in the documentation on the medicinal product referred to in the previous paragraph so that the tests can be repeated in order to ensure data comparability.

(8) The minister shall determine more detailed methods and procedures of analytical non-clinical pharmacotoxicological tests as well as clinical trials, the contents of the application for obtaining the authorisation for analytical testing of medicinal products and the conditions which the business entities testing medicinal products must satisfy as well as the procedures of their verification.

Article 31

(Analytical testing of a medicinal product)

(1) Analytical testing shall mean microbiological, chemical-physical and biological quality testing of a medicinal product in compliance with the principles and guidelines of good manufacturing practice.

(2) The aim of analytical testing is to obtain data in pharmaceutical development of a medicinal product and to define control of medicinal product's constituents, packaging and finished product, the adequacy of manufacturing procedures as well as the stability of the active substances and the finished product.

Article 32

(Non-clinical pharmacotoxicological testing of a medicinal product)

(1) Non-clinical pharmacotoxicological testing of a medicinal product is 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.

(2) Non-clinical pharmacotoxicological testing must define pharmacodynamic, pharmacokinetic and toxicological properties demonstrated on laboratory animals, isolated organs and tissues and other pharmacological models, and foresee any possible effects in human beings or target animal species.

The non-clinical pharmacotoxicological testing concerning medicinal products for use in veterinary medicine must provide, in addition to the data specified in the previous paragraph, also the data on pharmacokinetics, especially metabolism and elimination of medicinal product residues and routine analysis method that can be applied to determine the level of such residues.

Article 33

(Clinical trials of a medicinal product)

(1) Clinical trials of a medicinal product for human use are trials involving healthy individuals and patients, with the purpose of demonstrating or ascertaining any clinical and pharmacological effects of the investigational medicinal product, demonstrating any adverse reactions to it, or investigating its absorption, distribution, metabolism and elimination during investigation with a view to proving its safety and efficacy in human use.

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

(3) Advanced therapy medicinal product prepared on a non-routine basis may not be clinically tried.

Article 34

(Conditions for clinical trial of a medicinal product)

(1) A medicinal product can be submitted 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 clinical trial of a medicinal product which is described in the documentation submitted for obtaining marketing authorisation must correspond to the requirements stipulated under the fifth paragraph of Article 30 hereof and the principles and guidelines of good clinical practice in clinical trials adopted and published by the European Commission as well as the principles of human medical and veterinary ethics and the guaranteed protection of personal data.

Article 35

(Commencement of clinical trial of a medicinal product)

(1) The applicant for a clinical trial of a medicinal product 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) Prior to the commencement of the clinical trial of a medicinal product, such trial must be notified to the Agency.

(3) Notwithstanding the provisions of the previous paragraph, an authorisation must be issued by the Agency before commencing clinical trials involving a human medicinal product

for gene therapy, somatic cell therapy including xenogenic cell therapy and a medicinal product containing genetically modified organisms.

Article 36

(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 of a medicinal product.

Article 37

(Approval and notification of a clinical trial)

(1) The Agency shall decide on the applications for the approval of a clinical trial of a medicinal product from the third paragraph of Article 35 hereof and the notification of the clinical trial of a medicinal product from the second paragraph of Article 35 hereof. Upon the request of the Agency, the committee from Article 4 hereof, operating in the area of clinical trials, shall issue an opinion on the proposed or notified clinical trial.

(2) The application for notification or approval of a clinical trial shall contain at least the data about the sponsor, the investigational medicinal product as well as the purpose and progress of the trial.

(3) The applicant shall enclose with the application from the previous paragraph for medicinal products for human use the opinion of the National Medical Ethics Committee within the ministry competent for health (hereinafter: NMEC).

(4) The Agency shall adopt a decision on the application for a clinical trial within two months of the day of receiving a complete application. For medicinal products obtained through a biotechnology process, the said deadline can be extended for further 30 days by a decision. If the application concerns human medicinal products for xenogenic cell therapy the deadline for the issue of a decision can be extended by the Agency up to 90 days. Clinical trial can commence once the decision on the approval of such clinical trial has been made final.

(5) The Agency decide on the notification of a clinical trial within two months of the day of receiving a complete notification application. If there is no response from the Agency it shall be deemed that the application for notification has been approved and the clinical trial can commence.

(6) In the procedure referred to in the third and fourth paragraph hereunder, the Agency may consider the assessment about the relevant clinical trial given by another EU Member State.

Article 38

(Changes in clinical trial of a medicinal product)

(1) In the case of any material changes to ongoing clinical trials of a medicinal product, the sponsor must notify the Agency thereof.

(2) The notified change can be introduced if the Agency does not issue a negative decision within 35 days of receiving a complete application for such change. In exceptional cases, this period of time may be extended to 60 days by the Agency, if such an extension is justified given the nature of the change or if the Agency has to consult the European Medicines Agency (hereinafter: EMA).

Article 39

(Discontinuation of a clinical trial on a medicinal product)

The Agency may, for the purpose of protecting public health or health of investigated subjects, order that a trial be temporarily or permanently discontinued.

Article 40

(Non-interventional clinical trial of a medicinal product)

(1) Any non-interventional clinical trial shall be notified by the sponsor to the Agency.

(2) The application for notification shall at least include the following data:

- - data on the medicinal product subjected to the trial,
- - data on the purpose of the trial,
- - for medicinal products for human use a positive opinion from the NMEC,
- - for non-interventional clinical trials of medicinal products for human use, for which the market authorisation holder must obtain prior consent referred to in Article 138 hereof, the relevant consent to the draft protocol and the non-interventional clinical trial protocol,
- - employer consents referred to in the sixth paragraph hereunder to the selection of physicians or veterinarians who will participate in the relevant non-interventional clinical trials,
- - anticipated period for the clinical trial with the appropriate reasoning should this period extend over one year,
- - an estimate of the value and structure of costs associated with the trial.

(3) The Agency shall adopt a decision on the notification of a clinical trial referred to in the first paragraph hereunder within two months of the day of receiving a complete application for notification.

If there is no response from the Agency it shall be deemed that the application for notification has been approved and the clinical trial can commence. The sponsor of the non-interventional clinical trial shall submit a report to the Agency on the progress, results and costs of the trial.

(4) The non-interventional clinical trial shall not promote the prescribing and use of the medicinal product. The patient or their guardian, or owner or keeper of an animal shall be informed of the inclusion in a non-interventional clinical trial. The inclusion of a patient in a non-interventional clinical trial may not be the reason for replacing the existing appropriate therapy.

(5) Prior to their participation in non-interventional clinical trials, a physician or veterinarian must obtain the consent of their employer, provided the latter is financed from public funds. Any payment to physicians or veterinarians for participation in non-interventional clinical trials during working hours shall be prohibited. Payment to physicians or veterinarians for participation in non-interventional clinical trials shall be limited to remuneration for work in their free time and costs incurred in relation thereto.

(6) During the non-interventional clinical trial the sponsor shall monitor the collected data and study any effect of the trial's results on the risk-benefit balance of such medicinal product. Any new information that could affect the assessment of the balance shall be reported to the Agency, all EU Member States that have granted a marketing authorisation for the medicinal product and the competent committee of the EMA if the trial is performed in several EU Member States, as the case may be.

(7) At the request of the Agency, the sponsor shall submit the protocol and progress reports to the Agency and for medicinal products for human use to the competent bodies for medicinal products of the EU Member States where the trial is performed.

(8) Following the completed non-interventional clinical trial the holder of the marketing authorisation for medicinal products for human use that are subject to prior consent referred to in Article 138 hereof, shall submit to the Agency or the competent committee of the EMA, whenever the non-interventional clinical trial is performed in several EU Member States, the final report including an abstract for publication within 12 months after the completed gathering of data unless the Agency or the competent committee of the EMA withdraw the request in writing.

(10) When the marketing authorisation holder assesses that the results of the non-interventional clinical trial affect the provisions of the marketing authorisation, it shall submit to the Agency an application for a change in the marketing authorisation for a medicinal product pursuant to Article 62 hereof.

(11) After the commencement of the non-interventional clinical trial, the holder of the marketing authorisation for medicinal products for human use, for which the marketing authorisation holder shall obtain prior consent referred to in Article 138 hereof, shall submit to the Agency or the competent committee of the EMA, whenever the trial is performed in several EU Member States, any substantive change of the trial's protocol before it is enforced.

(12) The minister shall determine detailed conditions for the performance of non-interventional clinical trials and the detailed content of the application related thereto.

Article 41

(Application for compassionate use of medicinal products)

(1) The compassionate use of a medicinal product application may be filed with the Agency by:

- - the applicant whose medicinal product is the subject of an application for a centralised marketing authorisation;
- - the sponsor of a clinical trial if the medicinal product is undergoing clinical trial to obtain a marketing authorisation under a centralised procedure.

(2) The application from the previous paragraph shall contain the following evidence, statements and attachments:

- the medicinal product is the subject of an application for a centralised marketing authorisation or is undergoing clinical trial for the purpose of obtaining a marketing authorisation under a centralised procedure;
- - the medicinal product is not authorised for marketing in any EU Member State, but is authorised for marketing in a third country that has equivalent requirements concerning quality, safety and efficacy of medicinal products, and is accompanied by a report on quality analysis of a medicinal product;
- - the medicinal product constitutes a significant therapeutic, scientific and technical innovation;
- - the medicinal product is intended for a group of patients with a chronically or seriously debilitating disease who cannot be treated satisfactorily by authorised medicinal products;
- - the manufacturer of the medicinal product submits a statement obligating them to supply the medicinal product even one year after the conclusion of the compassionate use programme to all patients included in the programme of compassionate use in the Republic of Slovenia even if, after the expiry of the projected programme supply period, public funds are not provided for this medicinal product, provided that the patients' benefit of the treatment with such medicinal product is documented according to the protocol referred to in indent 6 of this paragraph;
- - the protocol of treatment with the medicinal products for compassionate use in written or electronic form, which shall contain the criteria for the start of treatment, monitoring of treatment efficacy, the criteria for continued treatment and monitoring of adverse reactions to treatment, and which shall be prepared or approved by the competent clinical department;
- - a statement of the manufacturer of the medicinal product that the medicinal product from the programme of compassionate use is free of charge and they themselves cover all additional costs of supplying the relevant medicinal product, including the costs of wholesale of the medicinal product from the programme;
- - a manufacturer's statement that the outer packaging shall clearly state that the medicinal product is for compassionate use of a medicinal product.

(3) If a medicinal product is undergoing clinical trial referred to in the second indent of the first paragraph hereunder, the application shall contain a positive opinion of the NMEC.

Article 42

(Compassionate use authorisation)

(1) The Agency shall decide on the issue of compassionate use of a medicinal product authorisation in 30 days of receiving a complete application.

(2) Pursuant to Article 83 of Regulation (EC) No 726/2004 the Agency shall obtain an opinion of the Committee for Medicinal Products of the EMA. The deadline referred to in the previous paragraph shall not apply until such opinion is obtained.

(3) The minister shall determine in greater detail the conditions, the contents of the application, the method and the procedure for obtaining a compassionate use authorisation for a medicinal product.

IV. MARKETING AUTHORISATION

Article 43

(Applicant for a marketing authorisation)

(1) The procedure for the issue of marketing authorisation shall begin with the submission of an application by a business entity with registered office in the European Union. This can be either the manufacturer of the medicinal product or another business entity that has concluded a written agreement with the manufacturer of the medicinal product.

(2) The applicant shall be responsible for the adequacy and authenticity of documents and the accuracy of the submitted data.

Article 44

(Application for a marketing authorisation)

(1) The application for a marketing authorisation shall comprise the following documentation:

1. General part, including data on the manufacturer of the medicinal product, a written certificate of the manufacturer of the medicinal product that they have inspected the compliance of the manufacturing of active substance with the principles and guidelines of good manufacturing practice, the summary of the pharmacovigilance system, the risk management plan proportionate to the established and potential risks that shall be introduced by the applicant for marketing authorisation of the respective medicinal product, accompanied by a summary of the plan, data on the medicinal product, data on all previously issued or rejected marketing authorisations, including the specifics and reasons for rejection or the revocation of the marketing authorisation, the summary of product characteristics, package leaflet, draft packaging, data on the status of orphan medicinal products, if obtained, expert reports and summaries, estimates of risk-benefit balance, environmental risk assessment and other data necessary for public health protection;
2. Pharmaceutical-chemical and biological part including data on quality and quantity of the composition, description of the method of manufacturing, quality control of starting materials, quality control carried out at intermediate stages of the manufacturing process, quality control of the finished product and stability studies;
3. Non-clinical pharmacotoxicological part, including data on the pharmacodynamic and pharmacokinetic properties of a medicinal product, its toxicity and effect on the reproductive function, data on embryo-foetal toxicity, mutagenic potential and carcinogenic potential, data on local tolerance and excretion. The pharmacotoxicological part of the documentation related to veterinary medicinal products should also include data on residues and proposed withdrawal periods and data on environmental risks;
4. a clinical part, including general data on trials, how they have been carried out and ensuing results, clinical and pharmacological data, data on bioavailability or 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 authorised marketing.

(2) On the request of the Agency the applicant shall also submit samples of medicinal products that are subject to the proposed marketing authorisation and reference standards.

(3) The competent minister shall determine more specific conditions, form and content of the application and documentation required for the issue of marketing authorisation.

Article 45

(Abbreviated application for marketing authorisation for a medicinal product for human use and period of protection)

(1) Notwithstanding the provisions of the previous paragraph, the applicant need not submit the results of non-clinical pharmacotoxicological tests or clinical trials, if proven that the subject of the procedure is a generic medicinal product whose reference medicinal product has been granted marketing authorisation in the Republic of Slovenia or the European Union at least eight years earlier.

(2) A generic medicinal product referred to in the previous paragraph may not be marketed for ten years after obtaining the marketing authorisation for the reference medicinal product.

(3) If the reference medicinal product referred to in the first paragraph hereunder did not obtain marketing authorisation in the Republic of Slovenia, the applicant shall state in the application for obtaining marketing authorisation the EU Member State in which such authorisation had been obtained. The Agency shall obtain from the competent authority of the selected EU Member State a certificate of issued marketing authorisation for the reference medicinal product concerned and the qualitative and quantitative particulars of the reference medicinal product composition and, if necessary, any other relevant documents.

(4) The ten-year period referred to in the second paragraph hereunder shall be extended to a maximum of 11 years if, during the first eight years of the period the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which are established to bring a significant clinical benefit for the patient in comparison with existing therapies.

(5) If various salts, esters, ethers, isomers, mixed isomers, complexes or active substance derivatives differ considerably in terms of safety or efficacy or both, the applicant shall submit additional information on the safety or efficacy of various salts, esters or active substance derivatives of the medicinal product that has been authorised for marketing. Different oral forms with immediate release are considered to be the same pharmaceutical forms. Bioavailability studies need not be submitted if so stipulated by the EMA instructions prepared in accordance with the scientific and technical knowledge.

(6) If a medicinal product does not correspond to the definition of a generic medicinal product or if bioequivalence cannot be proven by means of bioavailability studies or in case of changes in the active substances, indications, strength, pharmaceutical form or method of administration in respect to the reference medicinal product, it shall be necessary to submit the results of the relevant non-clinical pharmacotoxicological studies or clinical trials.

(7) If the active substance of the medicinal product has a well-established medicinal use and the application has been submitted for a new indication for which significant non-clinical pharmacotoxicological studies or clinical trials have been submitted, a non-cumulative one-year period of data protection shall apply in addition to the provisions of the first through fourth paragraphs hereunder, preventing other applicants from referring to this part of the documentation.

(8) Notwithstanding the provisions of regulations governing patent rights or rights of an additional protection certificate for a medicinal product, the implementation of studies required for the fulfilment of requirements of the present Act and other requirements related to the acquisition of a marketing authorization, shall not be deemed a violation of patent rights or rights of an additional protection certificate for medicinal products.

(9) The provisions on the periods of protection shall not apply to reference medicinal products for which an application for marketing authorisation was submitted by 30 October 2005. These applications shall be subject to the period of data protection that applied on the day the application was submitted in the EU Member State which authorised the reference medicinal product.

Article 46

(Abbreviated application for marketing authorisation for a medicinal product for veterinary use and period of protection)

(1) Notwithstanding the provisions of Article 44 of this Act, the applicant need not submit the results of non-clinical pharmacotoxicological tests or clinical trials nor the results of residue tests, if proven that the subject of the procedure is a generic medicinal product whose reference medicinal product has been granted marketing authorisation in the Republic of Slovenia or the European Union at least eight years earlier.

(2) A generic medicinal product referred to in the previous paragraph may not be marketed for ten years after obtaining the marketing authorisation for the reference medicinal product.

(3) If the reference medicinal product referred to in the first paragraph hereunder did not obtain marketing authorisation in the Republic of Slovenia, the applicant shall state in the application for obtaining marketing authorisation the EU Member State in which such authorisation had been obtained. The Agency shall obtain from the competent authority of the selected EU Member State a certificate of issued marketing authorisation for the reference medicinal product concerned and the qualitative and quantitative particulars of the reference medicinal product composition and, if necessary, any other relevant documents.

(4) The ten-year period referred to in the second paragraph hereunder shall be extended to a maximum of 13 years in respect of veterinary medicinal products for fish, bees and other animal species stipulated by the European Commission, if during the first eight years of the ten-year period referred to in the second paragraph hereunder, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which are established to bring a significant clinical benefit in comparison with existing therapies.

(5) In veterinary medicinal products foreseen for one or more species of food producing animals which contain new active substances and have not been allowed in the European Union before 30 April 2004, the ten-year period stipulated by the second paragraph of Article 48 hereof shall be extended by one year in each case of extension to the marketing authorisation for another species of food producing animals, provided that such extension to the marketing authorisation is obtained within five days of issuing the first marketing authorisation for the medicinal product.

(6) The period stipulated by the second paragraph hereunder, together with any extensions under the previous paragraph may not be longer than 13 years
which also applies to the extension to marketing authorisation for the medicinal product related to four or more species of food producing animals.

(7) The extension of the ten-year period to 11, 12 or 13 years for a veterinary medicinal product, foreseen for food producing animals, shall only be granted if the marketing authorisation holder has previously submitted the application for determination of maximum residue limit for those species covered by the marketing authorisation for the medicinal product.

(8) If various salts, esters, ethers, isomers, mixed isomers, complexes or active substance derivatives differ considerably in terms of safety or efficacy, the applicant shall submit additional information on the safety or efficacy of various salts, esters or active substance derivatives of the medicinal product that has been authorised for marketing. Different oral forms with immediate release are considered to be the same pharmaceutical forms. Bioavailability studies need not be submitted if so stipulated by the relevant instructions prepared in accordance with the scientific and technical knowledge.

(9) If a medicinal product does not correspond to the definition of a generic medicinal product or if bioequivalence cannot be proven by means of bioavailability studies or in case of changes in the active substances, indications, strength, pharmaceutical form or method of administration in respect to the reference medicinal product, it shall be necessary to submit the results of the relevant non-clinical pharmacotoxicological studies or clinical trials and the results of the safety trials and residues of the medicinal product.

(10) Notwithstanding the provisions of regulations governing patent rights or rights of an additional protection certificate for a medicinal product, the implementation of studies required for the fulfilment of requirements of the present Act and other requirements related to the acquisition of a marketing authorization, shall not be deemed a violation of patent rights or rights of an additional protection certificate for medicinal products.

(11) The provisions on the periods of protection shall not apply to reference medicinal products for which an application for marketing authorisation was submitted by 30 October 2005. These applications shall be subject to the period of data protection that applied on the day the application was submitted in the EU Member State which authorised the reference medicinal product.

Article 47

(Well established use of a medicinal product for human use)

(1) Notwithstanding the provisions of Article 44 hereof, the applicant need not submit own data on non-clinical pharmacotoxicological tests or clinical trials if it is able to prove that the active substance of the medicinal product for the relevant indication has a well-established medical use with recognised efficacy and an acceptable level of safety, and that it has been used on the territory of the European Union in appropriate scope for at least ten years and if sufficient publicly accessible expert literature on the characteristics and use of medicinal products with the active substance in question assures sufficient data for the assessment of the safety and effectiveness of the medicinal product. In such case, adequate data from the available literature shall be submitted in the application instead of own data.

Article 48

(Well established use of a medicinal product for veterinary use)

(1) Notwithstanding the provisions of Article 44 of this Act, the applicant need not submit own data on non-clinical pharmacotoxicological tests or clinical trials nor the results of residue tests of the veterinary medicinal products, if proven that the active substance of the medicinal product for the relevant indication has a well-established veterinary use, with recognised efficacy and an acceptable level of safety, and that it has been used on the territory of the European Union in appropriate scope for at least ten years and if sufficient publicly accessible expert literature on the characteristics and use of medicinal products with the active substance in question assures sufficient data for the assessment of the safety and effectiveness of the medicinal product. In such case, adequate data from the available literature shall be submitted in the application instead of own data and the applicant may also use the report on the assessment of the application for the establishment of maximum residue limits which is conducted and published by the EMA according to Regulation (EC) 470/2009.

(2) If the applicant has used scientific literature for obtaining marketing authorisation for a veterinary medicinal product for use in food producing animals and has submitted, in respect of the same medicinal product and for the needs of obtaining authorisation for another species of food producing animals, new studies on medicinal product residues in accordance with Regulation 470/2009/EC together with further clinical trials, then a three-year period of data protection shall apply in addition to the provisions of Article 46 hereof, preventing other applicants from referring to this part of the documentation.

Article 49

(Combination of active substances)

(1) If the marketing authorisation application concerns new medicinal products containing active substances present in the medicinal products for which marketing authorisations have already been issued, however, not hitherto used in the proposed combination of active substances for therapeutic purposes, the results of non-clinical pharmacotoxicological tests and of clinical trials relating to that combination shall be provided in the marketing authorisation application, but it shall not be necessary to provide references relating to each individual substance.

(2) In addition to the data from the previous paragraph, the marketing authorisation application for veterinary medicinal products must also contain the results of safety and residue tests, if so assessed by the applicant or required by

Article 50

(Approved use of documentation)

Holder of a marketing authorisation valid in the Republic of Slovenia may authorise the use of data from the pharmaceutical, chemical, biological, non-clinical pharmacotoxicological and clinical part of documentation for veterinary medicinal products as well as data from the documentation on safety and residue tests which is a constituent part of the application on the basis of which the marketing authorisation has been obtained, for compiling or processing the subsequent applications for other medicinal products with the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.

Article 51

(Exceptional circumstances)

Notwithstanding the provisions of Article 44 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 on-the-field tests carried out in the target species if such tests cannot be carried out because of well-grounded reasons.

Article 52

(Herbal medicinal products and traditional herbal medicinal products)

(1) Marketing authorisation for herbal medicinal products must be obtained pursuant to Articles 43 to 50 hereof.

(2) Notwithstanding the previous paragraph, a simplified procedure for obtaining the marketing authorisation (hereinafter: the traditional medicine registration procedure) shall be applied to a traditional herbal medicinal product, provided that it meets the following requirements:

- - it has therapeutic indications, suitable for traditional herbal medicinal products only, which, by virtue of their composition and purpose, are intended for self-medication;
- - it can only be used in accordance with the prescribed strength and dosage;
- - it is intended for oral or external use or for inhalation;
- - the period of its traditional use has expired;
- - the data on the traditional use of medicinal product must be sufficient; in particular, it must be proved that the product is not harmful if used as foreseen and that the pharmacological effects or efficacy of the medicinal product are probable on the basis of long-term use and experience.

(3) Traditional herbal medicinal products may also contain vitamins and minerals provided that there exists documented evidence on their safety and that such vitamins and minerals support the activity of herbal substances in terms of the stated therapeutic indications.

(4) If the Agency establishes that the traditional herbal medicinal product meets the conditions for obtaining the marketing authorisation or registration for the homeopathic medicinal product, the provisions applicable to traditional herbal medicinal product hereunder shall not apply.

(5) The application for acquiring the marketing authorisation for traditional herbal medicinal products under the traditional medicinal product registration procedure shall be comprised of a general part of documentation and the pharmaceutical-chemical and biological documentation in accordance with the first and the second item of the first paragraph of Article 44 hereof, except for the summary of the pharmacovigilance system and the plan for risk management. Instead of data referred to in items 3 and 4 of the first paragraph of Article 44 of this Act, the following shall be submitted:

1. Bibliographic or expert evidence that the medicinal product concerned, or other appropriate medicinal product had been used for medical purposes for at least 30 years prior to the date of application, of which at least 15 years in the European Union. If a medicinal product had been used in the European Union for less than 15 years and nevertheless meets the conditions prescribed for traditional herbal medicinal products, the Agency shall submit evidence of long-term use of such medicinal product or another adequate medicinal product to the EMA; and
2. Bibliographic overview of data on the safety, together with the expert opinion submitted by the applicant and, if requested by the Agency, other data needed for the assessment of safety of the medicinal product.

(6) More detailed conditions, form and content of the required documentation in the procedures for obtaining, modifying, extending, transferring and cancelling the marketing authorisation for a traditional herbal medicinal product, as well as the method of labelling and advertising traditional herbal medicinal products shall be determined by the competent minister.

Article 53 (Homeopathic medicinal products)

(1) Marketing authorisation for homeopathic medicinal products must be obtained pursuant to Articles 43 to 50 hereof.

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

1. The outer packaging and the package insert, if attached, do not indicate any therapeutic indication or information relating to them, and

2. Have a sufficient degree of dilution to guarantee the safety of the product, as stipulated by the regulations applicable to homeopathic medicinal products.

(3) The application for obtaining the marketing authorisation for homeopathic medicinal products under the homeopathic medicinal product registration procedure shall contain:

- - a general part, including data on medicinal product, data on the manufacturer, data on the applicant, data on issued registrations or marketing authorisations in other EU Member States for the same medicinal product, one or several samples of packaging or drafts of immediate or outer packaging and package insert;
- - documentation describing how homeopathic substances are obtained and controlled and justification of their homeopathic nature;
- - documentation on the manufacturing and control of each pharmaceutical form with a description of dilution or potentiation;
- - data on the stability of the final product;
- - documentation on the safety of homeopathic medicinal products.

(4) More detailed conditions, form and content of the required documentation in the procedures for obtaining, modifying, extending, transferring and cancelling the marketing authorisation for a homeopathic medicinal product, as well as the method of labelling and advertising homeopathic medicinal products shall be determined by the competent minister.

Article 54

(Emergency procedures)

(1) Notwithstanding the provisions of Articles 44 through 51 hereof, the Agency may, in order to protect public health and animal health in the event of a threat to human life or health, issue ex officio a temporary marketing authorisation on the basis of the facts established in the valid marketing authorisation for the medicinal product concerned in the Member State and the report on the assessment of medicinal product obtained from the body competent for medicinal products in the selected EU Member State, if available.

(2) The Agency shall inform the marketing authorisation holder in the Member State of the European Union in which the medicinal product concerned is authorised for marketing of the application to issue a marketing authorisation referred to in the previous Paragraph.

(3) A business entity holding a temporary marketing authorisation referred to in the first paragraph hereunder shall be responsible for labelling, package insert, summary of the product characteristics, advertising and pharmacovigilance system.

Article 55

(Procedure for obtaining marketing authorisation)

(1) The Agency shall verify the completeness of the application for marketing authorisation within 30 days of receiving it.

(2) The applicant shall enclose with the application, if requested by the Agency the samples of the medicinal product, its starting materials and, if need be, its intermediates, intermediate products and other 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 Agency may order analytical testing of medicinal products in the official control laboratory, assessment of adherence to good practices by business entities stated in the documentation, verification of analytical methods aimed at discovering and defining residues of veterinary medicinal products, request additional data and explanations or other relevant evidence.

(4) In the fact-finding proceedings before the issue of the marketing authorisation, the Agency shall assess the quality, safety and efficacy of the medicinal product and the risk-benefit balance, check the compliance with the principles and guidelines of good practices at manufacturers and investigation institutions, indicated in the documentation, and compile a report on the assessment of the medicinal product.

(5) In the fact-finding proceedings, the Agency may obtain the opinion of the committee from Article 4 hereof and an additional opinion of individual external experts from Article 4 hereof regarding the adequacy of documents, individual parts or the complete submitted documentation for the assessment of the risk-benefit balance.

(6) The Agency shall adopt a decision on the application for marketing authorisation within 210 days of receiving a complete application and publish or enable access to a public report on the medicinal product on its website.

(7) Marketing authorisation shall, as a rule, be issued for a period of five years, unless otherwise determined by this Act.

Article 56

(Mutual recognition)

(1) Notwithstanding the provisions of the previous Article, the Agency 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, in which the Republic of Slovenia is the EU Member State concerned, on the basis of the assessment report compiled by the reference EU Member State.

(2) The competent minister shall lay down the detailed conditions for the mutual recognition procedure, the decentralosed procedure and the procedure from the previous Article.

Article 57

(Referral procedure)

(1) The Agency may initiate the referral procedure on behalf of the Republic of Slovenia before the competent committee of the European Union with the aim of protecting public health, animal health or environmental protection:

- - when it cannot approve the report on the assessment of medicinal product from the first paragraph of the previous Article;
- - when EU Member States have already adopted various decisions related to the marketing authorisation for a certain medicinal product or suspended or withdrew it temporarily;
- - when this is in the interest of the European Union for pharmacological reasons; or
- - when the Agency assesses that the marketing authorisation for a medicinal product must be amended.

(2) The competent minister shall lay down the detailed conditions and the procedures for the referral procedure from the previous paragraph.

Article 58

(Marketing authorisation with special conditions)

(1) In exceptional circumstances and following consultation with the applicant, the Agency may grant authorisation under special conditions, in particular concerning product safety,

notification of the relevant authorities of the European Union and the EU Member States of any incident relating to its use, and action to be taken. Such authorisation can only be issued if the applicant proves that it cannot submit more detailed data from Article 44 hereof for objective and verifiable reasons (e.g. current state of scientific discoveries, area of treatment of rare illnesses, principles of medical ethics). If necessary, the marketing authorisation shall stipulate the deadlines for fulfilling these conditions.

(2) Each year, the Agency shall check the fulfilment of the conditions from the marketing authorisation for a medicinal product from the previous paragraph.

(3) The Agency may on well-substantiated grounds direct holders that have previously been issued a marketing authorisation in accordance with the law to conduct a study on the safety and/or efficacy of the medicinal product, including also written objectives and deadlines for submitting and implementing the study.

(4) The marketing authorisation holder can submit to the Agency, within the deadline set by the Agency, written explanations in response to the imposed obligation from the previous paragraph, provided that the marketing authorisation holder asks for this within 30 days imposition of obligation. Based on the submitted written explanations, the Agency shall decide on the execution of a study on the safety and/or efficacy of the medicinal product.

(5) Based on the obligation to conduct the study from the third paragraph hereunder and considering the previous paragraph, the Agency issues the marketing authorisation by including the imposed obligation as a condition in such marketing authorisation.

(6) The Agency shall on its website publish a list of medicinal products hereunder and the conditions and deadlines for fulfilling them.

(7) The marketing authorisation holder shall include the conditions and obligations from the first, third and fifth paragraphs hereunder, related to the safety of medicinal product, in its risk management system.

(8) Detailed conditions from the first, third and fifth paragraphs hereunder are laid down by the competent minister.

Article 59

(Umbrella marketing authorisation)

(1) Notwithstanding the fact whether a separate marketing authorisation is issued for additional strengths, pharmaceutical forms, indications, routes of administration, packaging or other changes or extensions to the marketing authorisation, or if they are part of the underlying authorisation, all such marketing authorisations, and in the case of veterinary medicinal products also addition of another species, shall be treated as part of the same umbrella marketing authorisation.

(2) The umbrella marketing authorisation is used particularly for the needs of implementing the provisions from Articles 45 and 46 of this Act.

Article 60

(Refused issue of marketing authorisation)

(1) The issue of marketing authorisation shall be withheld if, during the examination of the documents and data, the Agency establishes that:

- - the risk-benefit balance of the use of medicinal product is not 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 in compliance with the documentation;
- - the label or the package insert, submitted by the applicant, is not in accordance with this Act and the regulations adopted on the basis hereof;
- - the indications in the documentation do not correspond to the actual state; or
- the data in the documentation are not compliant with Articles 44 through 50 hereof.

(2) The marketing authorisation for a veterinary product shall be withheld by the Agency in the cases from the previous paragraph and if it establishes that:

- - the efficacy of the medicinal product is insufficiently substantiated or that the medicinal product is not efficient;
- - 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 humans, or is insufficiently substantiated;
- - the medicinal product represents an environmental risk;
- - the medicinal product is offered for use that is prohibited under the applicable EU regulations; or
- - the medicinal product is intended for use in one or more species of food producing animals and contains one or more active substances which are not allowed and are listed in the Annex to Commission Regulation (EU) No 37/2010 or are not listed in the Annexes to Commission Regulation (EU) No 37/2010.

(3) The marketing authorisation for traditional herbal medicinal product shall be rejected in cases referred to in the first paragraph hereunder and also, if it is established:

- - that its therapeutic indications are not in line with the prescribed conditions;
- - that the data on the traditional use of medicinal product are insufficient; in particular, the pharmacological effects or efficacy of the medicinal product are not probable on the basis of long-term use and experience.

(4) The marketing authorisation for homeopathic medicinal product shall be rejected in cases referred to in the first paragraph hereunder and also, if it is established that the homeopathic medicinal product for which the application for obtaining the marketing authorisation under the simplified procedure has been filed does not meet the conditions from the second paragraph of Article 53 hereof.

Article 61

(Period for the placement of medicinal product on the market)

(1) If the medicinal product with the same proprietary name has not been placed on the market on the territory of the Republic of Slovenia for three consecutive years after the entry into force of marketing authorisation for the medicinal product, such marketing authorisation shall be withdrawn.

(2) If the medicinal products with the same proprietary name, to which the Agency issued the marketing authorisation and have previously been placed on the market but none of which has been marketed in the period of three consecutive years, such marketing authorisation shall be withdrawn.

(3) Notwithstanding the provisions of the first and the second paragraphs hereunder, the Agency shall be entitled not to cancel marketing authorisation in justified well-justified cases and for the needs of uninterrupted supply of medicinal products or protecting public health even if the medicinal product has not been actually marketed for three consecutive years after the issue of marketing authorisation.

(4) The Agency shall inform the marketing authorisation holder of the intended revocation at least three months prior to the issue of a decision on revocation of marketing authorisation.

Article 62

(Amendments to marketing authorisation) (1) After a marketing authorisation has been issued, the marketing authorisation holder shall, in respect of the methods of manufacture and control, take account of scientific and technical progress and introduce any variations that may be required to enable the medicinal product to be manufactured and checked by means of generally accepted scientific methods. The marketing authorisation holder must inform the Agency of any new information that could impact the variation of marketing

authorisation or the change in documentation on a medicinal product.

(2) Marketing authorisation holder must inform the Agency of any data that could impact the assessment of the risk-benefit balance and particularly of any measures, restrictions or prohibitions introduced by other EU Member States. Information includes positive and negative results of clinical trials or other studies for all indications and populations, regardless of whether they have been included in the marketing authorisation or not, and data on the use of medicinal product when such use is not in the framework of conditions from the marketing authorisation.

(3) The marketing authorisation holder shall ensure that the information on the medicinal product be regularly supplemented with new scientific findings, including the decisions and recommendations published on the European web portal on medicinal products, established pursuant to Article 26 of Regulation (EC) 726/2004.

(4) The Agency may at any time request that the marketing authorisation holder submit a copy of the master file on the pharmacovigilance system within seven days of receiving the request.

(5) To change the conditions of the marketing authorisation for a medicinal product referring to the provisions of the first, second and third paragraphs hereunder, the marketing authorisation holder must submit an application to the Agency.

(6) The Agency shall accept or refuse the application for the change in marketing authorisation conditions within the deadlines and according to the procedure stipulated by the Regulation (EC) 1234/2008.

(7) The competent minister shall determine more specific conditions, form and content of the documentation required for the variation of marketing authorisation.

Article 63

(Extension of marketing authorisation)

(1) In order to extend the marketing authorisation for a medicinal product, the marketing authorisation holder must submit the application for its extension at least nine months prior to the expiry of the marketing authorisation for a medicinal product for human use and at least six months prior to the expiry of the marketing authorisation for a medicinal product for veterinary use.

(2) The validity of marketing authorisation can be extended after the expiry of the five-year period on the basis of the application for extending the marketing authorisation and reassessment of the risk-benefit balance of the use of medicinal product.

(3) The Agency shall adopt a decision on the extension of marketing authorisation within 90 days of receiving a complete application.

(4) Once the marketing authorisation has been extended for the first time, it shall, as a rule, be valid for an indefinite period of time or until the termination of validity stipulated hereby.

(5) Notwithstanding the previous paragraph, the Agency may, based on justified reasons related to the data from the pharmacovigilance system, including the insufficient number of patients exposed to a certain medicinal product, stipulate that the marketing authorisation is extended for a definite period of five years.

(6) The Agency shall accept or refuse the application for the extension of marketing authorisation according to the mutual recognition procedure or the decentralised procedure on the basis of the assessment report of the medicinal product compiled by the reference EU Member State.

(7) The competent minister shall determine more specific conditions, form and content of the documentation required for the extension of marketing authorisation.

Article 64

(Cancellation and variation of marketing authorisation for medicinal products for human use ex officio)

(1) The marketing authorisation for medicinal products for human use shall be suspended, revoked or amended if the Agency establishes that:

- the medicinal product is harmful;
- the therapeutic efficacy is lacking, i.e. when it is established that therapeutic results cannot be obtained with the medicinal product;
- - the risk-benefit balance is not favourable, or this is evident from the regular safety update report assessment or other data from the pharmacovigilance system;
- - If the marketing authorisation holder does not meet the conditions and obligations from the first and third paragraphs of Article 58 hereof;
- - 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) Marketing authorisation for medicinal products for use in human medicine shall also be suspended, revoked or amended if it is subsequently established that the particulars supporting the application are, incorrect, on the basis of applicable 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 Agency shall cancel or temporarily suspend the marketing authorisation for a medicinal product, a group of medicinal products or all medicinal products for human use which are produced on the basis of a manufacturing authorisation whenever any of the conditions of such manufacturing authorisation is not met.

(4) The Agency may cancel, suspend or amend the marketing authorisation for a medicinal product for human use if the marketing authorisation holder fails to meet the requirements pursuant to the regulations within the deadlines for the cancellation, suspension or variation of the marketing authorisation for the medicinal product concerned as set by the Agency.

(5) In case of urgent measures for the protection of public health, the Agency may temporarily suspend the marketing authorisation for human use and prohibit the use of the medicinal product concerned in the Republic of Slovenia. It shall inform the European Commission, the EMA and authorities competent for medicinal products in other EU Member States by no later than the following working day of the reasons for its actions. Suspension of the marketing authorisation and prohibition to use the medicinal product concerned apply until the Agency renders a decision, adopted ex officio based on measures adopted at the EU level.

(6) The Agency shall amend, suspend or cancel the marketing authorisation for a medicinal product for use in human medicine ex officio based on the adopted measures at the EU level, which in case of urgent action is induced by bodies competent for medicinal products of other EU Member States or of the European Commission.

Article 65

(Cancellation and variation of marketing authorisation for veterinary medicinal products ex officio)

(1) The marketing authorisation for medicinal products for veterinary use shall be suspended, revoked or amended if the Agency establishes that:

- - the assessment of the risk-benefit balance of such medicinal product is unfavourable in terms of the conditions of use as stated in the marketing authorisation, taking into account above all health and wellbeing 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 for which the treatment is intended;
- its qualitative and quantitative composition is not as declared;
- 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 for humans;
- - 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 data from the documentation have not been changed 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 EU Member State or new information on the risk-benefit balance;

- - the medicinal product was marketed contrary to the provisions of the marketing authorisation; or

- - medicinal product was marketed contrary to this Act and the regulations adopted on the basis hereof or the EU regulations on medicinal products.

(2) Marketing authorisation for medicinal products for use in veterinary medicine shall also be suspended, revoked or amended if it is subsequently established that the particulars supporting the application are, pursuant to relevant rules, incorrect, on the basis of applicable 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 Agency shall cancel 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 manufacturing authorisation if any of the requirements of such manufacturing authorisation is not met and cancel or suspend the manufacturing authorisation for such group of medicinal products or all medicinal products.

(4) The Agency may cancel, suspend or amend the marketing authorisation of a medicinal product for use in veterinary medicine if the marketing authorisation holder fails to meet the requirements pursuant to the regulations within the deadlines it set.

(5) In case of urgent measures for the protection of public health, the Agency may temporarily suspend the marketing authorisation for use in veterinary medicine and prohibit the use of the medicinal product concerned in the Republic of Slovenia. It shall inform the European Commission, the EMA and authorities competent for medicinal products in other EU Member States by no later than the following working day of the reasons for its actions. Suspension of the marketing authorisation and prohibition to use the medicinal product concerned apply until the Agency renders a decision, adopted ex officio based on measures adopted at the EU level.

(6) The Agency shall amend, suspend or cancel the marketing authorisation for a medicinal product for use in veterinary medicine ex officio based on the adopted measures at the EU level, which in case of urgent action is triggered by authorities competent for medicinal products of other EU Member States or the European Commission.

Article 66

(Termination of validity of marketing authorisation)

(1) The validity of the marketing authorisation shall expire:

- - after the expiry of authorisation validity;

- - based on the applicants application for the cancellation of marketing authorisation; or

- - because of the withdrawal of the marketing authorisation for a medicinal product pursuant to Articles 64 or 65 hereof.

(2) The Agency shall initiate the procedure for the termination of validity of a marketing authorisation for a medicinal product referred to in indent 2 and 3 from the previous paragraph:

- ex officio, or

- based on the application of the relevant marketing authorisation holder.

(3) The competent minister shall determine the detailed content of the application and the procedure for the termination of marketing authorisation.

Article 67

(Sale of medicinal product following the amendment or expiry of validity of marketing authorisation)

(1) A medicinal product whose marketing authorisation has been amended and which has been manufactured, entered or imported prior to the notification or approval of amendment to the marketing authorisation may be marketed until the expiry date of such medicinal product, unless prohibited or stipulated otherwise by the Agency, based on the assessment of the risk-benefit balance, with the aim of protecting public health.

(2) A medicinal product whose marketing authorisation has expired or is no longer valid upon the proposal of the marketing authorisation holder for a medicinal product which has been manufactured, entered or imported prior to the expiry of marketing authorisation may be marketed until the expiry date of such medicinal product, subject to a proposal of the marketing authorisation holder, received by the Agency at least two months before the expiry of validity, but for no longer than 18 months after the expiry of the marketing authorisation, unless objected by the Agency in 30 days following the day of receipt of the proposal. The marketing authorisation holder shall commit, in its proposal, to provide for further implementation of pharmacovigilance tasks.

(3) The Agency may object to the proposal referred to in the previous paragraph or prohibit the sale of a medicinal product at any time within the 18-month period, based on the assessment of the risk-benefit balance in the interest of protecting public health.

Article 68

(Documentation as trade secret)

The documentation enclosed in the application for the issue of, amendment to or extension of a marketing authorisation is the property of the applicant and a trade secret, with the exception of data stated in the marketing authorisation, the summary of product characteristics of the medicinal product, its instructions for use and data on the packaging.

Article 69

(Publication of data on marketing authorisation for a medicinal product)

The Agency shall publish, on its website the data or links to the data on medicinal products for human use, for which a marketing authorisation has been issued or for which the validity of marketing authorisation has expired or has been amended, extended, suspended or revoked.

Article 70

(Transfer of marketing authorisation)

(1) A marketing authorisation holder may transfer its marketing authorisation to another business entity that meets the conditions stipulated herein.

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

V. ADVANCED THERAPY MEDICINAL PRODUCTS PREPARED ON A NON-ROUTINE BASIS

Article 71

(Advanced therapy medicinal products)

(1) The marketing authorisation for advanced therapy medicinal products must be obtained according to the centralised procedure in line with Regulation (EC) 1394/2007 and Regulation (EC) 726/2004 except for advanced therapy medicinal products prepared on a non-routine basis, the preparation of which requires authorisation referred to in Article 83 hereof.

(2) Advanced therapy medicinal product prepared on a non-routine basis for human or veterinary use may be prepared by a business entity holding the Agency's authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis in accordance with the quality standards and conditions for the preparation, stipulated hereby, in the framework of the issued authorisation. A medicinal product prepared on a non-routine basis is prepared on an individual written purchase order issued by a physician or veterinarian, which is a type of

medical or veterinarian prescription on the basis of which a physician or veterinarian prescribes an advanced therapy medicinal product prepared on a non-routine basis for the treatment of a patient or an animal with the healthcare or veterinary activity provider.

(3) The holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis shall be responsible for the quality, safety and efficiency of advanced therapy medicinal products prepared on a non-routine basis.

(4) When an advanced therapy medicinal product contains human cells or tissues, the donation, procurement and testing of these cells or tissues is carried out pursuant to the regulations governing the supply of human cells or tissues intended for the treatment.

Article 72

(Conditions for the preparation of advanced therapy medicinal product prepared on a non-routine basis)

(1) A business entity that prepared advanced therapy medicinal products prepared on a non-routine basis shall fulfil the following conditions:

1. It shall employ an adequate number of experts with adequate qualifications depending on the extent and complexity of the preparation of the non-routine advanced therapy medicinal product;
2. It shall be equipped with adequate facilities, devices and equipment for the preparation, control, storage and transport of advanced therapy medicinal products prepared on a non-routine basis;
3. It shall appoint, from among the experts from item 1 hereunder a person responsible for the quality of advanced therapy medicinal products prepared on a non-routine basis who shall be responsible for ensuring that the preparation of the advanced therapy medicinal products prepared on a non-routine basis is in compliance with this Act and the implementing regulations based on it;
4. It shall maintain a quality assurance system that it updates regularly,
5. It shall mutatis mutandis comply with the guidelines and principles of good manufacturing practice, taking into account the specific features of advanced therapy medicinal products prepared on a non-routine basis and the produced risk assessment and shall ensure at least the standards stipulated in the regulations of the Republic of Slovenia covering the supply of human cells or tissues intended for treatment;
6. It shall have concluded adequate agreements with business entities providing materials and services that affect the quality and safety of advanced therapy medicinal products prepared on a non-routine basis, which specify the responsibilities and tasks, and professional qualification of all contracting parties;
7. It shall arrange, in accordance with good distribution practices, for the transport of advanced therapy medicinal products prepared on a non-routine basis to the client.

(2) Full traceability from the donor to the recipient of these medicinal products must be ensured for the preparation and use of advanced therapy medicinal products prepared on a non-routine basis containing or composed from human tissues and cells.

(3) The minister shall determine more detailed conditions regarding the employees, premises and equipment for the preparation of advanced therapy medicinal product prepared on a non-routine basis and the method of using the guidelines and the principles of good manufacturing practice in the preparation of advanced therapy medicinal products prepared on a non-routine basis.

Article 73

(Person responsible for quality)

The responsible person from item 3 of the first paragraph of the previous Article shall have a medical or veterinary degree or a degree in pharmacy or other relevant second cycle biomedical studies, or an equivalent degree corresponding to this level pursuant to the law, additional knowledge and skills in this area and at least two years of practical experience in the area of the preparation of advanced therapy medicinal products prepared on a non-routine basis.

Article 74

(Obligations of the holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis)

(1) A holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis shall:

1. Use material and reagents of appropriate quality in accordance with the principles and guidelines of good manufacturing practice and, if such do not exist, the material and reagents of the highest quality, based on expert justification;
2. Have established a risk management system which is mutatis mutandis compliant with the guidelines and principles of good manufacturing practice, taking into account the specific features of advanced therapy medicinal products prepared on a non-routine basis and the produced risk assessment and ensure at least the standards stipulated in the regulations of the Republic of Slovenia covering the supply of human cells or tissues intended for treatment;
3. Have established a quality control system for advanced therapy medicinal products prepared on a non-routine basis which is mutatis mutandis compliant with the guidelines and principles of good manufacturing practice, taking into account the specific features of advanced therapy medicinal product prepared on a non-routine basis and a risk assessment and ensure at least the standards stipulated in the regulations of the Republic of Slovenia covering the supply of human cells or tissues intended for treatment;
4. Ensure that all tests required for approving compliance with the specifications and standards are carried out on the samples of input material and the end product of advanced therapy medicinal product prepared on a non-routine basis or an intermediate product;
5. Issue the client a certificate of compliance for the preparation of advanced therapy medicinal products prepared on a non-routine basis with the specifications and standards provided by the authorisation holder;
6. Obtain a positive opinion of the NMEC for the preparation of individual groups of human medicinal products, namely separately for the medicinal products used for gene therapy, somatic cell therapy and tissue engineered products;
7. Pay special care to ensuring that all information on input material, intermediate products and final advanced therapy medicinal products prepared on a non-routine basis, including the data on incompatibility of individual components of a multi-component advanced therapy medicinal product prepared on a non-routine basis and the packaging, which are relevant for the assessment of safety, quality and efficiency, are true and are not misleading;
8. Ensure that the information referred to in the previous item and all records on the details of the preparation of advanced therapy medicinal products prepared on a non-routine basis are stored in such a form that they are available and readable for at least 30 years following the use of advanced therapy medicinal products prepared on a non-routine basis.

(2) A holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis may not:

1. Prepare advanced therapy medicinal products prepared on a non-routine basis that are not covered by the authorisation for preparation of non-routine advanced therapy medicinal products;
2. Prepare advanced therapy medicinal products prepared on a non-routine basis at locations and in facilities that are not specified in the authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis;
3. Prepare advanced therapy medicinal products prepared on a non-routine basis in premises not specified in the documentation used as the basis for the issue of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis;
4. Perform other activities in the same premises without having acquired the consent of the Agency;

5. Prepare advanced therapy medicinal products prepared on a non-routine basis which contain human tissues and cells if the donation, procurement of human tissues and cells and testing of donors of human tissues and cells had not been carried out in accordance with the fourth paragraph of Article 71 hereof;

6. Prepare advanced therapy medicinal products prepared on a non-routine basis for the purpose of clinical trials.

Article 75

(Reporting)

(1) The holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis shall submit to the Agency the annual report on its activities by 31 January of the current year for the previous year, which shall contain the following data:

- - number of advanced therapy medicinal products prepared on a non-routine basis;
- - prepared advanced therapy medicinal product prepared on a non-routine basis for advanced treatment for which the Agency has issued the authorisation;
- - number of patients or animals treated with individual advanced therapy medicinal product prepared on a non-routine basis;
- - name of the physician or veterinarian who prescribed the advanced therapy medicinal product prepared on a non-routine basis and is responsible for the monitoring of patient or animal;
- name of the donor centre.

(2) A holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis for use in veterinary medicine shall submit the data on the medicinal product for veterinary use from the previous paragraph to the body competent for veterinary medicine within the deadline specified in the previous paragraph.

Article 76

(Exit and export and entry and import of advanced therapy medicinal product prepared on a non-routine basis)

Exit and export and entry and import of advanced therapy medicinal products prepared on a non-routine basis shall be prohibited.

Article 77

(Responsibility of the physician or veterinarian)

(1) A physician or veterinarian shall prescribe and use an advanced therapy medicinal product prepared on a non-routine basis subject to their exclusive professional liability.

(2) In the case of a provider of healthcare or veterinary services, the physician or the veterinarian prescribing and using advanced therapy medicinal products prepared on a non-routine basis shall cover their professional liability for potential damages caused to the patient or the animal in the amount of at least EUR 100,000.

(3) Before using an advanced therapy medicinal product prepared on a non-routine basis for a patient or the owner or keeper of an animal, the physician or veterinarian must inform the latter with the process of treatment and the risks involved in the treatment by advanced therapy medicinal products prepared on a non-routine basis. The physician or veterinarian shall store a statement signed by a patient or owner or keeper of animal that they have been duly informed, in the form available on the Agency's website.

(4) Upon the use of an advanced therapy medicinal product prepared on a non-routine basis, the physician or veterinarian shall submit to the patient or owner or keeper of animal the package insert.

(5) The physician or veterinarian may not use the advanced therapy medicinal product prepared on a non-routine basis without the certificate of conformity of the preparation of advanced therapy medicinal products prepared on a non-routine basis with the specifications and guidelines and the principles of good manufacturing practice, issued by the holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis.

(6) The physician or the veterinarian prescribing and using an advanced therapy medicinal product prepared on a non-routine basis shall have established a system that enables traceability of the used advanced therapy medicinal product prepared on a non-routine basis for each patient or animal and product.

(7) The physician or veterinarian shall monitor the progress of treatment of a patient or animal for which an advanced therapy medicinal product prepared on a non-routine basis was used.

Article 78

(Register of physicians or veterinarians using advanced therapy medicinal products prepared on a non-routine basis for treatment)

(1) The physician or the veterinarian prescribing and using an advanced therapy medicinal product prepared on a non-routine basis shall be entered in the Agency register of physicians or veterinarians using advanced therapy medicinal products prepared on a non-routine basis for treatment.

(2) The application for entry in the register of physicians or veterinarians using advanced therapy medicinal products prepared on a non-routine basis for treatment shall be submitted to the Agency by the provider of healthcare or veterinary activity no later than 15 days prior to the beginning of prescribing and using advanced therapy medicinal products prepared on a non-routine basis and shall contain:

- - the name, surname, academic title and biographic and bibliographic details of physicians or veterinarians using advanced therapy medicinal products prepared on a non-routine basis for treatment, with appropriate specialisation;
- - the name and address of the provider of healthcare or veterinary activity in which the physician or veterinarian from the previous indent uses advanced therapy medicinal products prepared on a non-routine basis;
- - an insurance policy copy for covering the liability of a physician or veterinarian in accordance with the second paragraph of the previous Article.

(3) The provider of healthcare or veterinary activity shall inform the Agency of any change to the data indicated in the previous paragraph within seven days.

(4) The Agency shall delete a physician or veterinarian from the register referenced in the first paragraph hereunder upon a request of the provider of healthcare or veterinary activity from the previous paragraph.

(5) The minister shall determine in greater detail the procedure and the contents of the application for the entry into, change of or deletion from the register of physicians or veterinarians that use non-routine advanced therapy medicinal devices.

Article 79

(Labelling of advanced therapy medicinal product prepared on a non-routine basis)

(1) An advanced therapy medicinal product prepared on a non-routine basis must be adequately labelled and equipped with the package insert ensuring its traceability and correct and safe use.

(2) The competent minister shall determine the detailed requirements regarding the labelling of advanced therapy medicinal products prepared on a non-routine basis.

Article 80

(Traceability of advanced therapy medicinal products prepared on a non-routine basis)

(1) The holder of authorisation for the preparation of an advanced therapy medicinal product prepared on a non-routine basis shall set up and maintain a system that ensures traceability of advanced therapy medicinal products prepared on a non-routine basis and the input substances and raw materials, including the materials that come into contact with tissues and cells that can be contained in the advanced therapy medicinal products prepared on a non-routine basis, from the origin, through preparation, packaging, storage, transportation and up to the delivery to the provider of healthcare or veterinary activity in which the advanced therapy medicinal product prepared on a non-routine basis is used.

(2) The holder of authorisation for the preparation of an advanced therapy medicinal product prepared on a non-routine basis shall store data on traceability for at least 30 years after the

expiry of the shelf life of an advanced therapy medicinal product prepared on a non-routine basis.

(3) The holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis shall ensure that the data on traceability is available to the Agency also in the event of revocation, cancellation or withdrawal of the authorisation. In case of bankruptcy or discontinuation of activity it shall deliver the data on traceability to

(4) The holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis must ensure that the system of traceability for an advanced therapy medicinal product prepared on a non-routine basis containing human tissues and cells supplements and is compatible with the requirements from Articles 8 and 14 of the Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (Official Journal L 102, 7. 4. 2004, p. 48), last amended by Regulation 596/2009/EC, and Articles 14 and 24 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 (Official Journal, L 33, 8. 2. 2003, p. 30), last amended by Regulation 596/2009/EC.

Article 81

(Advertising of advanced therapy medicinal product prepared on a non-routine basis)

Advertising of advanced therapy medicinal products prepared on a non-routine basis, preparation of advanced therapy medicinal products prepared on a non-routine basis or treatment with advanced therapy medicinal products prepared on a non-routine basis shall be prohibited.

Article 82

(Pharmacovigilance of advanced therapy medicinal product prepared on a non-routine basis)

(1) The holder of authorisation for the preparation of advanced therapy medicinal product prepared on a non-routine basis shall have a pharmacovigilance system that supports the gathering and keeping of the documentation on all suspected adverse reactions of an advanced therapy medicinal product prepared on a non-routine basis pointed out by the physicians and patients or veterinarians or owners or keepers of animals, scientific evaluation of all information, monitoring safety or the risk-benefit balance, establishment of changes in the risk-benefit balance, studying the possibility to minimise or prevent risks, informing the Agency of identified new or changed risks and changed risk-benefit balances, and adoption of adequate measures.

(2) The holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis shall have at their disposal a qualified person responsible for pharmacovigilance, working under contract and being available at all times, who is responsible for the establishment and operation of the pharmacovigilance system.

(3) The person responsible for pharmacovigilance shall have a second cycle degree in medical or veterinary studies, or an equivalent degree corresponding to this level of knowledge pursuant to the law in the field of pharmacovigilance. If the person responsible for the pharmacovigilance does not have an adequate second cycle degree in medical or veterinary studies, or an equivalent degree corresponding to this level of knowledge pursuant to the law, they must receive permanent and uninterrupted professional support from a person with adequate education.

(4) The holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis shall, upon a written request of the Agency, submit a risk management plan in the area of pharmacovigilance with a description of activity in the pharmacovigilance system and measures for identifying, defining, preventing or minimising risks arising from advanced therapy medicinal product prepared on a non-routine basis, including the impact assessment of the indicated activities and measures.

(5) The holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis shall immediately and no latter later within 15 days of establishment, inform the Agency of all suspected adverse reactions of an advanced therapy medicinal product prepared on a non-routine basis pointed out by the physicians and patients or veterinarians, owners or keepers of animals.

(6) A physician or a veterinarian shall be obliged to report to the Agency, immediately and no later than within 15 days of the day of establishment, about all suspected adverse reactions of an advanced therapy medicinal product prepared on a non-routine basis.

(7) The patients or the owners or keepers of animals may report any suspected adverse reactions of an advanced therapy medicinal product prepared on a non-routine basis to the physician or veterinarian or directly to the Agency.

Article 83

(Procedure for the issue of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis)

(1) A business entity with the registered office in the Republic of Slovenia can prepare an advanced therapy medicinal product prepared on a non-routine basis only on the basis of and in compliance with the authorisation issued by the Agency for the preparation of advanced therapy medicinal products prepared on a non-routine basis.

(2) The procedure for the issue of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis shall begin with an application submitted by an applicant that is a business entity with the registered office in the Republic of Slovenia for the preparation of individual types of advanced therapy medicinal product prepared on a non-routine basis, namely separately for medicinal products used for gene therapy, somatic cell therapy and tissue engineered products, indicating individual medicinal products in a group.

(3) The Agency shall issue or refuse the issue of the authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis within 180 days of receiving a complete application on the basis of an opinion issued by an expert commission for the establishment of fulfilment of conditions for the activity of preparation of advanced therapy medicinal products prepared on a non-routine basis and, if necessary, independent external experts in gene therapy, somatic cell therapy and tissue engineering, on the fulfilment of conditions stipulated herein.

(4) The Agency may request additional documents and/or data it requires to adopt a decision on the issue of the authorisation for the preparation of an advanced therapy medicinal product prepared on a non-routine basis pursuant to paragraph six of Article 3 hereof.

Article 84

(Application for the issue of authorisation for the preparation of advanced therapy medicinal product prepared on a non-routine basis)

(1) An application for obtaining authorisation for the preparation of an advanced therapy medicinal product prepared on a non-routine basis shall contain:

- - evidence on the fulfilment of conditions regarding the assurance of quality system, personnel, premises, equipment, traceability and pharmacovigilance system;
- - list of advanced therapy medicinal product prepared on a non-routine basis from the group of advanced therapy medicinal products to which the application refers;
- - description of procedures for the preparation of advanced therapy medicinal products prepared on a non-routine basis which shall contain the data on risk factors, such as the data on the origin and characteristics of cells, type of cell manipulation and method of use;
- - a positive opinion of the NMEC for the relevant group of advanced therapy medicinal products for human use to which the application refers.

(2) The minister shall determine the detailed content of the application, the requirements regarding the description of the preparation procedures for the specific group of advanced therapy medicinal products prepared on a non-routine basis, the method of establishing the fulfilment of conditions for obtaining the authorisation as well as the content of the required documentation.

Article 85

(Change in the conditions for the preparation of advanced therapy medicinal products prepared on a non-routine basis)

(1) The holder of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis shall inform the Agency of the changes to conditions that affect the issue of an authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis within no later than 15 days of the occurrence of such change.

(2) The Agency shall consider the application for the change referred to in the previous paragraph and shall reach a decision on the required procedures. The Agency shall adopt the decision within 30 days of receiving a complete application. If it is required to verify the conditions on site or obtain an opinion from an expert commission for the establishment of fulfilment of conditions for the activity of preparation of advanced therapy medicinal products prepared on a non-routine basis or an additional opinion from an external expert, referred to in the third paragraph of Article 83 hereof, the Agency shall issue a decision within 180 days of the day of receiving a complete application.

(3) The competent minister shall determine in greater detail the contents of the application for the change of conditions on the basis of which the authorisation from Article 83 hereof has been issued and specify the conditions and the method of establishing that such conditions are met.

Article 86

(Revocation of authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis)

(1) The authorisation for the preparation of an advanced therapy medicinal product prepared on a non-routine basis shall be temporarily suspended or revoked should the pharmaceutical inspector ascertain that the business entity to which the authorisation has been issued fails to satisfy the requirements defined in Article 72 hereof and the regulations adopted on the basis hereof, which also serves as the basis for prohibiting the performance of the activity.

(2) Should the Agency establish, by perusing the Slovenian Business Register, that the business entity which is the authorisation holder has already been deleted therefrom, the Agency shall establish ex officio that the authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis ceased to be valid.

(3) The authorisation for the preparation of an advanced therapy medicinal product prepared on a non-routine basis shall also be revoked on the proposal of the holder of authorisation for preparation of advanced therapy medicinal products prepared on a non-routine basis.

VI. LABELLING AND PACKAGE INSERT Article 87

(Labelling and package leaflet)

(1) A medicinal product put on the market on the basis of the first or the second paragraph of Article 20 hereof and medicinal products referred to in indent 2, 3, and 4 of the third paragraph of Article 20 hereof, intended for dispensing in pharmacies or specialised stores, shall be labelled in the Slovene language on the outer packaging or, if one does not exist, on the immediate packaging, at least with the data on medicinal product, the marketing authorisation holder, method of dispensing, method of use, required warnings, shelf life and other data for ensuring traceability and safe use of medicinal products. Data must be legible, understandable and indelible.

(2) The provisions of the previous paragraph shall not apply to medicinal products with authorisation for compassionate use.

(3) A medicinal product placed on the market there must be a package insert containing instructions for use in the Slovene language in line with the summary of product characteristics, unless the information stipulated in the provision of the seventh paragraph hereof is given on the outer packaging or, where there is no outer packaging, on the immediate packaging. Data must be legible and understandable for the end user.

(4) The data for labelling and package insert of a medicinal product, in accordance with the first and the second paragraph hereunder, can be provided in one or several foreign languages, in addition to the Slovene language, while ensuring the legibility of data in the Slovene language.

(5) Regardless of the provisions of the first and second paragraphs hereunder, the Agency may exceptionally allow, taking into account the measures required for protecting public health:

- - use of packaging in a foreign language with a label in the Slovene language and the package insert in a foreign language if the package insert in the Slovene language is added to the medicinal product in the prescribed way in printed form and can also be available in electronic form for medicinal products for which it is established that they are indispensable for the protection of public health and that the requirement for the manufacturing of the medicinal product with labelling and package insert in the Slovene language would be disproportionate because of the limited scope of their use;

- - full or partial exemption from the provisions of the first and second paragraph hereunder for medicinal products intended for direct dispensing to patients in pharmacies or in the case of serious problems related to accessibility.

(6) The name of the medicinal product for human use on the packaging must also be printed in Braille. Marketing authorisation holder shall ensure that the packaging insert is available in the forms suitable for the blind and the partially sighted, if proposed by competent patient organisations.

(7) The minister shall determine a more detailed manner of labelling medicinal products, the form and contents of the package insert and the manner of using the labels, special labelling conditions and package inserts for individual medicinal products or groups of medicinal products.

Article 88

(Safety feature)

(1) In addition to the obligations from the previous Article, the manufacturer of medicinal products for human use shall affix a safety feature to the medicinal product, which allows for the verification of authenticity of medicinal product and identification of individual packaging.

(2) The manufacturer shall attach the safety feature to the medicinal products dispensed upon prescription, with the exception of those put on the list published by the European Commission and can be marketed without the safety feature, and for medicinal products dispensed without prescription and which the European Commission defines as those requiring the safety features.

(3) In addition to the safety feature, the manufacturer shall also provide a device for discovering a breach in the outer packaging.

(4) The above safety feature need not to be attached to radiopharmaceuticals.

(5) The marketing authorisation holder may only partially or completely remove or cover the safety feature on the medicinal product:

- if authenticity of a medicinal product has been identified in advance and established that there was no breach of packaging;

- if the removed or covered safety features are replaced with new ones that are equal as regards the possibility of verifying authenticity, identification and intactness; The replacement is carried out without opening the immediate packaging;

- if the replacement of safety features is carried out in accordance with good manufacturing practices for medicinal products.

(6) Characteristics and specifications of safety features and the devices for discovering a breach in the outer packaging shall be defined by the European Commission.

Article 89

(Message to the European Commission)

The Agency may communicate to the European Commission a different justified assessment of the adequacy of including individual medicinal products or categories of medicinal products in view of the obligation to affix protective elements.

VII. MANUFACTURE OF MEDICINAL PRODUCTS, ACTIVE INGREDIENTS AND CERTAIN EXCIPIENTS

1. **MEDICINAL PRODUCTS**

Article 90

(Authorisation for the manufacturing of medicinal products)

(1) Business entity may manufacture medicinal products only after they have been granted a manufacturing authorisation and in compliance with such authorisation.

The authorisation includes the manufacturing of medicinal products and their sales to business entities referred to in indent 1 of the second paragraph, the third and fourth paragraph of Article 104 hereof and must be obtained for:

- - an individual manufacturing site;
- - an individual manufacturing activity;
- - individual pharmaceutical forms, and
- - import of medicinal products from third countries.

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

(3) The medicinal product manufacturing activities and the pharmaceutical forms are stipulated in the Compilation of European Union Procedures on Inspection and exchange of Information (hereinafter: The Compilation of Community Procedures), as currently valid and published by the European Commission on its websites.

Article 91

(Conditions for the manufacturing of medicinal products)

The manufacturer of medicinal products shall fulfil the following conditions: 1. Given the volume and complexity of their medicinal product manufacture, to employ an adequate number of professionals holding second cycle degrees, or an equivalent degree corresponding to this level of knowledge in pharmacy, chemistry, chemical technology, medicine, stomatology, veterinary medicine or other appropriate discipline with adequate skills depending on the subject of operations;

2. They shall have concluded a contract with a responsible person adequately skilled to release individual batches 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 on the basis of a contract only in one of the members of the group, provided that there exists adequate legal and organisational delimitation of responsibilities and competencies.

3. 3. They shall have at their disposal adequate facilities, devices and equipment for the manufacture, control, storage and dispatching of medicinal products in accordance with the principles of good medicinal device manufacturing practice.

4. Manufacturing of medicinal products shall be performed in accordance with the guidelines and good manufacturing practices for medicinal products and active substances may be used that have been produced in accordance with good manufacturing practices for active substances and distributed in accordance with good distribution practice for active substances;

5. The qualified person referred to in the item 2 hereunder shall have the possibility to independently perform its tasks and have access to all necessary means.

Article 92

(Responsible person for releasing individual series of medicinal products)

(1) The responsible person for releasing individual batches of medicinal products from item 2 of the previous Article shall have a second cycle degree or other relevant level of education corresponding to this level pursuant to the law in pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry, technology or biology.

(2) The obtained degree referred to in the previous paragraph shall comprise the knowledge of applied physics, general and inorganic chemistry, organic chemistry, analytical chemistry, pharmaceutical chemistry, including the analysis of medicinal products, general and applied medical biochemistry, physiology, microbiology, pharmacology, pharmaceutical technology, toxicology and pharmacognosy.

(3) If the programme of studies shall not comprise either of the skills from the previous paragraph, the qualified person must submit appropriate evidence of having obtained such additional training.

(4) In addition to the training required hereunder, the responsible person shall have acquired practical experience over at least two years, at manufacturers of medicinal products holding adequate authorisations, in the activities of qualitative analysis of medicinal products, quantitative analysis of active substances and testing and verification necessary to ensure the quality of medicinal products. The period of required of practical experience may be reduced by one year where a study programme from the second paragraph hereunder lasts for at least five years and by a year and a half where the course lasts for at least six years.

Article 93

(Obligations of manufacturers of

medicinal products) Medicinal product

manufacturer:

1. Has available and may place on the market only medicinal products produced in accordance with the medicinal product marketing authorisation and the manufacturing authorisation;

2. Verifies the compliance of the manufacturers and the suppliers of active substances with good manufacturing practice or good distribution practice for active substances or with both by carrying out audits;

3. Ensures that excipients are suitable for use in medicinal products based on a documented assessment of risk in accordance with the guidelines of the European Commission stipulating good manufacturing practice in the area of excipients;

4. Verifies and makes sure that manufacturers, importers or suppliers from which they obtained the active substances were duly entered into registers with the competent authority of the EU Member State in which they have a registered office;

5. If it obtains information that medicinal products on the market that otherwise fell within the framework of their medicinal product marketing authorisation were falsified, or suspicion exists that they were falsified, it shall immediately inform the Agency and the marketing authorisation holder thereof, regardless of whether the falsified medicinal products were introduced on the market through an illegal or legal supply chain;

6. Provides for the authenticity and quality of active substances and excipients used;

7. Ensures that the safety features referred to in Article 88 hereof are attached to the external packaging in medicinal products intended to be marketed in the European Union;

8. If the safety features on the medicinal product are partially or fully removed or covered, ensures that these activities are implemented in accordance with the fifth paragraph of Article 88 hereof.

Article 94

(Procedure for obtaining authorisation for manufacturing medicinal products)

(1) The procedure for issuing a manufacturing authorisation shall be initiated on the basis of an application submitted by a business entity with a registered office in the Republic of Slovenia. The application for obtaining a manufacturing authorisation shall contain evidence on the fulfilment of conditions set out in Article 91 hereof.

(2) The Agency shall issue or refuse to issue a manufacturing authorisation within 90 days of receiving a complete application on the basis of an opinion of the expert commission for establishing the fulfilment of conditions for manufacturing medicinal products.

(3) The authorisation referred to in the previous paragraph may be issued for a definite period of time or under certain conditions.

(4) The Agency may request additional documents and/or data it requires to decide on the issue of the manufacturing authorisation in accordance with paragraph six of Article 3 hereof.

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

(6) The competent minister shall determine the detailed contents of the application, the conditions and the method of establishing the fulfilment of the conditions to obtain a manufacturing authorisation, the substance and form of the required documentation and authorization as well as the naming of the manufacturing activity.

Article 95

(Certificate of good manufacturing practice)

(1) The pharmaceutical inspector shall issue ex officio a certificate of good manufacturing practice to the inspected business entity within 90 days of the date of the inspection, should it be established that the business entity implements the activity of medicinal product manufacture in accordance with the guidelines and principles of good manufacturing practice for medicinal products or active substances or no later than within 15 days of the issue or change in the manufacturing authorisation or the entry or change in the register of manufacturers of active substances.

(2) The pharmaceutical inspector may ex officio by a decision invalidate the certificate of good manufacturing practice should it be established during the inspection that the holder of the manufacturing authorisation for medicinal products or the business entity, which is entered in the register of manufacturers of active substances, has failed to implement the activity in accordance with the guidelines and principles of good manufacturing practice for medicinal products or active substances.

(3) The certificate of good manufacturing practice shall be issued on a form written in the Slovenian and English languages, as defined in the Compilation of European Union Procedures.

(4) The competent minister shall determine in greater detail the procedure of issuing and revoking the certificate of good manufacturing practice.

Article 96

(Amended conditions for the manufacturing of medicinal products)

(1) The manufacturing authorisation holder shall inform the Agency of any change in the conditions stipulated under Article 91 hereof which served as the basis for issuing the manufacturing authorisation no later than within 15 days of the occurrence of such change.

(2) The Agency shall consider the application to change the conditions referred to in the previous paragraph and shall reach a decision within 30 days of receiving a complete application, except when special inspection is required for verifying the conditions on site, in which case authorisation shall be issued within 90 days of receiving the complete application.

(3) The competent minister shall determine in greater detail the contents of the application to change the conditions for issuing the medicinal product manufacturing authorisation and specify the conditions and the procedures for establishing whether such conditions for issuing a manufacturing authorisation or for issuing a decision on the assessed compliance of the change with the conditions for performing medicinal product manufacture have been met.

Article 97

(Revocation of manufacturing authorisation)

(1) A manufacturing authorisation shall be suspended or revoked, should the pharmaceutical inspector ascertain that the manufacturer of medicinal products did not meet the conditions defined in Article 91 hereof and the regulations adopted on the basis hereof, which also serves as the basis for prohibiting the performance of activity.

(2) The authorisation may also be revoked on the manufacturing authorisation holder's proposal.

(3) Should the Agency establish, by perusing the Slovenian Business Register, that the business entity which is the holder of authorisation for the manufacturing of medicinal products has already been deleted therefrom, it shall establish ex officio that the authorisation ceased to be valid.

Article 98

(Assessment of risk management adequacy in medicinal product manufacture)

The Agency may, on the manufacturing authorisation holder's proposal, issue an assessment of the risk management adequacy in the process of introducing medicinal products which contain new groups of special substances pursuant to the Compilation of Community Procedures in the manufacturing process.

Article 99

(Register of persons responsible for releasing medicinal products)

(1) The Agency shall keep a publicly available register of persons responsible for releasing individual batches of medicinal products, which shall include the persons responsible for releasing individual batches of medicinal products that comply with the conditions referred to in Article 92 hereof.

(2) The register of persons responsible for releasing individual batches of medicinal products shall include the following data:

- - name and surname and the professional title of the person responsible for releasing individual batches of medicinal products;
- - name and address of the business entity where they perform the tasks as the person responsible for releasing individual batches of medicinal products;
- - name and address of the manufacturing site where they perform the tasks as the person responsible for releasing individual batches of medicinal products.

(3) The application for the entry in, change of and deletion from the register referred to in the first paragraph hereunder may be filed by the applicants for and the holders of the manufacturing authorisations for medicinal products in the Republic of Slovenia.

(4) The Agency shall enter, change or delete the person responsible for releasing individual batches of medicinal products from the register referred to in the first paragraph hereunder within eight days of receiving a complete application and issue a certificate related thereto upon the request of the applicant.

(5) The Agency shall delete the person responsible for releasing individual batches of medicinal products from the register referred to in the first paragraph hereunder on the proposal by the applicant for the entry in the register, in the event the Agency cancels the manufacturing authorisation and in the event the manufacturing authorisation holder has been deleted from the Slovenian Business Register.

(6) The competent minister shall determine in greater detail the contents of the application for the entry in, change of or deletion from the register of the persons responsible for releasing individual batches of medicinal products as well as the conditions and the method of establishing whether the conditions for the entry in, change of or deletion from the register have been met.

2. **Active substances**

Article 100

(Conditions for the manufacturing of active substances)

(1) A manufacturer of active substances shall meet the following conditions: 1. Employ an adequate number of experts with adequate qualifications depending on the extent and complexity of the manufacture of active substances;

2. Shall have at their disposal adequate facilities, devices and equipment for the manufacture, control, storage and transport of active substances in accordance with the guidelines and principles of good manufacturing practice for active substances;

3. Shall perform the activity in accordance with the guidelines and principles of good manufacturing practice for active substances.

(2) A manufacturer of active substances shall forthwith inform the Agency and the manufacturing authorisation holder about any falsified active substances or any suspicion thereof.

Article 101

(Procedure for the entry in the register of manufacturers of active substances)

(1) A manufacturer of active substances with the registered office in the Republic of Slovenia, may start performing its activity after it has been entered in the register of manufacturers of active substances, kept by the Agency.

(2) The register of manufacturers of active substances shall include the following data:

- name, permanent address and contact information of the business entity (telephone, fax and e-mail); and
- active substances manufactured.

(3) The Agency shall issue a certificate upon entry in the register referred to in the first paragraph hereunder.

(4) The manufacturers of active substances shall notify their activity to the Agency at least 60 days before they start performing the activity, based on a written application which shall include the evidence that the conditions referred to in the first paragraph of the previous Article have been met, and a list of active substances they plan to manufacture.

(5) The Agency shall enter the manufacturer of active substances in the register of active substance manufacturers on the basis of a positive opinion of the expert commission for the establishment of fulfilment of conditions for manufacturing of medicinal products 90 days of receiving the complete application or 60 days if it estimates that the fulfilment of conditions need not be verified.

(6) Should the above referenced expert commission issue a negative opinion on the fulfilment of the conditions for performing the manufacture of active substances, the Agency shall refuse the entry in the register of manufacturers of active substances and issue a decision thereon.

(7) The Agency may request additional documents and/or data it requires to adopt a decision on the entry in the register of manufacturers of active substances in accordance with paragraph six of Article 3 hereof.

(8) The Agency may delete the manufacturer of active substances from the register of manufacturers of active substances, should the pharmaceutical inspector ascertain that the manufacturer of active substances did not meet the conditions from the previous article hereof and the regulations adopted on the basis hereof, which also serves as the basis for prohibiting the performance of activity. The Agency may delete the manufacturer of active substances from the register of manufacturers of active substances also on the manufacturer's proposal and if it establishes, by perusing the Slovenian Business Register, that the manufacturer of active substances has been deleted therefrom. The Agency shall issue a decision on the deletion from the register of manufacturers of active substances.

(9) The documentation from the application for notification in the register of manufacturers of active substances shall be deemed a business secret if defined as such by the applicant, in accordance with the regulations, except for the data referred to in the second paragraph hereunder.

(10) The Agency shall publish on its website the list of manufacturers of active substances which have been entered in the register of manufacturers of active substances, containing the name of the business entity and its permanent address.

(11) The competent minister shall determine in greater detail the contents of the application, the conditions, the method and the procedures required for the notification and deletion from the register of manufacturers of active substances as well as the contents of the register of manufacturers of active substances.

Article 102

(Amended conditions for the manufacturing of active substances)

(1) The manufacturer of active substances shall inform the Agency about any change in the conditions referred to in Article 100 hereof that significantly affects the quality or safety of the active substance it manufactures within seven days at the latest.

(2) The Agency shall enter the change referred to in the previous paragraph into the register of manufacturers of active substances based on an opinion of the expert commission for the establishment of fulfilment of conditions for manufacturing active substances within 90 days and shall issue a certificate thereon and/or enter the change referred to in the previous paragraph into the register of manufacturers of active substances within 30 days of receiving the complete application, if it estimates that the fulfilment of conditions need not be verified and issues a certificate thereon.

(3) In the event the change referred to in the first paragraph hereunder does not concern the data from the register of manufacturers of active substances, the Agency shall issue a decision on the assessed fulfilment of conditions for the performance of the activity of manufacture of active substances within 30 days, or 90 day of receiving a complete application, if it estimates that the fulfilment of the conditions should be verified.

(4) Should the expert commission referenced in the second paragraph above issue a negative opinion on the change in the fulfilment of the conditions for performing the manufacture of active substances, the Agency shall not enter the change in the register of manufacturers of active substances and issue a decision thereon.

(5) Notwithstanding the provisions of the first paragraph above, the manufacturer of active substances shall notify about other changes of conditions which are the basis for the entry in the register of manufacturers of active substances in its annual report which it shall submit to the Agency by 15 December of the current year at the latest, namely the report shall specify all changes in the current year. The Agency shall enter the changes within 30 days of receiving a complete report in the event of changes made to the data in the register of manufacturers and issues a certificate thereon.

(6) The competent minister shall determine in greater detail the contents of the application for the notification of changes of conditions, the contents of the annual report on changes, the procedure and the method of entry of the change in the register of manufacturers of active substances and the issue of the decision on the assessed fulfilment of conditions for performing the manufacture of active substances.

3. **Excipients**

Article 103

(Manufacturers of excipients)

The business entities manufacturing excipients shall carry out the manufacture in accordance with the guidelines and principles of good manufacturing practice for excipients as adopted and published by the European Commission.

VIII. WHOLESALE OF MEDICINAL PRODUCTS AND ACTIVE SUBSTANCES 1. **MEDICINAL PRODUCTS**

Article 104

(Wholesaling of medicinal products)

(1) A business subject with the authorisation for the wholesaling of medicinal products, is a wholesaler and may only purchase medicinal products from business entities holding appropriate authorisation for manufacturing or wholesaling of medicinal products.

(2) The wholesalers of medicinal products may sell medicinal products only to business entities engaging in:

- - wholesaling of medicinal products;
- - retailing of medicinal products.

(3) Notwithstanding the previous paragraph, wholesalers may sell medicinal products directly to the providers of healthcare activity, social security institutes, Slovenian Armed Forces, provided that they have pharmacies in their organisational structure and/or have established a system for receiving, storing and tracing medicinal products, and appointed a person with a second cycle degree in pharmacy, or an equivalent degree corresponding to this level pursuant to the law.

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

(5) Medicinal products referred to in the third paragraph hereunder may only be used for the performance of health activity or healthcare support in social security organisations and the Slovenian Armed Forces and medicinal products referred to in the above paragraph hereunder for the performance of veterinary activity.

(6) The minister shall determine more specific conditions for the responsible person, the system for receiving, storing and tracing medicinal products and the procedure for establishing whether the conditions from the third paragraph hereunder have been met.

Article 105

(Conditions for wholesalers of medicinal products)

(1) The wholesale of medicinal products may be undertaken by business entities which hold an appropriate authorisation issued by the Agency and fulfil the following requirements:

1. Have at their disposal an adequate number of experts holding a second cycle degree in the field of pharmacy or an equivalent degree corresponding to this level pursuant to the law working under a contract, or experts in other appropriate fields, if necessary;
2. Appoint from among the experts referred to in the previous item a person responsible for receiving, storing, issuing and transporting medicinal products as well as examining the documentation that enables traceability of medicinal products. The responsible person shall have a second cycle degree in pharmacy or an equivalent degree corresponding to this level of knowledge pursuant to the law;
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 resolving of complaints;
5. Organise the work in accordance with the principles of good distribution practice; and
6. Establish a system to ensure high quality of operations and define the responsibilities, procedures and measures concerning risk management related to their activities;

(2) If the person referred to in item 2 of the first Paragraph of the present Article does not hold a second cycle degree in pharmacy or an equivalent degree corresponding to this level of knowledge pursuant to the law, they must possess additional knowledge of applied physics, general and inorganic chemistry, organic chemistry, analytical chemistry, pharmaceutical chemistry, including the analysis of medicinal products, general and applied medical biochemistry, physiology, microbiology, pharmacology, pharmaceutical technology, toxicology and pharmacognosy. If the study programme does not include any of the abovementioned skills, the responsible person shall submit appropriate evidence of having obtained such skills.

(3) Wholesalers having obtained the marketing authorisation for wholesaling of medicinal products and having their registered office in another EU Member State that intend to wholesale medicinal products in the Republic of Slovenia can start performing such activity in the Republic of Slovenia once they have notified themselves with the Agency in accordance with the procedure prescribed by the competent minister.

(4) The competent minister shall determine in greater detail the conditions for wholesaling medicinal products, the procedure for establishing the fulfilment of the conditions and the procedure of notifying of wholesalers of medicinal products referred to in the previous paragraph as well as the form of the authorisation for wholesaling of medicinal products.

Article 106

(Obligations of wholesalers of medicinal products)

Wholesalers of medicinal products shall:

1. Verify whether the suppliers of medicinal products (manufacturers, importers and wholesalers) perform their activities in accordance with the guidelines and principles of good distribution practice and the regulations on medicinal products in the country in which they have the registered office, as well as whether they hold the authorisation for manufacturing and/or wholesaling of medicinal products;
2. Verify whether the business entities to whom they sell medicinal products have the authorisation for wholesaling or retailing medicinal products or the authorisation for performing the pharmacy activity and whether the business entities from the third paragraph of Article 104 hereof have set up an accepted system for receiving, storing and tracing medicinal products;
3. Verify the safety features on the received and/or supplied medicinal product and forthwith inform the Agency and the manufacturing authorisation holder, if needed, about any falsified products or any suspicion thereof;
4. Keep the documentation pertaining to all medicinal products in an electronic or any other form for up to five years. The invoices that are issued upon the receipt or dispatch of medicinal products shall contain at least the following data: date, name of medicinal product, national identifier, date of receipt or the issued quantity, name and address of the supplier or recipient and, in case of medicinal products bearing a safety feature, also the batch number; and
5. Take into account the good distribution practice when implementing the logistics functions of transporting medicinal products in the framework of:

- - the dispensing of medicinal products in pharmacies or specialised stores for medicinal products sold to end users who are patients or owners of animals or their keepers, or the retail sale of medicinal products to a provider of healthcare or veterinary activity, social security institutes and the Slovenian Armed Forces, which had not introduced a system for receiving, storing and tracing medicinal products on the basis of a contract with a pharmacy and/or a specialised store;
- - selling medicinal products by another business entity to providers of healthcare activity from the third paragraph of Article 104 hereof, based on the concluded agreement with the business entity concerned, which can itself be a manufacturer or another medicinal products wholesaler.

Article 107

(Issue of authorisation for wholesale of medicinal products)

(1) The procedure for the issue of the authorisation for wholesale of medicinal products shall be initiated on the basis of an application submitted by a business entity with the registered office in the Republic of Slovenia.

(2) The Agency shall decide on the issue of the authorisation for wholesale of medicinal products within 90 days of receiving a complete application, based on the opinion of an expert commission for the establishment of fulfilment of conditions for wholesale of medicinal products.

(3) The Agency may issue authorisation for wholesaling medicinal products:

- - covering the full extent of the activity of wholesaling of medicinal products that includes wholesaling of all medicinal products that may be marketed pursuant to this Act to all business entities referred to in the second, third and fourth paragraphs of Article 104 hereof;
- - covering a contact-limited scope of the activity of wholesaling of medicinal products that includes wholesaling of all

medicinal products that may be marketed pursuant to this Act only to other holders of authorisation for wholesaling of medicinal products; or

- - covering a product-limited scope of the activity of wholesaling of medicinal products that includes wholesaling of certain medicinal products to all business entities referred to in the second, third and fourth paragraphs of Article 104 hereof;

- - to the Institute of the Republic of Slovenia for Commodity Reserves.

(4) The authorisation referred to in the previous paragraph may also be issued for a limited period of time or under certain conditions.

(5) An authorisation for wholesale of medicinal products from the third paragraph hereunder shall be suspended or revoked, should the pharmaceutical inspector ascertain that the wholesaler of medicinal products did not meet the conditions defined in Article 105 hereof and issue a prohibition against wholesaling of medicinal products.

(6) The medicinal product wholesaling activities shall be defined in the Compilation of European Union Procedures as applicable at the time.

(7) The authorisation for wholesale of medicinal products shall also be revoked on the proposal by the holder of authorisation for wholesale of medicinal products and in case the pharmaceutical inspector, based on three pronounced fined resulting from the failure to meet the obligation to provide services in public interest from Article 108 hereof, orders prohibition to perform the activity of wholesaling of medicinal products.

(8) Should the Agency establish, by perusing the Slovenian Business Register, that the business entity which is the holder of authorisation for the wholesale of medicinal products has already been deleted therefrom, the Agency shall establish ex officio that the authorisation for wholesale of medicinal products has ceased to be valid.

Article 108

(Obligation to perform services in public interest)

(1) A wholesaler of medicinal products, whose authorisation covers the full extent of the activity of wholesaling of medicinal products, shall ensure a continuous and appropriate selection of medicinal products which can be marketed pursuant to the obligation to perform services in public interest in a relatively short time, namely within 24 hours during the week and 72 hours during weekends or holidays, from the received order for medicinal products from the first and the second paragraph and indent 3 of the third paragraph of Article 20 hereof. If the provider of medical or veterinary activity, or a pharmacy, requires delivery of medicinal products in shorter deadlines than those specified above, this shall be indicated in the order to the wholesaler based on an evidence-supported medical need or medical documentation.

(2) A wholesaler of medicinal products, whose wholesaling authorisation is product-limited, shall ensure a continuous and appropriate selection of medicinal products as specified in the authorisation issued by the Agency for performing this activity, so as to meet the requirements for an uninterrupted supply of medicinal products pursuant to the obligation to perform services in public interest within 24 hours during the week and 72 hours during weekends or holidays, from the received order for medicinal products from the first and the second paragraph and indent 3 of the third paragraph of Article 20 hereof. If the provider medical or veterinary activity, or a pharmacy, requires delivery of medicinal products in shorter deadlines than those specified above, this shall be indicated in the order to the wholesaler based on an evidence-supported medical need or medical documentation.

Article 109

(Certificate of good distribution practice)

(1) The pharmaceutical inspector shall issue a certificate of good distribution practice to the inspected business entity within 90 days of the date of inspection should it be established that the business entity's wholesale of medicinal products is in accordance with the guidelines and principles of good distribution practice for medicinal products or active substances, or no later than within 15 days of the issue or change to the marketing authorisation or the entry or change in the register of wholesalers of active substances.

(2) The pharmaceutical inspector may issue a decision to revoke the certificate of good distribution practice if it is ascertained upon the inspection that the holder of the authorisation for wholesaling of medicinal products and/or the business entity which is entered in the register of wholesalers of active substances fails to implement the guidelines and principles of good distribution practice for medicinal products or active substances.

(3) The certificate of good distribution practice shall be issued on a form written in the Slovenian and English languages, as defined in the Compilation of European Union Procedures, as applicable at the time.

(4) The competent minister shall determine in greater detail the procedure of issuing or revoking the certificate of good distribution practice.

Article 110

(Register of persons responsible for receiving medicinal products)

(1) The Agency shall keep a publicly available register of persons responsible for receiving, storing, issuing and transporting of medicinal products and for examining of the documentation, which shall include the responsible persons who have fulfilled the conditions laid down in Article 105 hereof.

(2) The register of persons responsible for receiving, issuing and transporting of medicinal products as well as examining the documentation shall include the following data:

- - name and surname and professional title of the person responsible for receiving, issuing and transporting medicinal products as well as examining the documentation;

- - name and address of the business entity where they perform the tasks as the person responsible for receiving, issuing and transporting medicinal products as well as examining the documentation.

(3) The Agency shall enter, change or delete the person responsible for receiving, issuing and transporting medicinal products as well as examining the documentation in/from the register referred to in the first paragraph of this Article within eight days of receiving a complete application and issue a certificate thereon upon the request of the applicant. The application for the entry in, change of and deletion from the register referred to in the first paragraph hereunder may be filed by the applicant for the authorisation for wholesale of medicinal products or the holder of the authorisation for wholesale of medicinal products in the Republic of Slovenia.

(4) The Agency shall delete the person responsible for receiving, storing, issuing and transporting medicinal products as well as examining the documentation on the proposal by the applicant for the entry in the register referred to in the first paragraph of this Article, if the Agency cancels the wholesale authorisation and if the holder of the wholesale authorisation has been deleted from the Slovenian Business Register.

(5) The competent minister shall determine in greater detail the contents of the application for the entry in, change of or deletion from the register of the persons responsible for receiving, storing, issuing and transporting of medicinal products and examining of the documentation as well as the conditions and the method of establishing the fulfilment of conditions for the entry in, change of or deletion from the register of the persons responsible for receiving, storing, issuing and transporting of medicinal products and examining of the documentation.

2. **Active substances**

Article 111

(Wholesaling of active substances)

(1) A business subject pursuing wholesale of active substances and duly entered into the register of manufacturers of active substances shall be a wholesaler of active substances. Wholesalers of active substances shall perform their activity in accordance with the guidelines and principles of good distribution practice for active substances.

(2) Wholesalers engaged in the wholesale of active substances shall fulfil the following conditions:

1. They shall employ an adequate number of experts with adequate qualifications depending on the extent and complexity of the wholesale in active substances;

2. They shall have at their disposal adequate facilities, devices and equipment for the storage and transport of active substances in accordance with the guidelines and principles of good distribution practice for active substances, and

3. They shall perform the activity in accordance with the guidelines and principles of good distribution practice for active substances.

(3) The wholesaler of active substances shall forthwith inform the Agency about any falsified active substances or any suspicion thereof.

(4) The wholesaler of active substances shall verify whether the suppliers of active substances comply with the guidelines and principles of good manufacturing and distribution practices for active substances and whether they comply with the regulations governing active substances in the country in which they have their registered office.

Article 112

(Procedure of entry into the register of wholesalers of active substances)

(1) The wholesalers with registered office in the Republic of Slovenia may start carrying out their activity after they have been entered in the register of wholesalers of active substances kept by the Agency.

(2) The Agency shall issue a certificate upon the entry in the register of wholesalers of medicinal products.

(3) The register of wholesalers of active substances shall include the following data:

- - name, permanent address and contact information of the business entity (telephone, fax and e-mail);

- - list of active substances the business entities wholesale.

(4) Wholesalers of active substances shall notify their activity to the Agency 60 days before they start performing the activity, based on a written application which shall include the evidence that the conditions referred to in the second paragraph of the previous Article have been fulfilled, and a list of active substances they plan to wholesale.

(5) The Agency shall enter wholesalers of active substances in the register of active substance wholesalers on the basis of a positive opinion of the expert commission for the establishment of fulfilment of conditions for wholesale of active substances 90 days of receiving the complete application or 60 days if it estimates that the fulfilment of conditions need not be verified.

(6) Should the above referenced expert commission issue a negative opinion on the fulfilment of the conditions for the wholesale of active substances, the Agency shall refuse the entry in the register referred to in the first paragraph of this Article by way of rendering a decision.

(7) The Agency may delete a wholesaler of active substances from the register, should the pharmaceutical inspector ascertain that it did not meet the conditions referred to in paragraph two of the previous Article and the regulations adopted on the basis thereof, which also serves as the basis for prohibiting the performance of the activity. The Agency may delete the wholesaler of active substances from the register referred to in the first paragraph of this Article also on the manufacturer's proposal and if it establishes, by perusing the Slovenian Business Register, that the wholesaler has been deleted therefrom. The Agency issues a decision on the deletion.

(8) The Agency may request additional documents and/or data so as to adopt a decision on the entry in the register of wholesalers of active substances pursuant to paragraph six of Article 3 hereof.

(9) The documentation pertaining to the application for the entry in the register of wholesalers shall be deemed a business secret if defined as such by the applicant, in accordance with the regulations.

(10) The Agency shall publish on its website the list of wholesalers that have been entered in the register of wholesalers engaged in the wholesale of active substances. The list shall contain the name of the wholesaler of active substances and its permanent address.

(11) The competent minister shall determine in greater detail the contents of the application, the conditions, the method and the procedures required for the entry into the register of wholesalers of active substances and deletion from the register as well as the contents of such register.

Article 113

(Change of conditions for the entry in the register of wholesalers of active substances)

(1) The wholesaler of active substances shall inform the Agency forthwith about any change in the conditions referred to in the second paragraph of Article 111 hereof that significantly affects the quality or safety of the active substance it wholesales.

(2) The Agency shall enter the change referred to in the previous paragraph in the register of wholesalers of active substances based on a positive opinion of an expert commission for establishing the fulfilment of conditions for wholesale of active substances within 90 days of receiving a complete application and shall issue a certificate thereon and/or enter the change referred to in the previous paragraph in the register of wholesalers of active substances within 30 days of receiving a complete application, if it estimates that the fulfilment of conditions need not be verified and issues a certificate thereon. If the change referred to in the previous paragraph does not concern the data from the register of wholesalers of active substances, the Agency shall issue a decision on the assessed fulfilment of conditions for the performance of the activity of wholesaling active substances within 30 days, or 90 days of receiving a complete application, if it estimates that the fulfilment of the conditions should be verified.

(3) Should the expert commission referred to in the previous paragraph issue a negative opinion on the fulfilment of the conditions for the wholesale of active substances, the Agency shall not enter the change in the register and shall issue a decision thereon.

(4) Notwithstanding the provisions of the first paragraph hereunder, the wholesaler which wholesales active substances shall notify about other changes of conditions which are the basis for the entry in the register of wholesalers of active substances in its annual report which it shall submit to the Agency by 15 December of the current year at the latest, namely the report shall specify all changes in the current year. The Agency shall, within 30 days of the day of receiving a complete report, issue a certificate on the change of entry in the register of wholesalers of active substances.

(5) The competent minister shall determine in greater detail the contents of the application for the notification of changes of conditions, the contents of the annual report on changes, the procedure and the method of entry of the change in the register of wholesalers of active substances and a detailed procedure the issue of the decision on the assessed fulfilment of conditions for performing the marketing of active substances.

IX. IMPORT AND ENTRY OF MEDICINAL PRODUCTS

AND ACTIVE SUBSTANCES 1. **MEDICINAL**

PRODUCTS

Article 114

(Import of medicinal products)

(1) The import of medicinal products may be performed by the holders of the manufacturing authorisation for medicinal products which also covers the import activity.

(2) Holders of authorisation for manufacturing of medicinal products importing medicinal products and who themselves have no appropriate facilities, equipment and devices to control the quality of each imported batch of medicinal products, can enter into a contractual relationship with a business entity for the

provision of the services of analytical testing of medicinal products, provided that such entity holds the manufacturing authorisation for medicinal products which also covers the activity of analytical testing of medicinal products.

(3) Batches of medicinal products manufactured in third countries, which have undergone the controls referred to in the previous paragraph in another EU Member State prior to their marketing in the Republic of Slovenia, shall be exempt from the controls and shall be accompanied by the reports on quality controls, signed by the person who released the batch in the relevant country.

(4) In the case of medicinal products imported from a country that has concluded with the European Union a mutual recognition agreement for the area of medicinal products, the analysis certificate obtained in the exporting country shall be recognised.

Article 115

(Entry of medicinal products)

(1) Importing of medicinal products can be carried out by wholesalers of medicinal products with registered headquarters in the Republic of Slovenia and wholesalers of medicinal products with registered headquarters in another EU member state, which are notified with the Agency.

(2) Those batches of medicinal products that were individually controlled before their entry in the Republic of Slovenia, shall be exempt from the controls.

Article 116

(Import or entry of medicinal products)

(1) Subject to the fulfilment of the conditions hereof, the entry and import shall be allowed for medicinal products with:

- - marketing authorisation;
- - marketing authorisation for parallel imported medicinal product;
- - compassionate use authorisation;
- - certificate of notification of parallel distribution of medicinal product; or
- authorisation for clinical trial or adequately notified clinical trial.

(2) The entry and import of medicinal products without the authorisation referred to in the previous paragraph shall only be allowed for the medicinal products referred to in the third paragraph of Article 20 hereof.

(3) The Agency may within 30 days of receiving the complete application temporarily allow the entry or import of the medicinal products referred to in the previous paragraph except in the cases referred to in indent 2 and indent 5 of the third paragraph of Article 20 hereof, when the decision is adopted within seven days.

(4) The applicant for the entry authorisation, as referred to in the second paragraph hereunder, may be a wholesaler in medicinal products and for the import authorisation, this may be a manufacturer of medicinal products whose manufacturing authorisation also covers the activity of import of medicinal products.

(5) For medicinal products without the marketing authorisation in the Republic of Slovenia, for which the entry or import authorisation can be obtained pursuant to this law, the applicants must obtain from the Agency, prior to obtaining such authorisation, a decision of the Agency on the quantities of medicinal products and their wholesale prices without VAT for each period.

(6) The decision of the Agency referred to in the previous paragraph shall be issued to the applicant that offered the lowest wholesale price without VAT for the tendered annual amount of medicinal products, expressed as the quantity of the relevant active substances, if there is no medicinal product with marketing authorisation containing the same active substance, pharmaceutical form and strength available on the Slovene market. The Agency informs all bidders and providers of healthcare, veterinary and pharmacy activity of the selection.

(7) The Agency establishes the required annual quantity of medicinal products from the previous paragraph based on the data on the quantities of necessary medicinal products from the third paragraph of Article 20 hereof for a period of one year with the presentation of the general names of medicinal products, the indication of pharmaceutical form and strength submitted by the providers of healthcare, veterinary and pharmacy activity upon its request.

(8) Notwithstanding the provisions of the fifth paragraph hereunder, the applicants may obtain the authorisation for the entry or import of medicinal products if they are able to prove in their application that the needs for the entry or import of medicinal products could not have been anticipated, so as to obtain the authorisation for the entry or import of medicinal products pursuant to the provisions of the fifth paragraph hereunder or if the holder of authorisation for the entry or import of medicinal products from the fifth paragraph hereunder informs the Agency that they cannot provide a specific medicinal product in the foreseen scope or within the foreseen deadline.

(9) A holder of authorisation for the entry or import of medicinal products that obtained the authorisation on the basis of the fifth paragraph hereunder shall provide the supply of medicinal products pursuant to this authorisation and in accordance with the requirements for the supply of medicinal products as specified by the providers of healthcare, veterinary and pharmacy activity.

(10) If the holder of authorisation from the previous paragraph fails to supply medicinal products to the providers of healthcare, veterinary and pharmacy activity for which the authorisation for entry or import was obtained, they shall not be allowed to submit their bids in the next process of collecting bids from the sixth paragraph hereunder.

(11) Entry or import of medicinal products entered or imported for the purpose of exit or export into other countries and placement on the market in such other EU Member States and not for sale on the market of the Republic of Slovenia shall be free if performed in the scope and on the basis of adequate manufacturing authorisation or wholesaling authorisation.

(12) The competent minister shall lay down detailed conditions, method and procedure of entry and import of medicinal products and the method of reporting by the providers of healthcare, veterinary or pharmacy activity on the necessary quantities of medicinal products from the third paragraph of Article 20 hereof.

Article 117

(Marketing of parallel imported medicinal products)

(1) The procedure for obtaining a marketing authorisation for a parallel imported medicinal product shall be initiated on the basis of an application submitted by the wholesaler in medicinal products which, in the marketing of such medicinal product, is not in a business relationship with the holder of marketing authorisation. The Agency shall issue the marketing authorisation for a parallel imported medicinal product within 60 days of receiving a complete application.

(2) The application for the obtaining, change or renewal of the marketing authorisation for a parallel imported medicinal product shall include the data on the applicant, the medicinal product for which parallel import is proposed, and the medicinal product which was issued the marketing authorisation in the Republic of Slovenia and against which the medicinal product in the application is compared.

(3) The competent minister shall determine in greater detail the contents of the application, the procedure and conditions for obtaining, changing and renewing the marketing authorisation for a parallel imported medicinal product, the reasons for cancelling the validity of the authorisation and the tasks of the holder of marketing authorisation for a parallel imported medicinal product.

Article 118

(Parallel distribution of medicinal products)

(1) Prior to starting parallel distribution of a medicinal product the wholesalers who are authorised for wholesaling medicinal products in the Republic of Slovenia shall notify the Agency in writing about the start of the parallel distribution.

(2) The notification referred to in the previous paragraph shall include evidence that the applicant has duly informed the EMA about the intended parallel distribution and that the EMA does not object to the intended parallel distribution, as well as data on the medicinal product which will be the subject of parallel distribution, along with the data on the outer packaging of the medicinal product, patient leaflet in the Slovenian language, data on the medicinal product manufacturer and the manufacturing site.

(3) After receiving the complete application referred to in the previous paragraph, the Agency shall issue a certificate of the receipt of notification on parallel distribution of medicinal products.

(4) The competent minister shall determine in greater detail the contents of the notification and the procedure for issuing the certificate of received notification on parallel distribution of medicinal product.

2. **Active substances**

Article 119

(Import of active substances)

(1) Active substances can be imported by business entities entered in the register of importers of active substances and holding the manufacturing authorisation for medicinal products as well as wholesalers of active substances (hereinafter: importer of active substances).

(2) The importer of active substances may only import those active substances which are manufactured in accordance with the guidelines and principles of good manufacturing practice for active substances, applicable in the European Union, or the guidelines and principles of good manufacturing practice applicable in a third country and at least equal, in terms of requirements, to those stipulated in the European Union.

(3) The importer of active substances that imports active substances intended for the manufacture of medicinal products for human use may only import those active substances that are accompanied by a written certificate of the competent authority from the exporting third country, namely that:

- - the standards of good manufacturing practice which are applied in the production site where the exported active substance is manufactured are at least equal to those prescribed by the European Union;
- - the manufacturing plant is subject to regular controls by the competent authority and
- - they shall immediately inform the EU Member States to which the active substances are being exported should incompliance with the standards of good manufacturing practice be ascertained.

(4) The written certificate referred to in the previous paragraph need not be submitted if the relevant third country has been included in the list of the European Commission as a country whose requirements and standards of good manufacturing practice are equivalent to those of the European Union.

(5) Only exceptionally and for the purpose of ensuring the availability of medicinal products, the written certificate referred to in the third paragraph hereunder need not be submitted, if the inspection was conducted in the exporting country by another EU Member State in the last three years, whereby it was established that the manufacture complied with the good manufacturing practice for active substances.

(6) The competent minister shall determine the detailed requirements regarding the import of active substances.

Article 120

(Conditions for the import of active substances)

(1) Importers of active substances shall meet the following conditions:

1. They shall employ an adequate number of experts with at least secondary degrees of an appropriate program depending on the extent and complexity regarding the importation of active substances;

2. They shall have at their disposal adequate facilities, devices and equipment for the storage and transport of active substances in accordance with the guidelines and principles of good distribution practice for active substances, and

3. They shall perform the activity in accordance with the guidelines and principles of good distribution practice.

(2) The importer of active substances shall forthwith inform the Agency about any falsified active substances or any suspicion thereof.

(3) The importer of active substances shall verify whether the suppliers of active substances comply with the guidelines and principles of good manufacturing and distribution practices for active substances and whether they comply with the regulations governing active substances in the country in which they have their registered office.

Article 121

(Procedure of entry in the register of importers of active substances)

(1) The importers of active substances with registered offices in the Republic of Slovenia, may start performing their activity after it has been entered in the register of importers of active substances, kept by the Agency.

(2) The Agency shall issue a certificate upon the entry in the register referred to in the previous paragraph.

(3) The register of importers of active substances shall include the following data:

- name, permanent address and contact information of the business entity (telephone, fax and e-mail);
- a list of active substances imported by the business entity.

(4) The importer of active substances shall notify its activity to the Agency 60 days prior to the commencement of activity, based on a written application that includes evidence that the conditions have been fulfilled and a list of active substances they intend to import.

(5) The Agency shall enter the importer of active substances in the register of importers of active substances, based on a positive opinion of an expert commission for establishing the fulfilment of conditions for importing active substances on the fulfilment of the conditions referred to in the first paragraph of the previous Article within 90 days or 60 days of receiving the complete application if it estimates that the fulfilment of conditions need not be verified.

(6) Should the expert commission referred to in the previous paragraph issue a negative opinion on the fulfilment of the conditions for performing the import of active substances, the Agency shall refuse entry in the register of importers of active substances and issue a decision thereon.

(7) The Agency may request additional documents and/or data required for the entry in the register of importers of active substances pursuant to paragraph six of Article 3 hereof.

(8) The Agency may delete the importer of active substances from the register of importers of active substances, should the pharmaceutical inspector ascertain that it failed to satisfy the requirements set out in the previous Article hereof and the regulations adopted on the basis hereof, and issue an order prohibiting the performance of the activity of importing active substances. The Agency may delete the importer of active substances from the register of importers of active substances also on the importer's proposal and if it establishes, by perusing the Slovenian Business Register, that the business entity has been deleted therefrom. The Agency issues a decision on the deletion.

(9) The documentation pertaining to the application for notification in the register of importers of active substances shall be deemed a business secret if defined as such by the applicant, in accordance with the regulations.

(10) The Agency shall publish a list of registered importers of active substances on its website. The list shall contain the name of the business entity and its permanent address.

(11) The competent minister shall determine in greater detail the contents of the application, the conditions, the method and the procedures required for the notification of the entry and deletion from the register as well as the detailed content of the register of importers of active substances.

Article 122

(Change of conditions for the entry in the register of importers of active substances)

(1) The importer of active substances entered in the register of importers of active substances shall inform the Agency forthwith about any change in the conditions referred to in the first paragraph of Article 120 hereof that significantly affects the quality or safety of the active substance it imports.

(2) The Agency shall enter the change referred to in the previous paragraph in the register of importers of active substances based on a positive opinion of the expert commission for establishing the fulfilment of conditions for the import of active substances within 90 days of receiving a complete application and shall issue a certificate thereon and/or enter the change within 30 days of receiving a complete application, if it estimates that the fulfilment of conditions need not be verified and issues a certificate thereon.

(3) If the change in conditions referred to in the first paragraph hereunder does not concern the data from the register of importers of active substances, the Agency shall issue a decision on the assessed fulfilment of conditions for the import of active substances within 30 days of receiving a compete application or 90 days if it estimates that the fulfilment of the conditions should be verified.

(4) Should the expert commission referenced in the second paragraph above issue a negative opinion on the fulfilment of the conditions for the importing of active substances, the Agency shall not enter the change in the register of importers of active substances and issue a decision thereon.

(5) Notwithstanding the provisions of the previous paragraph, the importer of active substances shall notify any other changes of conditions which are the basis for the notification of the import of active substances in its annual report which it shall submit to the Agency by 15 December of the current year at the latest, namely the report shall specify all changes in the current year. The Agency shall, within 30 days of the date of receiving a complete report, issue a certificate on the change of entry in the register of importers of active substances.

(6) The competent minister shall determine in greater detail the contents of the application for notification of changes in the conditions and annual reporting on changes as well as the method and procedure of entry of the change in the register of importers of active substances and procedure for the issue of decision on the assesment of fulfilment of conditions for importing of active substances.

X. WHOLESALE BROKERING OF MEDICINAL PRODUCTS AND ACTIVE SUBSTANCES

Article 123

(Conditions and obligations for brokers)

The wholesale brokers of medicinal products and active substances shall:

- - comply with the requirements of good distribution practice for those activities concerning brokerage;

- - set up a traceability system for medicinal products or active substances which supports the recalling of medicinal products or active substances;

- - keep the documentation on brokering of medicinal products and active substances;

- - maintain a quality system with clearly defined responsibilities and described procedures as well as define the risk management method in relation to their activities;

- - ensure that the medicinal products which are subject to brokerage have the medicinal product marketing authorisation or a temporary extraordinary medicinal product marketing authorisation;

- - verify and ensure that they do business only with the providers of medicinal products (manufacturers, importers and wholesalers) which comply with the requirements of good manufacturing or distribution practices and the regulations governing medicinal products and/or active substances in the country in which they have their registered office as well as hold the authorisation for manufacturing of medicinal products or wholesaling of medicinal products;

- - forthwith inform the Agency about any falsified medicinal products or active substances or any suspicion thereof;

- - Keep the documents related to the brokerage of medicinal products or active substances which shall be available to the Agency for inspection, and keep such documentation for at least five years.

Article 124

(Register of brokers in the marketing of medicinal products and active substances)

(1) Business entities with the registered office in the Republic of Slovenia carrying out the activity of wholesale brokerage of medicinal products or active substances shall prior to starting their activity notify it with the Agency so as to be entered in the publicly available register of brokers with medicinal products or active substances.

(2) The Agency shall issue a certificate of the entry into the register of brokers with medicinal products and active substances.

(3) The Notification for the entry into the register of brokers with medicinal products and active substances shall include the following data:

- name and registered office of the business entity;
- contact data (contact person, telephone, fax, e-mail).

(4) The medicinal product and active substance brokers shall forthwith inform the Agency about any changes to data entered in the register referred to in the first paragraph of this Article.

(5) Should the pharmaceutical inspector establish that the broker failed to meet the conditions referred to in the previous Article and issue a prohibition to perform the activity, the Agency shall delete the broker from the register referred to in the first paragraph hereunder and issue a decision thereon.

(6) The Agency may delete the broker of medicinal products and active substances from the register of brokers of medicinal products and active substances on the broker's proposal and if it establishes, by perusing the Slovenian Business Register, that the business entity has already been deleted therefrom.

(7) The competent minister shall determine in greater detail the contents of the application, the conditions, the method and the procedures for the entry in, change of and deletion from the register of brokers of medicinal products and active substances as well as the contents of the register of brokers of medicinal products and active substances.

Article 125

(Notification to the database of the European Union)

The Agency shall submit to the European Union (EudraGMDP) database the data on the business entities which were granted the manufacturing authorisation for medicinal products and the authorisation for wholesale of medicinal products, the information on the certificates of good manufacturing practice and good distribution practice as well as data on business entities which were entered in the registers applicable to manufacturing of medicinal products, wholesaling of medicinal products, importing of active substances or the activity of wholesale brokerage of medicinal products or active substances.

XI. RETAIL OF MEDICINAL PRODUCTS

Article 126

(Retail trade and dispensation of medicinal products through the Internet)

(1) Retail trade in medicinal products for human use, accompanied by adequate expert support and counselling, and retail trade in medicinal products for human use, used for the

treatment of animals, shall only be carried out in pharmacies and specialised stores, whereas retail trade in medicinal products for veterinary use shall also be carried out in veterinary organisations and other organisations that perform veterinary activities in accordance with veterinary regulations, together with the service provided for those animals that are kept in the records of such organisations or in case of preventive or therapeutic veterinary procedures performed by the veterinary organisation on animals at the place of their owner or keeper.

(2) Notwithstanding the previous paragraph, only those medicinal products can be sold in specialised retail stores which are not subject to medical or veterinary prescription and are authorised by the Agency in the marketing authorisation for medicinal products.

(3) When defining medicinal products that can be retailed in specialised stores, the Agency may impose certain restrictions concerning the strength, packaging size or number of units sold.

(4) The Agency shall publish on its website the list of medicinal products that may be issued in specialised stores. It only includes those herbal and synthetic medicinal products which have a favourable risk-benefit balance and are used for the elimination of mild symptoms and health problems and their pharmacovigilance data indicates a minor risk.

(5) Only a qualified person pursuant to Point 1 of the first paragraph of Article 127 hereof may sell medicinal products in specialised stores and must inform the buyer of the method of use of the medicinal product, potential precautions, adverse reactions and other important information regarding the medicinal product.

(6) Medicinal products in specialised retail stores may only be sold to adult persons.

(7) The business entities referred to in the first paragraph hereunder shall forthwith inform the Agency about any falsified medicinal products or any suspicion thereof.

(8) In the case of more serious health problems of a patient, the person referred to in item 1 of the first paragraph of Article 127 of the present Act working in a specialised store selling medicinal products shall refer the patient to a physician or a Master of pharmacy at a pharmacy.

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

(10) Homeopathic medicinal products shall only be dispensed in pharmacies, whereas the homeopathic medicinal products for veterinary use shall also be issued in providers of veterinary activity, together with the service, namely for those animals that are kept in the records of the provider of veterinary activity or in case of preventive or therapeutic veterinary procedures performed by the provider of veterinary activity on animals at the place of their owner or keeper.

(11) Commercial initiatives that encourage the end user to buy or use unnecessary or excessive medicinal products shall be prohibited in the retail trade in medicinal products.

(12) Medicinal products that are not dispensed based on a medical or veterinary prescription may be dispensed via the Internet with the permission of the minister.

(13) Dispensation of medicinal products via the Internet shall mean retail sale of medicinal products, including appropriate and expert independent support with consultation regarding the use of a medicinal product and transport and delivery of medicinal products that assures quality and safety of the use of medicinal products.

(14) Dispensation of medicinal products via the Internet shall be performed by pharmacies and specialised stores for medicinal products. Specialised stores may only dispense those medicinal products over the Internet that may be sold in specialised stores for medicinal products in accordance with the provisions of paragraph 2 hereof.

15 A pharmacy or specialised store for medicinal products shall fulfil the following conditions for dispensing medicinal products via the Internet:

- It shall have regulated Internet sales in accordance with regulations governing electronic commerce and protection of consumers in Internet sales;
- It shall assure security in the creation, delivery, reception, storage or other form of data processing in accordance with the law regulating the protection of personal data.
- It shall assure a system of quality that reasonably observes the principles and guidelines of good distribution practice for medicinal products regarding traceability, transport and delivery of medicinal products to the place of dispensation;
- It shall assure expert consultancy on individual medicinal products.

(16) A pharmacy or specialised store for medicinal products detailed in the above paragraph shall apply to its website a common logo selected by the European Union on the basis of Directive 2011/62/EU and shall include a secure Internet link to the list of dispensation providers published by the ministry competent for health. The common logo shall be applied to every page of the website of the pharmacy or specialised store for medicinal products.

(17) The ministry competent for health shall establish a website that shall contain information on:

- national legislation governing dispensation of medicinal products via the Internet;
- common logo referenced in the prior paragraph;
- list of providers of dispensation of medicinal products via the Internet and their website addresses;
- risks related to medicinal products being illegally sold to the public via the Internet;
- link to the website of EMA, containing information on applicable European Union legislation on counterfeit medicinal products and link to websites of competent bodies of member states with regard to information listed under indents one, two, three and four of the present paragraph.

(18) The website of the provider of dispensation of medicinal products via the Internet shall contain the following data:

- name and registered address of the pharmacy with a listing of the organisational unit dispensing medicinal products or specialized store for medicinal products that dispenses medicinal products via the Internet;
- person responsible for dispensing medicinal products via the Internet;
- contact data of the ministry competent for health;
- link to the website of the ministry competent for health, in accordance with paragraph seventeen of the present article.

(19) A pharmacy or specialised store for medicinal products shall apply for authorisation for dispensing medicinal products via the Internet at the ministry competent for health.

The application shall contain the following details:

- name and registered address of the pharmacy with a listing of the organisational unit that shall dispense medicinal products via the Internet or specialized store for medicinal products with a listing of location at which medicinal products shall be dispensed via the Internet;
- the number and date of certificate of fulfilment of conditions for performing pharmacy activities of number and date of authorisation for retail sale of medicinal products in specialised stores that shall be dispensing medicinal products via the Internet;
- evidence on the fulfilment of conditions set out in paragraph fifteen of the present Article;
- date of commencement of dispensation of medicinal products via the Internet;
- address of the website or other information required for the identification of website that dispenses medicinal products.

(20) The ministry competent for health shall revoke authorisation for dispensation of medicinal products via the Internet:

- should the pharmaceutical inspector prohibit the dispensation of medicinal products via the Internet due to the pharmacy of specialised store for medicinal products failing to fulfil the conditions set out in paragraph fifteen of the present Article;

- at the request of the pharmacy or specialized store for medicinal products that dispenses medicinal products via the Internet.

(21) Besides the responsibility of the Internet source of a medicinal product – which includes the liability of the manufacturer, the holder of the marketing authorisation or the pharmacy or specialised store for medicinal products which placed the medicinal product on the market, the wholesalers and retailers – the end 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 comply with the requirements referred to in the present Article.

(22) Retail sale of medicinal products that require a medical or veterinary prescription via the Internet is prohibited. Supervision of the sale of such medicinal products via the Internet shall be performed by the competent customs body in line with customs regulations.

(23) The competent minister shall determine a more detailed manner of dispensing medicinal products and associated classification, the conditions for the design and use of the common logo set out in paragraph sixteen of the present Article and procedure of issuing and revoking authorisation for sale of medicinal products via the Internet.

Article 127

(Specialised stores for medicinal products)

(1) The retail sale of medicinal products in specialised stores may be undertaken by business entities holding an appropriate authorisation issued by the Agency and satisfying, besides the general conditions for performing the retail sale activity and the following conditions:

1. They shall employ at least one qualified person with at least completed secondary education in the field of pharmacy (or veterinary medicine in case of medicinal products for veterinary use), who has passed the qualifying examination and can submit evidence on regular professional training and other independent professional trainings that are also mandatory for pharmacy or veterinary technicians, additional training of the expert body engaging in pharmacy activity and is put in charge of purchasing, storing and selling medicinal products and keeping the documentation;

2. The qualified person from the previous item shall be available at all times during the specialised store's business hours;

3. They shall dispose of the necessary equipment and adequate facilities in which the medicinal products or the activity of retailing medicinal products must be spatially or otherwise physically separated from other products or activities and appropriately marked;

4. They shall keep appropriate documentation which facilitates immediate recall of a medicinal product from the market and the resolving of complaints;

5. They shall appropriately mark the specialised store.

(2) The procedure for the issue of the authorisation for retailing of medicinal products in a specialised store shall be initiated on the basis of an application submitted by a business entity with the registered office in the Republic of Slovenia.

(3) The Agency shall issue the authorisation for the retail sale of medicinal products in a specialised store within 90 days of receiving a complete application on the basis of an opinion issued by an expert commission for the establishment of fulfilment of conditions for retail trading of medicinal products.

(4) The authorisation referred to in the previous paragraph may also be issued for a limited period of time or conditionally, if the expert commission referenced in the previous paragraph ascertains that the holder of the authorisation for retailing of medicinal products in specialised stores has not fulfilled the prescribed conditions.

(5) The authorisation referred to in the first paragraph of the present Article may be revoked temporarily or permanently, should the pharmaceutical inspector ascertain that the holder of the authorisation for retailing of medicinal products in specialised stores has not fulfilled the prescribed conditions, on the basis of which a prohibition to perform the activity is issued.

(6) The retail authorisation for the sale of medicinal products in specialised stores shall also be cancelled on the proposal by the authorisation holder.

(7) Should the Agency establish, by perusing the Slovenian Business Register, that the business entity which is the holder of retail authorisation for the sale of medicinal products in specialised stores has already been deleted therefrom, it shall establish ex officio that the authorisation for retailing medicinal products ceased to be valid, it shall be revoked on the basis of an issued decision.

(8) The competent minister shall determine in greater detail the conditions to be fulfilled by specialised stores for the retailing of medicinal products as well as the procedure and method of establishing these conditions.

Article 128 (Pharmacies)

Requirements for retailing medicinal products imposed on pharmacies shall be regulated by a separate act.

XII. PHARMACOVIGILANCE

1. **Pharmacovigilance system**

Article 129

(Obligation to report on supposed adverse reactions to medicinal products)

(1) A healthcare professional shall report to the national pharmacovigilance centre about the following adverse reactions to medicinal products for human use:

- all supposed serious adverse reactions;
- - all unexpected supposed adverse reactions which are not serious; and
- - all supposed adverse reactions which are the consequence of a mistake related to the use of medicinal product, incorrect use, abuse, overdosing, unauthorised use and professional exposure to the medicinal product.

(2) Notwithstanding the previous paragraph, a healthcare professional shall report on all supposed adverse reactions to medicinal products for human use which are included on the list of medicinal products under additional supervision as published by the EMA in compliance with Article 23 of the Regulation (EC) No 726/2004.

(3) A veterinarian who identifies or suspects any adverse reactions to medicinal products for veterinary use shall inform thereof the marketing authorisation holder in accordance with this Act and the regulations adopted on the basis hereof. In the event of serious adverse reactions caused to animals and human beings related to the use of veterinary medicinal products, the Agency shall also be informed thereon by the veterinarian, business entity or institution in the field of veterinary medicine, besides the marketing authorisation holder.

Article 130

(Patients' reports on supposed adverse reactions to medicinal products)

The patients may report on suspected adverse reactions to medicinal products referred to in the first and second paragraphs of the previous Article to healthcare professionals or directly to the national pharmacovigilance centre.

Article 131

(Collection and assessment of reports on adverse reactions to medicinal products)

(1) The collection of reports referred to in the first and second paragraphs of Article 129 and Article 130 hereof on the supposed adverse reactions to medicinal products for human use and their assessment shall be performed by the national pharmacovigilance centre.

(2) The national pharmacovigilance centre shall no later than within 24 hours after receiving the reports referred to in the previous paragraph submit to the Agency the collected information on supposed adverse reactions and other relevant data related to safety, efficiency and use of medicinal products as well as the functioning of the pharmacovigilance system.

Article 132

(Institutional co-operation)

Should the Agency – while collecting, reviewing and assessing the reports referred to in Articles 129, 130 and 131 hereof – establish a need for additional definition of their clinical relevance and public-health relevance and the related pharmacovigilance activities, it shall use the expert and expert opinion of external specialists in clinical and public-health fields.

Article 133

(Duties of the marketing authorisation holder)

(1) The marketing authorisation holder for medicinal products for human use shall:

- - establish, maintain and manage the pharmacovigilance system so as to ensure the collection and management of the documents about all suspected adverse reactions to medicinal products in the European Union or in third countries, scientific evaluation of all information, explore the possibilities for reducing and preventing risks, adopt necessary measures as well as exchange data with the authorities competent for medicinal products in the EU Member States;
- - regularly evaluate their pharmacovigilance system, compile a Pharmacovigilance system master file and submit it to the Agency at its request;
- - manage the risk management system for each medicinal product and upgrade it to correspond to the established risks as well as monitor pharmacovigilance data;
- - inform the Agency about the established new or changed risks, the changed risk-benefit balance with medicinal products and, either beforehand or immediately inform the Agency, the European Commission and the EMA about the contents of every publication of the information concerning pharmacovigilance;
- - immediately submit, upon the request of the Agency, data proving that the risk-benefit balance remains favourable;
- - fulfil the requirements and obligations for the supervision of non-intervention studies on safety or efficiency of medicinal products after obtaining the marketing authorisation as defined herein;
- - submit data on all suspected adverse reactions to medicinal products into the EudraVigilance database, except for the bibliographic reports on medicinal products with active substances listed in the publications that are monitored by the EMA;
- - Fulfils the obligations concerning the regularly updated reports on the safety of medicinal products in compliance with the first and the third paragraphs of Article 107b and the first, second, third and sixth paragraphs of Article 107c of the Directive 2001/83/EC;
- - consider the procedures while carrying out pharmacovigilance tasks which are described in detail in the implementing measures of the European Commission pursuant to Article 108 of the Directive 2001/83/EC, the guidelines on good practices in the field of pharmacovigilance pursuant to Article 108a of the Directive 2001/83/EC and the scientific guidelines on the efficiency studies after obtaining the marketing authorisation pursuant to Article 108a of the Directive 2001/83/EC.

(2) The holder of the marketing authorisation for medicinal products for veterinary use shall establish and maintain their own pharmacovigilance system which ensures collection, evaluation and exchange of data with the authorities competent for medicinal products in other EU Member States and the European Union. Holders of marketing authorisation for medicinal products for veterinary use shall report to the Agency about the adverse reactions to medicinal products and perform other tasks within the deadlines and using the method defined in Articles 74 and 75 of the Directive 2001/82/EC.

(3) The medicinal product marketing authorisation holder shall have at their permanent disposal a person responsible for the pharmacovigilance system and responsible for the establishment and maintenance of the pharmacovigilance system who shall be available at all times.

(4) The responsible person referred to in the previous paragraph shall have an adequate education, knowledge and experience in the field of pharmacovigilance and shall live and work in the European Union. In terms of medicinal products for human use, adequate education from the previous paragraph shall mean second cycle medical studies or an equivalent degree corresponding to this level of knowledge pursuant to the law, and in terms of medicinal products for veterinary use, it shall mean second cycle veterinary studies, or an equivalent degree corresponding to this level of knowledge pursuant to the law. If the person responsible for the pharmacovigilance system does not have adequate education, they shall receive permanent and uninterrupted professional support from a person with adequate education.

(5) If the marketing authorisation holder does not have the registered office in the Republic of Slovenia, it can appoint, besides the responsible person, also an appropriately qualified contact person in charge of pharmacovigilance in the Republic of Slovenia with a second cycle degree in medical, veterinary or pharmaceutical fields or an equivalent degree corresponding to this level of knowledge pursuant to the law. A contact person shall also be appointed upon the request of the Agency issued in a form of a decision. A contact person can be a business entity with the registered office in the Republic of Slovenia or an individual with permanent or temporary residence in the Republic of Slovenia performing pharmacovigilance activities for the needs of one or more business entities referred to in the first and the third paragraphs of Article 20 hereof or one or more business entities holding the authorisation to enter or import medicinal products.

Article 134

(Tasks of the Agency in pharmacovigilance)

(1) The Agency shall perform the following tasks in the field of pharmacovigilance:

- - manage the pharmacovigilance system for performing the tasks of pharmacovigilance and participating in the activities of pharmacovigilance of the European Union;
- - supervise the implementation of the pharmacovigilance system by the marketing authorisation holders and other participants in the pharmacovigilance system.

(2) The Agency shall perform the following tasks concerning medicinal products for human use, in addition to the tasks set out in the previous paragraph hereunder:

- - record all supposed adverse reactions to medicinal products noted by healthcare professionals and patients and determine and scientifically evaluate all information on the safety of medicinal products, study the possibilities for reducing and preventing risks and take action with the aim of reducing and preventing risks associated with medicinal products for human use;
- - regularly assess the pharmacovigilance system;
- - report the supposed adverse reactions to medicinal products in the EudraVigilance database;
- - set up and maintain a web portal on medicinal products and inform the public on the issues of pharmacovigilance via the web portal and other media;
- - manage the funds earmarked for pharmacovigilance-related activities, operation of communication networks and inspection related to pharmacovigilance in order to ensure independence in performing of those activities;

- - as regards the medicinal products approved in accordance herewith and in co-operation with the bodies of the European Union, monitor the results of measures aimed at reducing risks specified in the risk management plans and the conditions laid down in Article 58 hereof, and assess risk management system updates;

- - monitor data on medicinal products in the EudraVigilance database with the aim of determining whether any new risk has arisen, whether the risks have changed and whether the risks of a medicinal product have affected the risk-benefit balance. If any action is necessary, it will be taken under the urgent procedure in accordance with Articles 107i through 107k of the Directive 2001/83/EC.

- - consider the procedures while carrying out pharmacovigilance tasks which are described in detail in the implementing measures of the European Commission pursuant to Article 108 of the Directive 2001/83/EC and the guidelines on good practices in the field of pharmacovigilance pursuant to Article 108a of the Directive 2001/83/EC.

(3) The Agency shall perform the following tasks concerning medicinal products for veterinary use, in addition to the tasks set out in the first paragraph hereunder:

- – determine and scientifically evaluate all adverse reactions to medicinal products for veterinary use and other knowledge on the safety of medicinal products for veterinary use, and other tasks pursuant to Articles 92, 93 and 94 of Directive 2001/82/EC.

- - the Agency shall inform the competent authority for veterinary medicine of the pharmacovigilance measures adopted by the Agency in the case of serious risk to the health of people and animals.

(4) The Agency may impose special obligations on healthcare professionals to encourage reporting supposed adverse reactions to medicinal products or collect information and follow up reports on any supposed adverse reactions to biological medicinal products.

Article 135

(Delegation of tasks)

(1) If, due to a large-scale pharmacovigilance problem, the Agency's resources are exceeded, it may delegate any of its tasks in the area of pharmacovigilance of medicinal products for human use, in part or in full, to one of the EU Member States, subject to the latter's written approval.

(2) The ministry competent for health shall notify the Agency of the delegation of tasks referred to in the previous paragraph.

Article 136

(Pharmacovigilance in homeopathic products)

The provisions of Articles 131 through 135 hereof shall apply to homeopathic products except those under the second paragraph of Article 53 hereof. The minister may prescribe a pharmacovigilance system for those homeopathic products.

Article 137

(Specific conditions and requirements for the pharmacovigilance system)

The competent minister shall prescribe the specific conditions, methods and procedures applying to the pharmacovigilance system.

2. **Non-interventional clinical trial at the request of the competent authority**

Article 138

(Procedure of obtaining consent to the draft protocol of the non-interventional clinical trial)

(1) The marketing authorisation holder who at the request of the Agency or EMA conducts a non-interventional clinical trial after obtaining a marketing authorisation pursuant to Article 58 hereof shall obtain prior to the trial a written consent from the Agency to the draft protocol whenever the clinical trial is performed only in the Republic of Slovenia or an approval from the competent committee of the EMA in accordance with Articles 107n through 107q of the Directive 2001/83/EC whenever the clinical trial is performed in several EU Member States.

(2) The marketing authorisation holder shall submit for non-interventional clinical trials referred to in the previous paragraph hereunder a draft protocol to the Agency whenever the trial is performed only in the Republic of Slovenia or to the competent committee of the EMA in accordance with Articles 107n through 107q of the Directive 2001/83/EC whenever the trial is performed in another EU Member State as well.

(3) Within 60 days of submitting the draft protocol referred to in the previous paragraph the Agency shall issue:

- a decision on consent to the draft protocol referred to in the first paragraph hereunder, or

- a decision opposing the draft protocol by stating the reasons of opposition, provided:

1. It is established that the performance of the non-interventional clinical trial stimulates the prescription and consumption of medicinal products,

2. It is established that the non-interventional clinical trial plan fails to ensure the attainment of the trial objectives,

or

- a decision establishing that the non-interventional clinical trial complies with Articles 33 through 40 hereof.

(4) The competent minister shall determine the detailed conditions for obtaining consent to the draft protocol for the non-interventional clinical trial on safety or efficacy of a medicinal product for human use after obtaining a marketing authorisation.

3. **MEASURES IN THE CASE OF INAPPROPRIATE QUALITY OF MEDICINAL PRODUCTS AND MEASURES TAKEN IN PHARMACOVIGILANCE CASES**

Article 139

(Measures taken in the event of inappropriate quality of medicinal products)

(1) Business entities manufacturing or marketing medicinal products shall report all events or suspected events regarding inappropriate quality of medicinal products, which could affect the safety or efficacy of the medicinal product, to the Agency, the marketing authorisation holder and the business entity marketing the medicinal products.

(2) The marketing authorisation holder referred to in Article 20 hereof shall withdraw the deficient medicinal product from the market and/or take any other necessary measures as well as regularly and promptly inform the Agency of the action taken.

(3) The marketing authorisation holder referred to in Article 20 hereof shall notify the competent authorities of the EU Member States in which the medicinal product is marketed forthwith of any action taken by him to withdraw a medicinal product from the market or to suspend or cancel 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 Agency shall monitor and, if necessary, direct the activities of the marketing authorisation holder in relation to the measures taken in the event of inappropriate quality of medicinal products and report the findings according to the international rapid alert system of authorities responsible for medicinal products of EU Member States and of EU bodies as well as, if required, of authorities of third countries.

(5) The Agency shall immediately inform the EMA 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.

(6) The competent minister shall determine in greater detail the measures to be taken in the case of inappropriate quality.

Article 140

(Measures taken in pharmacovigilance cases)

(1) Provisions of the previous Article shall apply mutatis mutandis in the cases of increased risk arising from adverse reactions that could be harmful to the health of people or animals or impact the risk-benefit balance of the medicinal product and should be reported according to the international rapid alert system of authorities competent for medicinal products of EU Member States and of EU bodies.

(2) The competent minister shall determine more detailed measures to be taken in the cases stated in the previous paragraph.

XIII. PROVISION OF MEDICINAL PRODUCTS IN EXTRAORDINARY CASES AND DONATIONS

Article 141

(Provision of medicinal products in extraordinary cases)

(1) Medicinal products that are at the proposal of the Minister provided by the Republic of Slovenia in accordance with the law regulating commodity reserves in case of natural or other large scale disasters and wars, shall be provided if the shelf life of medicinal products allows consumption before expiry and:

- if the medicinal product is authorised or temporarily authorised for marketing in the Republic of Slovenia;
- - If the medicinal product is not authorised for marketing in the Republic of Slovenia, but is authorised for marketing in another EU Member State, or
- - If the medicinal product is not authorised for marketing in any EU Member State, but is authorised for marketing in a third country that has equivalent requirements concerning quality, safety and efficacy of medicinal products, and has a report attached on quality analysis.

(2) The marketing authorisation holder shall be liable for any damage incurred as a result of inappropriate quality of the medicinal product listed in the above paragraph, if the damage arose from their action. If such damage results from distribution or dispensation of medicinal products, liability shall be assumed by the business subject carry out said activities.

(3) If a medicinal product from the first paragraph hereunder is provided to end users that are individuals and the medicinal product is intended to be dispensed to such individuals by a pharmacy or another place of delivery, as specified in the instruction in Paragraph eight of Article 141, the costs of healthcare services pertaining to prescribing and dispensing of a medicinal product shall be covered from the public funds of the compulsory health insurance provider or budgetary funds for persons without health insurance.

(4) The compulsory health insurance provider shall monitor and record the prescribing and dispensing of medicinal products detailed under paragraph one of the present Article, that are pursuant to provisions of paragraph eight hereof dispensed at pharmacies, and shall prepare financial analyses and reports on prescribed and dispensed medicinal products for end users. The compulsory health insurance provider shall use the following data for preparing financial analyses and reports on prescribed and dispensed medicinal products in line with paragraph one hereof:

- personal data of end users - insured persons - from the records of the compulsory health insurance provider (ID number (Health Insurance Institute of Slovenia number) in line with regulations on healthcare and health insurance, name and surname, sex, date of birth, permanent or temporary residence of insured person) and personal data from the central population register (personal identification number);
- personal data of end users who are uninsured and are citizens of the Republic of Slovenia from the central population register (personal identification number, name and surname, year of birth, sex, permanent or temporary residence);
- personal data from personal identification documents of end users for persons who are not citizens of the Republic of Slovenia and are not insured (name and surname, citizenship, year of birth, sex, permanent or temporary residence);
- data of the manager of databases pursuant to the act governing databases in the field of healthcare, on consumption of medicinal products, healthcare providers and providers of pharmacy services.

(5) The compulsory health insurance provider shall use the personal identification number to link data of end users listed under indents one and two of the prior paragraph for the purposes of collecting, processing and disclosure of data on prescribed and dispensed medicinal products detailed under paragraph one of the present Article in accordance with the directions of the minister under paragraph eight hereof.

(6) The compulsory health insurance provider shall prepare financial analyses and reports on prescribed and dispensed medicinal products detailed under paragraph one of the present Article based on acquired data under paragraph eight hereof and shall submit it to the Agency, the ministry competent for health and, in case of instituted protective measures, to the relevant authorised institution charged with implementation of such a protective measure.

(7) The business subject that carries out dispensing of medicinal products outside a pharmacy or applies medicinal products pursuant to instructions under paragraph eight of the present Article shall report on dispensed or applied medicinal products to the Agency, the ministry competent for health and, in case of instituted protective measures, to the relevant authorised institution charged with implementation of such a protective measure in accordance with the directions of the minister under paragraph eight hereof.

(8) The Minister shall issue a direction to prescribe the manner of prescribing and dispensing or application of each medicinal product under paragraph one of the present Article to end users at a pharmacy or another place of dispensing or application of medicinal products and the form and content of financial analyses and reports on presribed and dispensed or applied medicinal products from paragraph one of the present Act and the manner of submission of analyses and reports to the Agency, the ministry competent for health and, in case of instituted protective measures, to the relevant authorised institution charged with implementation of such a protective measure.

Article 142

(Business donation of medicinal products and assurance of medicinal products for the purpose of iodine prophylaxis)

(1) A business donation of medicinal products shall be a purposeful and unconditional gift a business entity provides to a healthcare provider free of charge on the basis of an expressed and substantiated need for the medicinal product that is the subject of a business donation and is required for the provision of healthcare activities.

(2) Recipient of a business donation may be a healthcare provider that is financed from public funds. If the recipient of a business donation of medicinal products is a healthcare provider that has an organised hospital pharmacy, the donated medicinal products shall be acquired and recorded in such a hospital pharmacy.

(3) Pharmacies that are independent business subjects may not be recipients of a business donation.

(4) Business donation shall not be allowed for medicinal products intended for compassionate use in accordance herewith.

(5) Medicinal products that are the subject of a business donation shall not be resold.

(6) The donor shall be the business entity or an individual who covers the cost of the donated medicinal product, including the costs of wholesale.

(7) Business donations of medicinal products for which the healthcare provider has expressed and substantiated a need, shall be allowed:

- - if conditions laid down in the third paragraph of Article 143 hereof are met;

- - if the outer packaging of the donated medicinal product clearly states that it is a donated medicinal product;

- - if the donor of the medicinal product submits a statement obligating them to supply the medicinal product even one year after the conclusion of the business donation programme to all patients included in the programme, provided that the patients' benefit of the treatment with such medicinal product is documented even if, after the expiry of the projected programme supply period, public funds are not guaranteed for funding this medicinal product,

- - if the donation has been notified to the Agency and the compulsory healthcare insurance provider and information on the donation published on their websites.

(8) A business donation may not promote prescribing, dispensing, selling or using of the medicinal product concerned with the healthcare providers for activities financed from the public funds, or medicinal product that was rejected in the process of reimbursement classification or inclusion in publicly financed healthcare programmes.

(9) In medicinal products participating in public procurement procedures, business donation may not affect such procedures, their outcomes and the client's use of selected medicinal products in the implementation period.

(10) Notwithstanding the previous paragraph, business donations of medicinal products, which are subject to public procurement and the term of public procurement is not yet completed, shall be prohibited.

(11) Donors must report business donations of the following medicinal products to the Agency:

- - under indent 2 of the first paragraph of Article 143 hereof, based on an application containing an expressed and justified position of the donation recipient;

- - for which the supplier selected in the public procurement process fails to provide the necessary quantities of the same medicinal product.

(12) Potassium Iodide tablets within a 10 km radius around NEK for the purpose of implementing the protective measure of prophylactic administration of iodine shall be provided by NEK, along with the financing of all healthcare services prescribing and dispensing medicinal products in pharmacies or at other delivery points according to instructions referred to in the eighth paragraph of Article 141 hereof associated with the protective measure. Protective measures of iodine prophylaxis shall be subject to paragraphs four through eight of Article 141 hereof.

(13) The activities related to wholesaling of medicinal products related to donated medicinal products and medicinal products detailed in the previous paragraph may be performed by wholesalers of medicinal products and notified wholesalers with registered office in the European Union.

(14) A more detailed manner of assurance of potassium iodide tablets for the purpose of implementing the protective measure of iodine prophylaxis on the entire territory of the Republic of Slovenia shall be prescribed by the Minister.

Article 143

(Criteria for the provision of medicinal products from budgetary funds and for business donation of medicinal products)

(1) The provision of medicinal products from budgetary funds and business donation of medicinal products shall be allowed:

- - in the case of large-scale natural or other disasters (nuclear, ecological disasters, terrorism or industrial disasters) or other emergency situations or in the case of managing threats to health (large-scale accidents, threatening infections, epidemics, pandemics, poisonings, ionising radiation, including protection against the above and similar events), or for other reasons in the interest of protection of public health or in the case of other circumstances endangering public health and animal health;

- - if the medicinal product that is subject to donation constitutes a significant therapeutic, scientific and technical innovation.

(2) Provisions of the previous paragraph refer to medicinal products, the shelf life of which enables their consumption prior to expiry.

(3) Provision of medicinal products from budgetary funds and business donation of medicinal products in the cases referred to in the indent 1 of the first paragraph hereunder shall be permitted subject to a need expressed by the Government of the Republic of Slovenia or the recipient of a business donation from the second paragraph of the previous Article:

- if the medicinal product is authorised or temporarily authorised for marketing in the Republic of Slovenia;

- - If the medicinal product is not authorised for marketing in the Republic of Slovenia, but is authorised for marketing in another EU Member State,

- - If the medicinal product is not authorised for marketing in any EU Member State, but is authorised for marketing in a third country that has equivalent requirements concerning quality, safety and efficacy of medicinal products, and has a report attached on quality analysis.

(4) The import of medicinal products that are the subject of provision from budgetary funds or business donation is performed by business entities having authorisation to manufacture medicinal products, including the activity of import.

(5) The marketing authorisation holder shall be liable for any damage incurred as a result of inappropriate quality of the medicinal product that is the subject of provision from budgetary funds or business donation if the damage arose from their action. If damage was caused during the distribution of medicinal product, the liability for it shall lie with the distributor.

(6) The process of issuing consent to the donation of medicinal products, the content of the application, the documentation, detailed criteria for the issue of consent to the donation of medicinal products, detailed conditions on the substance, the process of notification and publication from indent 4 of the seventh paragraph of the previous Article shall be determined by the competent minister.

Article 144

(Humanitarian aid in the form of medicinal products)

(1) The Government of the Republic of Slovenia may receive humanitarian aid from other EU Member States or third countries in the form of medicinal products:

- in cases of natural and other disasters on a larger scale (nuclear, ecological disasters, terrorism and industrial disasters);

- in cases of managing threats to health (harmful infections, epidemics, pandemics, mass poisonings, radiation - ionising and similar), or

- - in other exceptional circumstances that pose a threat to public health and health of animals.

(2) If a medicinal product referred to in the previous paragraph is provided to an end user that is an individual, the costs of healthcare services pertaining to prescribing and dispensing, delivery or application of a medicinal product by a healthcare practitioner in accordance with the provisions of Article 181 shall be covered by the compulsory health insurance provider and shall be repaid by the Republic of Slovenia from budgetary funds.

(3) The Government of the Republic of Slovenia may provide humanitarian aid in the form of medicinal products to recipients in other EU member states or third countries. Humanitarian aid in the form of medicinal products is an unconditional gift for a specific purpose which the Government of the Republic of Slovenia or a business entity gives to the donation's recipient which may be another country or national or international governmental or non-governmental or international humanitarian organisation which performs work in the territory of another country in accordance with the humanitarian principles and conventions, based on an expressed need and made without expecting any benefit in return.

(4) The Government of the Republic of Slovenia shall cover the expenses of humanitarian aid and the costs of its delivery to the recipient, as detailed in the above paragraph.

(5) Humanitarian aid detailed in Paragraph three above shall be permitted in the case of large-scale natural disasters or other emergency situations such as wars, terrorist attacks etc. in which health and life of people are endangered and if the medicinal product's shelf life enables its consumption prior to its expiry.

(6) For the purpose of providing humanitarian aid referred to in the third paragraph hereunder, the competent ministry for foreign affairs in cooperation with the competent ministry for healthcare carries out a public procurement contract for the purchase of medicinal products for humanitarian aid and grants authorisation to a wholesaler of medicinal products to export such medicinal products or deliver them to the recipient of humanitarian aid.

(7) The activities of marketing of medicinal products pertaining to humanitarian aid detailed in the first and third paragraph above may be performed by business entities having an authorisation for wholesaling of medicinal products and notified wholesalers of medicinal products with registered office in the EU.

(8) Financing of prescribing, delivery, dispensation or application set out in the first paragraph of the present Article and recording and reporting on the prescribed, delivered, dispensed or applied medicinal products shall be subject to the provisions of paragraphs one through eight Article 141 hereof.

Article 145

(Sale of medicinal products from national commodity reserves)

The Government of the Republic of Slovenia may in exceptional cases sell-off part of its medicinal products from its commodity reserves to other EU Member States or third countries, provided that in such countries health and life of people or animals are endangered, based on the request made by such country, provided that this does not increase the risk to public health and life of people or animals on the territory of the Republic of Slovenia and where the medicinal product's shelf life enables its consumption before expiry.

XIV. ADVERTISING OF MEDICINAL PRODUCTS

Article 146

(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, dispensing, sale or consumption of medicinal products.

Article 147

(Terms and conditions of advertising)

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

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

(3) All parts 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 148

(Advertising in general public)

(1) It is only allowed to advertise in the mass media medicinal products dispensed without prescription.

(2) It is prohibited to advertise to the general public the following:

- medicinal products dispensed only on medical or veterinary 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;

- - medicinal products which can be used as growth promoters or production stimulator (for example, hormones, beta-agonists, thyrostatic substance, bovine somatrophin).

(3) The advertising of a medicinal product for which no prescription is required to the general public shall not contain any material:

- - giving 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;

- - suggesting that the effects of taking the medicinal product are absolutely guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;

- - suggesting that the health of the person or animal can be enhanced only by taking the advertised medicine;

- - suggesting that the health of the person or animal could deteriorate without taking the advertised medicine. This prohibition shall not apply to vaccination programmes;

- directed exclusively or principally at children;

- - referring to a recommendation by scientists, healthcare professionals or publicly renowned persons who could encourage the use of medicinal product because of their media influence;

- - suggesting that the medicinal product is a foodstuff, cosmetic or other product;

- - suggesting that the safety and efficacy are due to the fact that it is natural;

- - That could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;

- - referring, in improper, alarming or misleading terms, to claims of recovery; or

- - using, in improper, alarming or misleading terms, pictorial representations of changes in the human or animal body caused by disease or injury, or of the action of a medicinal product on the human or animal body or parts thereof;

(4) Direct distribution of medicinal products for promotional purposes to the end users of medicinal products, healthcare professionals and performers of healthcare activity shall be prohibited.

(5) Notwithstanding the first paragraph hereunder, the Agency, based on the opinion of an institution authorised to develop programmes of prevention, management, elimination and eradication of infectious diseases, may permit the manufacturers of medicinal products to perform vaccination campaigns, including the relevant data on vaccines included in the program of vaccination and protection with medicinal products, to provide information on the possible vaccinations against individual diseases for those vaccinations that are included in the national programme by applying this Article mutatis mutandis.

(6) The competent minister shall determine in greater detail the conditions and method of advertising of medicinal products to the general public.Article 149 (Advertising of medicinal products to the expert community)

(7) Marketing authorisation holders may advertise medicinal products with marketing authorisation to the expert community in professional publications and by directly informing experts who prescribe or dispense medicinal products and exceptionally handing out samples.

(8) Notwithstanding the above paragraph, holders of authorisation for marketing medicinal products may use direct information to inform or train healthcare workers in connection with a medicinal product, the trading authorisation or healthcare provider authorisation for marketing which shows that its correct and appropriate administration essentially requires informing or training of patients as part of their healthcare of training of healthcare professionals.

(9) Advertising of medicinal products by means of direct advertising to persons authorised to prescribe and dispense medicinal products or healthcare workers detailed above who are participating in the performance of their activity in the framework of public health service can only be carried out during the time of expert preparation for work not intended for direct work with the patients.

(10) The marketing authorisation holder shall:

- - keep a list of expert colleagues who advertise medicinal products by means of direct advertising to persons authorised to

prescribe and dispense medicinal products and persons referenced in the second paragraph above, including data on their education;

- - keep a record of advertising and communication from the previous paragraph hereunder;

- - submit the list referred to in indent 1 and the record referred to in the previous indent hereunder to the Agency with the aim of performing expert supervision in the scope of pharmaceutical control pursuant to the law.

(11) The provisions of the third and fourth paragraph shall not apply to the advertising of medicinal products through direct informing of persons performing the veterinary activity.

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

(13) Organisation, implementation and hospitality of promotional meetings shall be strictly limited to the professional purpose of the meeting which includes obtaining of new skills and knowledge on new medicinal products and may only be provided to persons authorised to prescribe and dispense medicinal products and persons referenced in the second paragraph above.

(14) Marketing authorisation holders, manufacturers of medicinal products, business entities acting on behalf of manufacturers and business entities marketing medicinal products, as well as subsidiaries of foreign manufacturers may enable persons who prescribe or dispense medicinal products and persons referenced in the second paragraph above to acquire additional knowledge on new medicinal products in scientific and expert meetings, however, only subject to the restrictions referred to in the sixth and seventh paragraph hereof.

(15) Persons authorised to prescribe or supply medicinal products and persons from the second paragraph hereunder shall not solicit or accept any inducement prohibited under the sixth and seventh paragraph hereunder.

(16) The marketing authorisation holder shall establish a professional service for advertising medicinal products with experts to advertise medicinal products to persons prescribing and dispensing medicinal products and to persons referenced in the second paragraph of this Article.

The experts on medicinal products shall have a second cycle degree in pharmacy, medicine or veterinary medicine or a second cycle degree or a legally equivalent degree in another field which, in accordance with the applicable classification of professions, presents knowledge on the functioning of the human or animal organism and additional knowledge related to medicinal products, and shall be entered in the register of experts for advertising medicinal products kept by the Agency.

The experts on medicinal products that may be dispensed in specialised stores shall have at least completed secondary technical school education in pharmacy, subject to the conditions under item 1 of the first paragraph of Article 127 hereof.

(17)The minister shall determine in greater detail the conditions and method of advertising medicinal products to the expert community.

Article 150

(Register of experts for advertising medicinal products)

(1) Marketing authorisation holders shall notify to the Agency prior to commencement of advertising of medicinal products the experts for entry in the register of experts for advertising medicinal products, kept by the Agency. The Agency shall publish data from the register in accordance with the regulations governing the protection of personal data.

(2) The notification for entry in the register referred to in the previous paragraph hereunder shall include name and address of the marketing authorisation holder, and name, surname and professional qualifications of the expert for advertising medicinal products.

(3) The marketing authorisation holder shall notify the Agency on any change of experts for advertising medicinal products.

(4) The Agency shall delete an expert from the register of experts for advertising medicinal products upon a proposal of the marketing authorisation holder.

(5) The expert for advertising medicinal products shall present a certificate on entry in the register referred to in the first paragraph hereunder to providers of health care, veterinary and pharmacy services.

(6) The minister shall determine in greater detail the contents of the application, the conditions, the method and the procedures required for the entry, change and deleting from the register of experts for advertising medicinal products and the detailed contents of the register of experts for advertising medicinal products.

Article 151

(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 or other disaster or in similar emergencies, allow 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 information on the use of certain medicinal products in public media in agreement with the minister competent for veterinary medicine.

Article 152

(Exclusion from the scope of advertising of medicinal products)

(1) The following activities shall not be deemed advertising or advertising material, subject to the condition that their aim is not to promote prescribing, dispensing or consuming medicinal products:

- – information on a medicinal product: the summary of product characteristics, packaging and package leaflet approved in the marketing authorisation, which the patient can receive upon his request;

- – material approved by the Agency in the scope of risk management plan;

- – published information related to the approved changes in packaging, warnings of adverse reactions and other general precautionary measures aimed at safer and more efficient consumption of the medicinal product;

- – sales catalogues and pricelists not including statements on properties of medicinal product;

- – correspondence on specific issues concerning a medicinal product, including any non-promotional material enclosed;

- – publications and materials of an institution authorised to prepare programmes aimed at prevention, management, elimination and eradication of infectious diseases concerning the possibilities of vaccination against individual diseases;

- – information related to human health or diseases subject to the condition that no reference, including any indirect, is made to medicinal products.

(2) All information concerning the medicinal product have to be of quality, objective, impartial, unambiguous, integral, balanced, comprehensible to patients, healthcare professionals and entities performing healthcare activity, verifiable, updated, reliable, correct, eligible, not misleading and not containing elements of direct or hidden advertising.

(3) The minister shall prescribe in greater detail the conditions for information related to medicinal products excluded from the scope of advertising of medicinal products.

XV. OFFICIAL QUALITY CONTROL OF MEDICINAL PRODUCTS

Article 153

(Official control laboratory)

(1) The tasks of an official control laboratory included in the activities of the European network of Official Medicines Control Laboratories at the European Directorate for the Quality of Medicines and Healthcare (hereinafter: EDQM), shall be performed by the National Laboratory for Health, the Environment and Food (hereinafter: NLHEF), pursuant to permission referenced in Paragraph three, Article 30 hereof.

(2) NLHEF shall comply with the requirements of the ISO 17025 standard and provide for inter-laboratory verification of qualifications and periodic assessments of the quality assurance system implemented by EDQM.

Article 154

(Types of official controls)

(1) The types of official controls of the quality of medicinal products are as follows:

- - Regular control of the quality of marketed medicinal products performed ex officio as a rule once every five years for each pharmaceutical form and strength of a medicinal product unless the Agency determine otherwise based on a risk assessment. Regular control of the quality of marketed medicinal products for which a marketing authorisation has been granted under the centralised procedure shall be performed according to the annual programme adopted by the EMA in co-operation with EDQM;

- - Extraordinary control of quality of medicinal products performed upon a request of a pharmaceutical inspector in the case of suspected inappropriate quality or falsified medicinal products;

- - special control of quality of medicinal products to be assured before marketing by authorisation holders referred to in the first paragraph of Article 20 hereof, except for the holders of authorisations for compassionate use of medicinal products and holders of authorisations referred to in indents 1, 2, 3, 4, and 5 of the third paragraph of Article 20 hereof for each batch of vaccines, serums and blood products of human origin and immunological medicinal products for veterinary use intended for diagnosing the state of immunity;

- - quality control of medicinal products required by the Agency in the framework of the procedure for obtaining a marketing authorisation for a medicinal product or a parallel imported medicinal product.

(2) The marketing authorisation holder referred to in the first paragraph of Article 20 hereof shall provide the necessary documentation and reference material for regular and extraordinary quality controls of medicinal products within 30 days of receiving the request of NLHEF unless the Agency determines otherwise.

Article 155

(Report on the performed quality control of a medicinal product)

(1) NLHEF shall issue a report on the performed quality control of a medicinal product and submit it to the marketing authorisation holder, the parallel import authorisation holder, the temporary marketing authorisation holder or the entity proposing the control of quality of medicinal product and the Agency.

(2) The cost of official control of the quality of medicinal products is borne by:

- - in the case of regular quality control of medicinal products, the marketing authorisation holder, the parallel import marketing authorisation holder or the temporary marketing authorisation holder;

- - in the case of extraordinary quality control of medicinal products, the marketing authorisation holder or the parallel import marketing authorisation holder for medicinal products with a marketing authorisation and the temporary marketing authorisation holder for medicinal products without a marketing authorisation if it turns out that the quality of a medicinal product is deficient. If the quality control of a medicinal product is performed due to suspected falsification of the medicinal product, the cost of the extraordinary quality control shall be borne by the business entity marketing the medicinal product. If the medicinal product's quality is deemed appropriate or if the medicinal product is not falsified, the cost of the extraordinary control of quality incurred on the business entity shall be remunerated from the budget of the Republic of Slovenia;

- - in the case of special quality control of medicinal products, the entity proposing the special quality control detailed in item three of Paragraph one of the previous Article;

- - In the case of quality control of medicinal products required in the framework of the procedure for obtaining a marketing authorisation or a parallel import marketing authorisation, the applicant specified in Article 43 or Article 117 hereof.

(3) The minister shall determine the detailed substance and the deadlines of official quality controls of medicinal products, the sampling method and the price of service.

INSPECTION PRICES OF MEDICINAL PRODUCTS

Article 156

(Pricing of medicinal products)

The prices of medicinal products are not regulated and follow the market conditions except in cases stipulated herein.

Article 157

(Submitting data on the free prices of medicinal products)

(1) In the interest of public health protection, the minister or the minister competent for veterinary medicine may specify medicinal products or groups thereof not financed from public funds with prices freely determined in the market for which the business entities participating in marketing of medicinal products must submit data to the Agency on purchase and sale prices of those medicinal products and on the quantities of medicinal products sold over a certain period.

(2) The reporting agents for data on prices of medicinal products shall be business entities having an authorisation referred to in the first and second paragraph and indent 3 of the third paragraph of Article 20 hereof, holders of authorisations for wholesaling of medicinal products, pharmacies and specialised stores for medicinal products

(3) The minister shall prescribe specific requirements for reporting data used for the purpose under the first paragraph hereunder, elements to be monitored, medicinal products or groups of medicinal products the prices of which are monitored, the method of the Agency reporting to the ministry competent for health on the monitoring of prices and publication of data on the monitored prices.

Article 158

(Setting prices of medicinal products)

(1) The Agency shall set the maximum allowed price based on an application for medicinal products for human use, which may be marketed in accordance with the first and second paragraph or indent 3 of the third paragraph of Article 20 hereof and are financed from public funds or intended to be financed from public funds.

(2) The Agency may, on the basis of an application for the increase of the maximum allowed price, an opinion issued by the competent committee detailed in indent 4 of the fifth paragraph of Article 4 hereof, and the established public interest in the area of health and economic justifications of risk that might arise from interrupted supply of the market with medicinal products and provable, unavoidable and disproportionate

costs that would be incurred exclusively in meeting of public service obligations, determine exceptionally allowed higher price.

(3) The minister shall prescribe the method, criteria, obligatory elements of the application, the level of marketing and the procedure for determining the maximum allowed price of medicinal products and the exceptionally allowed higher price of medicinal products and the method, criteria and period for changing the maximum allowed price.

(4) The prices of medicinal products for veterinary use which may be marketed in accordance with the first or second paragraph or indent 3 of the third paragraph of Article 20 hereof, the level of which could impact animal health care and consequently harm the health of human beings, may in exceptional cases (e.g. epizootics, epidemics arising from epizootizcs, zoonoses, illnesses that are fought pursuant to regulations of veterinary medicine, in disproportionate influences of the price of medicinal products on the price of food) be formed or determined according to the method specified by the competent minister for veterinary medicine.

Article 159

(Prices of medicinal products that are lower than their maximum allowed price and exceptionally allowed higher prices)

(1) Prices of medicinal products may be lower than their maximum allowed price and exceptionally allowed higher price based on an agreement made between marketing authorisation holders referred to in the first paragraph of the previous Article or wholesalers and:

- - providers of healthcare insurance who settle the costs of dispensed medicinal products;
- – providers of healthcare services financed from public funds in public procurement procedures;
- – providers of pharmacy services financed from public funds in public procurement procedures;
- - business entities at which healthcare activities are performed for their care recipients in social security programmes;
- - the Slovenian Armed Forces for the purpose of providing healthcare support to its members; or
- - holders of system competencies in public health and national commodity reserves.

(2) Holders of authorisation under Article 20 hereof, which are public law entities established in the Republic of Slovenia, shall set prices under the previous paragraph considering the standpoints based on cost-justified setting of prices.

With such prices they shall enter into agreements with the entities from the previous paragraph, subject to prior consent of the competent ministry of health.

Article 160

(Mandatory discounts)

(1) If it is in the public interest of maintaining sustainable financing of medicinal products from public funds or in case of absent or inappropriate competition in the market for medicinal products, the minister may set by a decree a mandatory discount to marketing authorisation holders referred to in the first and second paragraph of Article 20 hereof, except for the holders of authorisation for compassionate use of medicinal product. A mandatory discount is set for one or more elements of the maximum allowed price of the medicinal product.

(2) The mandatory discount referred to in the previous paragraph hereunder may only be set for medicinal products financed from public funds:

1. If they are not on the list of essential or indispensable medicinal products referred to in Article 17 hereof;

2. For which one or more business subjects from paragraph one of the prior Article have submitted an incentive for the conclusion of an agreement that would achieve a lower price of the medicinal product from paragraph one of the prior Article for business subjects:

- the total value of purchases of which or the value of the medicinal product in question that was the basis for coverage of costs in medical insurance programs in the past calendar year, or
- the total value of expressed needs for purchase of the medicinal product in question in the current calendar year

represents at least three quarters of the value of sale of the medicinal product in question in the Republic of Slovenia in the past calendar year or expressed need for said medicinal product in the current year, the agreement for which was not concluded;

3. which are not on the list of interchangeable medicinal products with the highest recognised value; or

4. which do not have determined exceptionally allowed higher price.

(3) A mandatory discount is set for a period not exceeding 12 months.

Article 161

(Procedure for setting prices of medicinal products)

(1) The procedure for setting the maximum allowed price of a medicinal product referred to in the first paragraph of Article 158 hereof or setting the exceptionally allowed higher price of a medicinal product referred to in the second paragraph of Article 158 hereof shall be initiated by the Agency based on an application from the authorisation holder referred to in the first or second paragraph or the indent 3 of the third paragraph of Article 20 hereof.

(2) The Agency shall set the maximum allowed price of a medicinal product in 90 days of receiving a complete application.

(3) The Agency shall set an exceptionally allowed higher price of a medicinal product in 90 days of receiving a complete application. In the case of excessive workload related to the number of applications for the increase of exceptionally allowed higher prices, the deadline may be extended once, by a maximum of 60 days.

(4) The Agency may request additional evidence or documentation from the applicant in accordance with paragraph six of Article 3 hereof in the procedure of setting prices referred to in the first paragraph hereunder.

(5) The deadline set out in the second and third paragraph of the present Article shall be suspended from the date of serving of notification for hearing in the procedure for setting the maximum allowed price or exceptionally allowed higher price of a medicinal product to the date of receiving a response from the authorisation holder referred to in the first or second paragraph or the indent 3 of the third paragraph of Article 20 hereof. The response period set out by the Agency shall not be less than 15 days.

(6) If the price is not set within the deadlines from the second and third paragraph hereunder, it shall be deemed that the application has been granted and the applicant can market the medicinal product at the price proposed in the application.

(7) Appeal against the decision from the second and the third paragraphs of this Article shall not stay the execution of the decision.

Article 162

(Withdrawal of the measure of pricing regulation of medicinal products)

(1) Regardless of the law regulating pricing regulation, the authorisation holder referred to in the first or second paragraph or the indent 3 of the third paragraph of Article 20 may submit a proposal to the Government of the Republic of Slovenia on the withdrawal of the measure of pricing control which the Government of the Republic of Slovenia has introduced based on the law regulating pricing regulation. The proposal must state the reasons for the proposed withdrawal. The Government of the Republic of Slovenia shall submit a substantiated proposal for assessment to the ministry competent for pricing regulation.

(2) The ministry competent for price regulation may within 15 days of receiving the proposal from the Government of the Republic of Slovenia require the applicant to submit additional data and substantiations that the applicant is obliged to submit within 30 days.

(3) The ministry competent for pricing regulation shall apply the provisions of regulations for pricing regulation in preparing its opinion on the substantiation of the above proposal.

(4) The opinion on substantiation of the proposal under paragraph one of the present Article shall be submitted by the ministry competent for pricing regulation to the Government of the Republic of Slovenia within 15 days of receiving the proposal for withdrawal or supplemented proposal under paragraph two of the present Article, whereby the Government of the Republic of Slovenia shall within 75 days decide on the proposal and notify the applicant of the decision.

(5) In case of a great number of proposals for withdrawal from this Article, the deadline for preparing the opinion set out in paragraph four of the present Article may be extended one time for a period of 60 days, of which the Government of the Republic of Slovenia shall notify the applicant before the primary deadline expires.

Article 163 (Obligation to use the applicable price)

(1) Business entities that purchase and sell or issue medicinal products shall use the valid price of a medicinal product.

(2) The valid price of a medicinal product for human use hereunder can be:

- - the maximum allowed price of a medicinal product;
- - the maximum allowed price of a medicinal product;
- the lower price of medicinal product than the maximum allowed price based on agreement from the first paragraph Article 159 hereof;
- - the price from the second paragraph of Article 159 hereof.
- - the maximum allowed price with mandatory discount form Article 160 hereof; or
- - the price of medicinal product that is set freely under the conditions of the market of medicinal products which are not financed from public funds or are not earmarked to be financed from public funds.

(3) Prices detailed in indents 1 through 5 of the previous paragraph shall be the maximum prices of medicinal products, whereby business subjects shall not be allowed to sell medicinal products above the price, but shall be allowed to sell at a lesser price.

(4) If business subjects reduce the prices detailed in points one to five in the second Paragraph of the present Article during the term of their validity, such reduced prices shall be deemed valid prices of medicinal products, provided the Agency was duly notified and has recorded and published the price on its website.

(5) Business entities that set a valid reduced price of a medicinal product in accordance with the provisions of the above paragraph, sell medicinal products, that are financed from public funds or are intended for financing from public funds in the period until its revocation by the business subject that the Agency records and publishes at its website within five working days of receiving notice of revocation.

(6) A business entity that purchases and sells or issues medicinal products shall invoice medicinal products financed from public funds at the applicable medicinal product price that is most cost effective for the business entity listed in the first paragraph of Article 159 hereof.

(7) A central medicinal product database shall be established for the purpose of monitoring the prices of medicinal products and shall be managed by the compulsory health insurance provider. The database shall keep the following data on medicinal products:

- under items 1 to 4 of Article 187 hereof;
- on the prices and beginning of validity of prices from indents one through five of the second and fourth paragraph hereunder, on the withdrawal of price set out under paragraph five hereof and prices of medicinal products set out pursuant to the law regulating pricing;
- on maximum recognised values of medicinal products as set out by the compulsory health insurance provider.
- on financing of medicinal products from public funds;
- on presence of medicinal products on the market.

(8) Data from the above paragraph shall be submitted to the central database of medicinal products on the basis of computerised data exchange by the following:

- the Agency - for data on medicinal products under indent one of the prior paragraph, data on prices of medicinal products from indents one and two of the second and fourth paragraph hereof and data on presence of medicinal products on the market as set out by indent five of the previous paragraph;
- subjects from indents one through six of paragraph one of Article 159 hereof - for data on medicinal product pricing from indent three of paragraph two hereof;
- holders of authorisation pursuant to paragraph two of Article 159 hereof - for data on medicinal product pricing from indent four of paragraph two hereof;
- the compulsory health insurance provider - for highest recognised values of medicinal product from indent thee and data on medicinal product financing from public funds from indent four of the prior paragraph;
- ministry competent for health - for data on medicinal product pricing from indent five of paragraph two hereof;
- ministry competent for pricing regulation - for data on medicinal product pricing set out pursuant to the law governing pricing regulation.

(9) Subjects listed in the above paragraph shall submit data on medicinal product prices and the commencement and expiry of their validity into the central medicinal product database no later than two working days prior to commencement or expiry of validity of price of a medicinal product, while other data listed in the prior paragraph shall be entered within 8 days of its creation.

(10) The manner of submission of data under paragraphs eight and nine hereof and access to such data shall be set out by the Minister.

Article 164

(Obligation to report medicinal product pricing data)

Business entities authorised for retail and wholesale of medicinal products or holding an appropriate certificate of notification, specified in the third paragraph of Article 105 hereof shall submit to the Agency all data on the prices of medicinal products in a manner stipulated herein, while data on medicinal products for veterinary use shall also be submitted to the authority competent for veterinary medicine.

XVII. INSPECTION

Article 165

(Competencies in supervising the implementation of the Act)

(1) The inspection of the implementation of this Act and the regulations issued on the basis hereof shall be performed by pharmaceutical inspectors, official veterinarians, market inspectors and customs authorities.

(2) Pharmaceutical inspectors shall perform inspections within the competencies of the Agency.

(3) The official veterinarians supervise the provisions of this Act and the regulations issued on the basis hereof relating to the use of medicinal products and the related traceability of medicinal products for veterinary use.

(4) The import of medicinal products shall be supervised by the customs authorities with expert support provided by the Agency and the official veterinarians.

Article 166

(Competencies of pharmaceutical inspectors)

(1) In addition to the tasks specified in the previous Article hereof, pharmaceutical inspectors shall perform inspection tasks based on:

- - the law governing medical devices;
- - the law governing supply of blood;
- – the Act regulating the quality and safety of human tissues and cells intended for treatment; and
- – the Act regulating manufacturing of and trade in illicit drugs in the part related to illicit drugs of groups II and III which are medicinal products.

(3) The Act regulating inspections shall apply to the rights, duties, powers, procedures and measures in performing of inspection tasks by pharmaceutical inspectors unless specified otherwise by this Act or the regulations and laws of the European Union.

Article 167

(Pharmaceutical inspector)

(1) A pharmaceutical inspector may be a person meeting the conditions for performing inspections laid down by the Act regulating inspections.

(2) The Minister shall prescribe the additional expertise of a pharmaceutical inspector in individual areas of inspections in accordance with the specific regulations.

(3) Pharmaceutical inspectors shall be independent in performing of their tasks in accordance with their powers and within and based on the Constitution and the law.

(4) Pharmaceutical inspectors shall undertake ongoing professional training and education in accordance with a programme prescribed by the director of the Agency within the scope set for individual areas of inspection.

(5) Pharmaceutical inspectors shall sign a statement on any financial or other relation or otherwise with business entities subject to inspections, which shall be taken into account when individual inspection tasks are given to pharmaceutical inspectors in accordance with internal acts adopted by the Director of the Agency.

(6) If a pharmaceutical inspector declines to sign the statement set out above, he may be allocated to other systemised jobs and tasks within the Agency.

Article 168

(Appointment to expert commission)

Pharmaceutical inspectors may be appointed to an expert commission detailed in the eighth paragraph of Article 4 hereof.

Article 169

(verification of fulfilment of the conditions of good practices abroad)

(1) Based on co-operation between European Union Member States, a request from the competent body of a European Union Member State, the European Medicines Agency or the European Commission or a request from the competent body or business entity from the European Union or a third country, pharmaceutical inspectors perform expert tasks related to verifying compliance with the good manufacturing or distribution practice related to medicinal products, active substances and certain excipients at any business entity with a registered office in any European Union Member State or a third country, in accordance with the Regulation (EC) 726/2004, Directive 2001/83/EC, Directive 2001/82/EC, Directive 2001/20/EC, Directive 2005/28/EC and the Compilation of European Union Procedures.

(2) The pharmaceutical inspector shall issue a certificate on good manufacturing or distribution practice based on the results of the verification referred to in the previous paragraph hereunder if it is established that the business entity is implementing the principles and guidelines of good manufacturing or distribution practice.

Article 170

(Method of exercising inspections)

(1) Pharmaceutical inspectors shall perform inspections within their powers in the Republic of Slovenia as regular, extraordinary and repeated inspections, which may be unannounced.

(2) Regular pharmaceutical inspections shall be performed by pharmaceutical inspectors ex officio or based on an application submitted by a business entity. The frequency of regular inspections shall be determined with regard to the risk assessment and in accordance with the requirements set out by the regulations governing the relevant area of inspection.

(3) Extraordinary inspections shall be performed based on a grounded suspicion of non-compliance with the regulatory requirements or risk assessment in a case, a decision of the Agency or a request from bodies competent for medicinal products of European Union Member States or competent authorities of the European Union.

(4) Repeated inspections may be performed after the deadline set to eliminate deficiencies identified within the scope of regular or extraordinary inspection and to implement the imposed measures and tasks has expired.

(5) Pharmaceutical inspectors shall exchange information on the planned and performed inspections with the competent medicinal product bodies of European Union Member States and other authorities of the European Union.

(6) The pharmaceutical inspector may be accompanied at an inspection by another Agency employee or external expert in the relevant field.

(7) The pharmaceutical inspector shall draw up a record of the performed inspection and shall deliver it to the inspected business subject no later than within 30 days of the performed inspection. A record of inspection of good manufacturing and distribution practices shall be drawn up in the form set out in the Compilation of European Union Procedures.

Article 171

(Inspections in the area of advanced therapy medicinal products prepared on a non-routine basis)

Pharmaceutical inspectors carry out inspection referred to in the previous Article hereof also at providers of healthcare or veterinary services ordering and using advanced therapy medicinal products prepared on a non-routine basis.

Article 172

(Mutual recognition of documents on inspections)

Documents on inspections performed by competent bodies of European Union Member States or countries having concluded an agreement on mutual recognition of documents concerning medicinal products with the European Union shall be mutually recognised.

Article 173

(Measures of pharmaceutical inspectors in the field of medicinal products)

(1) Pharmaceutical inspectors determining in the course of an inspection violations of the law and the regulations issued on the basis thereof concerning their areas of competence shall

have the following rights and duties in addition to the rights and duties laid down in the Act regulating inspections:

- – Prohibit performing of an activity due to non-meeting of the prescribed conditions;

- – prohibit marketing or order destruction or recall of certain batches of medicinal products; if it is found that:

a)the medicinal product is harmful in the normal conditions of use;

b)the medicinal product is lacking in therapeutic efficacy;

c)the risk-benefit balance is unfavourable under the prescribed condition of consumption;

d)- its quality and quantitative composition is not as declared;

e)if the medicinal product and/or its ingredients have not been tested and the interim stages of the manufacturing process have not been tested or if certain other requirements or obligations related to the issued marketing authorisation for the medicinal product have not been met;

(f) the medicinal product is falsified;

(g) the medicinal product should not be marketed in accordance herewith;

- – inform all European Union Member States, business entities in the supply chain and the general public; if it is assumed that the medicinal product concerned poses a serious risk to public health;

- - prohibit entry or import of a medicinal product without due authorisation granted by the Agency;

- - order the removal or destruction of the material used for illegal advertising of medicinal products;

- - prohibit the advertising and information that are not in compliance with the provisions hereof;

- - order other measures and perform tasks necessary for the implementation of this Act and the regulations issued on the basis hereof;

- - notify other European Union Member States, the European Commission and the EMA of the results of inspections related to pharmacovigilance and the proposed measures.

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

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

Article 174

(Competencies of pharmaceutical inspectors in the area of advanced therapy medicinal products prepared on a non-routine basis)

To ensure compliance with the requirements laid down herein, pharmaceutical inspectors conduct regular, extraordinary and repeated supervision inspections also at the medical practitioners and veterinarians ordering and using advanced therapy medicinal products prepared on a non-routine basis.

Article 175

(Sampling of marketed medicinal products) Sampling of marketed medicinal products for the purpose of quality assurance shall be performed by authorised persons of NLHEF.

Article 176

(Competencies of pharmaceutical inspectors related to prices of medicinal products)

(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:

- Observation of the valid price of medicinal product;

- that they refund to the payer the undue amounts resulting from the difference in the price, with accrued interest.

(2) If a participant in the marketing of a medicinal product failed to comply with the price stipulated on the basis of the present Act and regulations under Articles 158 and 160 hereof and charged too high prices of medicinal products to the payers, such participant shall refund such unduly charged amounts to the payers within 15 days of the issue of a final decision by the pharmaceutical inspector, 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 pharmaceutical inspector shall inform of its decision the authority competent for veterinary medicine in the case of medicinal products for veterinary use.

Article 177

(Obligation to supply the market in accordance with the decision issued by the pharmaceutical inspector)

(1) If the participants in the marketing of a medicinal product fail to start or stop selling a medicinal product due to setting prices of a medicinal product pursuant to this Act or regulations specified in Articles 158 and 160 hereof upon their own initiative and if such action could seriously jeopardise the supply of medicinal products to the population, the pharmaceutical inspector may issue a decision referred to in the first paragraph of the previous Article imposing on them to immediately start or continue selling such medicinal product, applying the prices stipulated herein or in regulations adopted on its basis referred to in Articles 158 and 160 hereof.

(2) In such decision, the pharmaceutical 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 decision is final.

Article 178

(Execution of decisions)

An appeal against the decision referred to in Article 177 hereof shall not prevent its execution with the exception of refunding the unduly charged amounts in accordance with the second paragraph of the stated Article.

Article 179

(Competences of official veterinarians)

Official veterinarians shall have the following rights and duties in addition to those laid down by the Act regulating inspections:

- - right and duty to conduct the violations procedure and impose sanctions for such violations;

- - impose on the legal entity or natural person to harmonise the operations with the provisions of this Act and the regulations adopted on its basis;

- - order prohibition of the use of medicinal products and active substances for the treatment of animals that are not compliant with the provisions hereof;

- - confiscate medicinal products in violation of this Act from the owner or keeper of the animal;

- - order the owner or keeper of the animal to destroy medicinal products in violation of this Act at their own cost.

XVIII. PUBLIC AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

Article 180

(Operation and supervision)

(1) The Agency is a legal entity of public law.

(2) The founder of the Agency shall be the Republic of Slovenia. Rights of the founder shall be exercised by the Government of the Republic of Slovenia.

(3) The Agency shall be independent in performing its tasks.

(4) Operations of the Agency shall be supervised by the ministry competent for health.

(5) The law regulating public agencies shall apply to the Agency, unless the present Act provides otherwise.

Article 181

(Personnel management)

(1) In its working program and financial plan, the Agency also determines a staffing plan in coordination with the ministry.

(2) The work program and financial plan of the Agency shall be adopted by the Agency council and submitted to the founder for consent.

(3) The employees of the Agency are subject to the act governing the public sector salary system.

Article 182

(Tasks of the Agency)

(1) The Agency shall perform the following tasks concerning medicinal products:

- administrative and expert tasks related to marketing authorisations for medicinal products in national and international procedures of assessing quality, safety and efficacy and the risk-benefit balance in consumption of medicinal products;
- administrative, expert and supervisory tasks related to clinical trials;
- tasks in the pharmacovigilance system for managing and reducing risks related to medicinal products, informing of the public, setting up and maintenance of a web portal on safety of medicinal products and participation in pharmacovigilance activities of the European Union;
- expert tasks and participation in the distribution of work among European Union Member States related to regulation of medicinal products;
- expert tasks in the work of committees and task forces of the EMA and other institutions and inclusion in international initiatives in accordance with the system guidelines of the Republic of Slovenia;
- administrative and expert tasks related to classification of products for which there is a serious doubt whether they should be classified among medicinal products or in another product group;
- administrative and expert tasks related to determining meeting of the conditions and principles and guidelines of good manufacturing practice concerning medicinal products, active substances and excipients;
- administrative and expert tasks related to determining the fulfilment of the conditions and principles of good distribution practice in the field of medicinal products and active substances;
- administrative and expert tasks related to determining meeting of the conditions and principles of good clinical practice in clinical trials of medicinal products;
- administrative and expert tasks related to determining meeting of the conditions and principles of good pharmacovigilance practice;
- administrative and expert tasks related to determining meeting of the conditions for the activity of preparation of advanced therapy medicinal products prepared on a non-routine basis;
- supervision over medicinal products, active substances and excipients concerning medicinal products for human use and advanced therapy medicinal products prepared on a non-routine basis;
- administrative, supervisory and expert tasks related to handling specific deviations from the conditions specified in the marketing authorisation;
- supervision tasks related to medicinal products for veterinary use with the exception of defining doctrinal solutions in terms of safe use of medicinal products in veterinary medicine and the supervision over use and use-related traceability of medicinal products for veterinary use;
- administrative and expert tasks related to pricing of medicinal products and supervision over prices of medicinal products;
- administrative, expert and supervisory tasks related to the monitoring of presence of medicinal products in the market and assigning the national identifier of medicinal products;
- administrative and expert tasks related to medicinal products without a
- marketing authorisation in the Republic of Slovenia;
- administrative and expert tasks related to essential and indispensable medicinal products;
- administrative and expert tasks related to donations of medicinal products;
- administrative and expert tasks related to interchangeable medicinal products;
- administrative and expert tasks related to evaluating health technologies;
- tasks related to pharmacoepidemiological and pharmacoeconomic monitoring of the market in medicinal products and the pertaining methodologies, records and analyses of consumption and use of medicinal products;
- expert support for the tasks of the official control laboratory;
- tasks and measures related to falsified medicinal products;
- devising, preparing and keeping official records related to medicinal products, active substances and excipients, which comprise products and business entities;
- participation in preparation of the European Pharmacopoeia and preparation of the National Annex to the European Pharmacopoeia;
- providing for translation of the ATC classification of medicinal products by the World Health Organisation, web publication of the defined daily doses for medicinal products marketed in the Republic of Slovenia and uniform national naming of active substances;
- Participation with in the European network of competent bodies for medicinal products in the area of normative regulation of medicinal products and pricing of medicinal products;
- Participation with the official control laboratory and its inclusion into the European network of Official Medicines Control Laboratories with EDQM;
- other tasks related to medicinal products for human and veterinary use.
- The Agency shall also perform the following tasks:
- participation in drafting laws and implementing regulations concerning the Agency's area of competence;
- keeping of official records based on this Act;
- tasks associated with establishing and maintaining an information system within the scope of official records;
- the tasks establishing an internationally recognised quality assurance system within the framework of good practices of normative administration in the field of medicinal products;
- expert support in implementing system policies associated with medicinal products;
- the tasks that involve co-operation with other management, expert and scientific institutions within the areas of its competence in Slovenia and abroad, and
- other tasks within its area of competence.

(3) In addition to the tasks specified in the first and second paragraph hereunder, the Agency shall also perform tasks related to medical devices, blood and blood preparations, quality and safety of human tissue and cells intended for treatment, and production of and trade in Schedule II and Schedule III illicit drugs, in accordance with the specific regulations.

Article 183

(Sources of Agency financing)

(1) Funding for the Agency is provided from:

- fees; funds from the budget of the Republic of Slovenia;
- compensation for other services;
- other revenues.

(2) Funds from the budget of the Republic of Slovenia shall be provided for salaries, costs of material and services and costs of investments for those jobs within the Agency necessary for performing the tasks and services in individual areas of competencies for which this Act or other regulations of the Republic of Slovenia or the European Union do not foresee or allow the charging of fees or tariffs.

(3) The minister and minister competent for veterinary medicine shall define the nature and scope of tasks and programmes of the Agency to be financed from the budget of the Republic of Slovenia.

Article 184

(Bodies of the Agency)

(1) The bodies of the Agency shall be its Director and the Council of the 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 either employed by, or perform any form of work in, any organisation engaged in any form of for-profit activities activity in the area of medicinal products and medical devices, and may not have any function whatsoever in such organisations.

(4) Besides the reasons, stipulated by the act regulating public agencies, the Government of the Republic of Slovenia shall dismiss the Director or a council member of the 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 reason listed in the prior paragraph comes into existence;

- In the event of final judgement sentencing the Director to imprisonment for a criminal offence or for causing economic losses.

Article 185

(Reporting on the work of the Agency)

(1) The Agency shall submit an annual report to the founder at least once a year by 28 February.

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

Article 186

(Administrative decisions and decision in violation procedures)

(1) The Agency shall decide in accordance herewith in administrative matters at first instance pursuant to the act governing the general administrative procedure, unless otherwise stipulated by this Act.

(2) Appeals against decisions adopted by the Agency shall be decided on by the ministry competent for health, with the exception of the decisions falling within the competence of the official veterinarian, which shall be decided on by the ministry competent for veterinary medicine.

(3) The Agency shall be the minor offence authority for the areas lying within the competence of a pharmaceutical inspector.

(4) A violations procedure shall be conducted and decided upon by a pharmaceutical inspector, who fulfils the conditions laid down in the act regulating violations, and regulations adopted on the basis thereof.

Article 187

(Official records of the Agency)

The Agency shall keep the following official records for the purpose of protecting public health:

1. Records on data on medicinal products arising from marketing authorisation for medicinal products (name, pharmaceutical form, strength, packaging, classification with regard to prescribing and dispensing, marketing authorisation holder, maximum allowed price and exceptionally allowed higher price);
2. Records on data on medicinal products arising from marketing authorisation for parallel import of medicinal products (name, pharmaceutical form, strength, packaging, parallel import marketing authorisation holder, maximum allowed price and exceptionally allowed higher price);
3. Records on medicinal products with temporary marketing authorisation (name, pharmaceutical form, strength, packaging and authorisation holder);
4. Records on data on medicinal products with authorisation for import (name, pharmaceutical form, strength, packaging and authorisation holder);
5. Records on data on medicinal products with marketing authorisation for compassionate use (name, pharmaceutical form, strength, packaging and authorisation holder);
6. Records on donated medicinal products (name, pharmaceutical form, strength, packaging, quantity and donor);
7. Data on holders of authorisations for manufacturing of medicinal products (name, registered office and legal form of organisation and name and surname of qualified person in charge of release of individual batches of medicinal products);
8. Data on holders of authorisations for wholesaling of medicinal products (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);
9. Records on holders of authorisations for preparation of advanced therapy medicinal products prepared on a non-routine basis (name, registered office and legal form of organisation, and name and surname of qualified person in charge of quality);
10. Records on notified foreign wholesalers (name and legal form of organisation, and registered office);
11. Records on brokers of medicinal products and active substances (name and registered office of the business entity);
12. Records on manufacturers, importers and distributors of active substances (name and legal form of organisation, and registered office).
13. Records on experts for advertising medicinal products;
14. Records on physicians and veterinarians ordering and using advanced therapy medicinal products prepared on a non-routine basis (name, surname and professional title, and name and address of the business entity where they perform healthcare activity);
15. Records on holders of authorisation for retailing of medicinal products (name and legal form of organisation, and registered office);

Article 188

(Publications)

The Agency may publish professional and general informative publications in its areas of competence.

Article 189

(Fees)

(1) The applicant shall pay fees to cover the cost of performing administrative tasks subject to the public authority carried out by the Agency, unless stipulated otherwise by law.

(2) The holders of marketing authorisations or the authorisations for parallel import of medicinal products and the holders of authorisation to perform activity, issued by the Agency, 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.

Article 190

(Tariffs)

The Agency Council shall issue Tariffs setting the amounts due for performing expert tasks and rendering services related to its areas of competence. Tariffs and their amendments shall come into force once the founder issues consent.

XIX. PENAL PROVISIONS

Article 191 (Offences)

(1) A fine of 800 to 4,000 euros shall be imposed for an offence on a legal entity:

- - dispensing galenic medicinal products more than six months after the entry of an equivalent or comparable industrially manufactured medicinal product on the market (third paragraph of Article 8 hereof);
- – acting contrary to Article 16 hereof in the import and entry of medicinal products for personal use and use on their animal;
– for acting contrary to the second paragraph of Article 16, Point (d) of the second paragraph of Article 23, the fifth paragraph of Article 24 and Article 26 of the Regulation (EC) 726/2004;
– failing to submit information listed in Article 24 hereof;
- - failing to report data on prescription and volume of consumption of medicinal products (Article 25 hereof);
- - promoting the use of a medicinal product and replacement of an existing therapy without reason (paragraph five of Article 40 hereof);
- – carrying out non-interventional testing of medicinal products contrary to paragraphs six or seven of Article 40 hereof;
- - failing to inform the Agency of new information that could impact the assessment of the risk-benefit balance pursuant to the seventh paragraph of Article 40 hereof,
- – failing to inform the patient or the owner or keeper of animal of the treatment procedure and the risks related to the treatment with advanced therapy medicinal product prepared on a non-routine basis, or to store such signed statement (third paragraph of Article 77 hereof);
- – failing to issue to the patient or the owner or keeper of animal the package leaflet in accordance with the fourth paragraph of Article 77 hereof;
- – failing to communicate a change in the data in accordance with the third paragraph of Article 78 hereof;
- – failing to inform the Agency of the changes that affect the conditions for the issue of an authorisation for the preparation of advanced therapy medicinal product prepared on a non-routine basis as specified by the first paragraph of Article 85 hereof,
- – failing to register the activity with the Agency in accordance with the fourth paragraph of Article 101 hereof;
- - failing to register with the Agency the activity of wholesaling medicinal products in the Republic of Slovenia in accordance with the third paragraph of Article 105 hereof;
- – failing to register the activity with the Agency in accordance with the fourth paragraph of Article 112 hereof;
- – failing to register the activity with the Agency in accordance with the fourth paragraph of Article 121 hereof;
- – failing to register the activity with the Agency in accordance with the first paragraph of Article 124 hereof;
- – failing to notify the Agency prior to advertising medicinal products of the experts for entry in the register of experts for advertising medicinal products (first paragraph of Article 150 hereof);
- - failing to report changes to the list of experts for advertising medicinal products to the Agency (third paragraph of Article 150 hereof);
- - failing to provide documentation and reference material for the performance of ordinary and extraordinary quality control of medicinal products pursuant to the second paragraph of Article 154 hereof,
- - failing to forward data on the purchase and sale prices of medicinal products not financed from public funds with the prices of these medicinal products being freely determined under market conditions, and data on the quantities of medicinal products sold over a certain time period (first paragraph of Article 157 hereof),
- – failing to communicate to the Agency all data on the prices of medicinal products in a manner stipulated herein, with data on medicinal products for veterinary use also being submitted to the authority competent for veterinary medicine (Article 164 hereof).

(2) A fine of 500 to 3,000 euros shall be imposed for an offence listed in the previous paragraph hereunder on a sole proprietor or an individual engaging in a registered activity.

(3) A fine of 200 to 1,000 euros shall be imposed for an offence listed in the first paragraph hereunder on the responsible person of a legal person, the responsible person of a sole proprietor or the responsible person of an individual engaging in a registered activity.

(4) A fine of 100 to 500 euros shall be imposed on an individual committing an offence specified in the first paragraph hereunder.

Article 192 (Serious offences)

(1) A fine of 8,000 to 120,000 euros shall be imposed for an offence on a legal entity for:

- – exceeding the annual quantity manufactured exceeding 50,000 packaging units (first paragraph of Article 8 hereof);
- – manufacturing galenic medicinal products contrary to the second paragraph of Article 8 hereof;
- – using industrially manufactured medicinal products, intermediates or intermediate products or semi-finished products for producing galenic products contrary to the fourth paragraph of Article 8 hereof;
- - manufacturing galenic medicinal products in a greater quantity without prior approval from the Agency (fifth paragraph of Article 8 hereof),
- – advertising or placing on the market any products with an alleged healing properties or disease prevention properties for use in human or veterinary medicine which pursuant to this Act are not considered a medicinal product (first paragraph of Article 9 hereof);
- - presenting products that are not classified as medicinal products pursuant hereto to patients or customers as having healing properties or disease prevention properties (second paragraph of Article 9 hereof).
- – not acting in compliance with Article 14 hereof when prescribing and dispensing medicinal products;
- - marketing medicinal products listed in Article 21 hereof;
- – failing to inform the Agency about inadequate quality of a medicinal product or suspected falsification of a medicinal product (Article 23 hereof);
- – not having concluded a contract with the manufacturer according to the second paragraph of Article 27 hereof;
- – Failing to manufacture and control medicinal products in line with Article 28 hereof;
- – performing clinical trials with advanced therapy medicinal products prepared on a non-routine basis (third paragraph of Article 33 hereof);
- – not performing clinical trials of medicinal products in accordance with Articles 34 and 35 hereof;
- – failing to insure its responsibility for damages incurred during clinical trials in accordance with Article 36 hereof;
- – failing to notify the agency of any material changes to ongoing clinical trials (first paragraph of Article 38 hereof);
- – failing to notify the non-interventional clinical trial with the Agency in accordance with the first paragraph of Article 40 hereof;
- - failing to compile a report for the Agency on the progress and outcome of the trial pursuant to the fourth paragraph of Article 40 hereof;
- - failing to notifying patients on their inclusion in a non-interventional clinical trial (fifth paragraph of Article 40 hereof),
- – marketing a generic medicinal product contrary to Articles 45 and 46 hereof;
- – failing to include the conditions and obligations related to the safety of medicinal product in the risk management system (seventh paragraph of Article 58 hereof);
- – failing to inform the Agency of the new information or all information pursuant to the first and second paragraph of Article 62 hereof;
- – selling medicinal products after the change or expiry of the marketing authorisation contrary to Article 67 hereof;
- - placing medicinal products for advanced therapy on the market contrary to the first paragraph of Article 71 hereof,

- – marketing or preparing advanced therapy medicinal products prepared on a non-routine basis contrary to Article 71 hereof;

- – failing to fulfil the requirements under Article 72 hereof;

- – acting contrary to the first and the second paragraphs of Article 74 hereof;

- – Failing to submit the annual report in accordance with Article 75 hereof;

- - exit and exporting and entry and importing advanced therapy medicinal products prepared on a non-routine basis (Article 76 hereof);

- – failing to establish damage liability for potential damage caused to a patient or an animal (second paragraph of Article 77 hereof);

- – using advanced therapy medicinal products prepared on a non-routine basis without obtaining and reviewing the certificate of conformity (fifth paragraph of Article 77 hereof);

- – failing to establish a system that provides sufficient data for the traceability of each patient or animal and product and monitor the progress of treatment (sixth and the seventh paragraph of Article 77 hereof);

- – not being registered in the register of physicians or veterinarians (first paragraph of Article 78 hereof);

- - failing to notify the change in data to the Agency pursuant to the third paragraph of Article 78 hereof;

- – failing to mark or label the advanced therapy medicinal product prepared on a non-routine basis with the package insert pursuant to Article 79 hereof;

- – failing to establish and maintain a system that guarantees traceability of advanced therapy medicinal products prepared on a non-routine basis and the input substances and raw materials, including the materials pursuant to the first paragraph of Article 80 hereof;

- – failing to store or provide data on traceability pursuant to the second and third paragraph of Article 80 hereof;

- - failing to assure a system of traceability of advanced therapy medicinal products prepared on a non-routine basis in accordance with the fourth paragraph of Article 80 hereof;

- – failing to inform the Agency of possible adverse reactions in accordance with the fifth paragraph of Article 82 hereof;

- – advertising advanced therapy medicinal products prepared on a non-routine basis, its preparation or treatment method (Article 81 hereof);

- – failing to institute a system of pharmacovigilance in line with the first paragraph of Article 82 hereof;

- – failing to appoint a person responsible for pharmacovigilance pursuant to the second and third paragraph of Article 82 hereof;

- - failing to submit at the request of the Agency a risk management plan in accordance with the fourth paragraph of Article 82 hereof;

- – preparing non-routine medicinal products contrary to the first paragraph of Article 83 hereof;

- if it fails to notify the Agency of the changes pursuant to the first paragraph of Article 85 hereof;

- The medicinal product is not marked and does not have the package leaflet in line with Article 87 hereof;

- – the medicinal product for human use does not have attached a safety feature for the medicinal product as stipulated by Article 88 hereof;

- - failing to assure a device for discovering a breach in the outer packaging (Paragraph three of Article 88 hereof);

- – If the safety feature on the medicinal product is partially or fully removed or covered contrary to the fifth paragraph of Article 88 hereof;

- - manufacturing medicinal products contrary to the medicinal product marketing authorisation (Article 90 hereof);

- – failing to fulfil the requirements for manufacturing medicinal products pursuant to Article 91 hereof;

- – the responsible person for releasing individual batches of medicinal products failing to meet the conditions in line with Article 92 hereof;

- – acting contrary to the obligations of manufacturers of medicinal products as specified in Article 93 hereof;

(18)– failing to inform the Agency of any change to conditions from Article 91 hereof (Article 96 hereof);

(19)- failing to fulfil the conditions for manufacturing active substances (first paragraph of Article 100 hereof);

(20)– failing to inform the Agency and the marketing authorisation holder of any falsified active substances or any suspicion thereof (second paragraph of Article 100 hereof);

(21)– performing the activity contrary to Article 101 hereof;

(22)– failing to inform the Agency of any change to conditions from Article 100 hereof that significantly impact the quality or safety of the active substance it manufactures (Article 102 hereof);

(23)– manufacturing excipients contrary to the guidelines and principles of good manufacturing practice for excipients (Article 103 hereof);

– acting contrary to Article 104 hereof;

– failing to fulfil the provisions applicable to wholesalers of medicinal pursuant to the first and second paragraph of Article 105 hereof;

– failing to meet the obligations of wholesalers from Article 106 hereof;

- – failing to ensure the fulfilment of public service obligations in line with Article 107 hereof;

- – failing to perform the activity of wholesale of active substances pursuant to the first, second and fourth paragraph of Article 111 hereof;

- – failing to inform the Agency of falsified active substances pursuant to the third paragraph of Article 111 hereof;

- – failing to immediately inform the Agency of any change to conditions from the second paragraph of Article 111 hereof that significantly impact the quality or safety of the active substance it markets (Article 113 hereof),

- – importing medicinal products contrary to Article 114 hereof;

- – entry or importing medicinal products contrary to the second paragraph of Article 116 hereof;

- - failing to ensure the supply of medicinal products to the providers of healthcare, veterinary and pharmacy services pursuant to the ninth paragraph of Article 116 hereof;

- – failing to inform the Agency prior to starting parallel distribution in accordance with the first and the second paragraph of Article 118 hereof;

- – importing active substances contrary to Article 119 hereof;

- – failing to fulfil the conditions for importing active substances specified in Article 120 hereof;

- - failing to notify the Agency of falsified active substances or the suspicion thereof (second paragraph of Article 120 hereof);

- – performing the activity of importing active substances without the entry in the register of importers of active substances (fourth paragraph of Article 121 hereof);

- – failing to inform the Agency of any change to conditions referred to in the first paragraph of Article 120 hereof that materially impact the quality or safety of the active substance it imports (first paragraph of Article 122 hereof);

- – acting contrary to broker obligations pursuant to Article 123 hereof;

- – performing the brokerage of medicinal products or active substances without the entry in the register of brokers of medicinal products and active substances kept by the Agency (first paragraph of Article 124 hereof);

- – failing to inform the Agency of changes to information listed under the fourth paragraph of Article 124 hereof;

- – retailing medicinal products contrary to Article 126 hereof;

– dispensing medicinal products via the Internet contrary to Article 126 hereof;

– failing to meet the conditions for retail of medicinal products in specialised stores in accordance with the first paragraph of Article 127 hereof;

– failing to implement the tasks stipulated in Article 133 hereof;

- - performing non-interventional clinical trials without Agency consent to the draft protocol pursuant to paragraph one of Article 138 hereof;

- - performing non-interventional clinical trials without consent detailed in the third paragraph of Article 138 hereof;

- – failing to notify the Agency, the marketing authorisation holder and business entities marketing the medicinal products

concerned of events or suspected events of inappropriate quality of medicinal products that could affect the safety or efficacy of a medicinal product (first paragraph of Article 139 hereof);

- – failing to withdraw a deficient medicinal product from the market or take other necessary measures and inform, forthwith and without delay, the Agency of its activities (second paragraph of Article 139 hereof);

- – failing to immediately notify the competent authorities of the EU Member States in which the medicinal product is marketed of any action taken by him to withdraw a medicinal product from the market or to suspend or cancel 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 (third paragraph of Article 139 hereof);

- – not acting in line with the seventh paragraph of Article 141 hereof;

- – business donation of medicinal products contrary to the third paragraph of Article 142 hereof;

- - business donation of medicinal products intended for compassionate use (fourth paragraph of Article 142 hereof);

- – pursuing resale of medicinal products subject to business donation (fifth paragraph of Article 142 hereof);

- – donating medicinal products contrary to the seventh, eighth and ninth paragraph of Article 142 hereof;

- – business donation of medicinal products contrary to the tenth paragraph of Article 142 hereof;

- - not acting in line with the eighth paragraph of Article 144 hereof;

- - failing to report a business donation pursuant to the eleventh paragraph of Article 142 hereof;

- – advertising medicinal products contrary to Article 147 hereof;

- – advertising medicinal products to the general public contrary to Article 148 hereof;

– advertising medicinal products to the expert public contrary to Article 149 hereof;

- – failing to submit data or failure to submit data within the deadlines set out under the ninth paragraph of Article 163 hereof;

- - failing to sell medicinal products at the price stipulated in the fifth paragraph of Article 163 hereof;

- – failing to charge the price in line with the sixth paragraph of Article 163 hereof;

(2) A fine of 500 to 3,000 euros shall be imposed for an offence listed in the previous paragraph hereunder on a sole proprietor or an individual engaging in a registered activity.

(3) A fine of 500 to 5,000 euros shall be imposed for an offence listed in the first paragraph hereunder on the responsible person of a legal person, the responsible person of a sole proprietor or the responsible person of an individual engaging in a registered activity.

(4) A fine of 400 to 4,000 euros shall be imposed on an individual committing an offence specified in the first paragraph hereunder.

Article 193

(Authorisation to impose a fine within the specified limits)

In the cases listed in Articles 191 and 192 hereof, a pharmaceutical inspector may impose a fine, in an expedited minor offence procedure, in any amount within the specified limits stipulated by individual Articles.

XX. XVIII. TRANSITIONAL AND FINAL PROVISIONS

Article 194

(Issuance of implementing regulations)

(1) The implementing regulations under this Act shall be adopted within 18 months of this Act entering into force.

(2) Notwithstanding the previous paragraph the implementing regulations shall be adopted:

1. within two months following the entry into force hereof:

- – under the third paragraph of Article 44 hereof;
- – under the eighth paragraph of Article 58 hereof;
- – under the seventh paragraph of Article 62 hereof;
- – under the seventh paragraph of Article 63 hereof;
- – under the seventh paragraph of Article 87 hereof;
- - under Article 137 hereof,
- – under the fourth paragraph of Article 138 hereof and
- - under the second paragraph of Article 140 hereof.

2. within three months following the entry into force hereof:

- – under the sixth paragraph of Article 94 hereof;
- – under the fourth paragraph of Article 95 hereof;
- – under the third paragraph of Article 96 hereof;
- – under the sixth paragraph of Article 99 hereof;
- – under the eleventh paragraph of Article 101 hereof;
- – under the sixth paragraph of Article 102 hereof;
- – under the sixth paragraph of Article 104 hereof;
- – under the fourth paragraph of Article 105 hereof;
- – under the fourth paragraph of Article 109 hereof;
- – under the sixth paragraph of Article 110 hereof;
- – under the eleventh paragraph of Article 112 hereof;
- - under the fifth paragraph of Article 113 hereof;
- – under the sixth paragraph of Article 119 hereof;
- – under the eleventh paragraph of Article 121 hereof;
- – under the sixth paragraph of Article 122 hereof;
- – under the seventh paragraph of Article 124 hereof;

(3) Until the implementation of the implementing regulations issued on the basis of this Act, the following implementing regulations issued on the basis of the Medicinal Products Act (Official Gazette of the Republic of Slovenia, Nos 31/06 and 45/08) shall apply, unless contrary to this Act or unless specified otherwise herein:

- – Regulations on conditions for completing activities of making medicinals and determining of conditions and procedure of publishing or revocation of execution good production practices (Official Gazette of the Republic of Slovenia, No 91/08),

- - Regulations on the conditions and procedures for granting import permit for medicinal products for human use (Official Gazette of the Republic of Slovenia, Nos. 65/12 and 20/13);

- – Regulations on detailed conditions of wholesale of medicinal products and determining of fulfilment of these conditions and procedure of gain the permission for traffic of wholesale of medicinal products (Official Gazette of the RS, no. 46/09),

– Regulations on authorisation of parallel imported product and parallel distribution of medicines (Official Gazette of the Republic of Slovenia, No. 49/09),

- - 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, no. 64/09),

- Regulations on the conditions to be met by analysts in analytical testing of medicinal products and procedure for the verification of these conditions (Official Gazette of the RS, no. 16/10);

- – Rules on labelling of medicinal products and on patient information leaflet of medicinal products for human use (Official Gazette of the RS, nos. 21/12 and 52/12),

- – Regulations on the traditional medicinal products of plant origin (Official Gazette of the Republic of Slovenia, no. 55/06);

- – Regulations on the marketing authorisation for medicinal products for human use (Official Gazette of the RS, no. 109/10),

- – Regulations on permitted colouring agents for medicinal products (Official Gazette of the RS, no. 86/08),

- - Rules on the Classification, Prescribing and Dispensing of Medicinal Products for Human Use (Official Gazette of the Republic of Slovenia, Nos 86/08, 45/10 and 38/12);

- – Regulations on homeopathic medicines for human use (Official Gazette of the Republic of Slovenia, No 94/08),

- Rules on advertising of medicines (Official Gazette of the Republic of Slovenia, No 105/08, 98/09 - ZMedPri and 105/10);

- – Rules on the charges in the field of medicine (Official Gazette of the Republic of Slovenia, No 65/11);

- – Regulations on analytical, pharmacological-toxicological and clinical testing of medicinal products for human use (Official Gazette of the Republic of Slovenia, Nos 86/08 and 37/10);

- – Rules on analytical testing of medicinal products to perform state control of their quality (Official Gazette of the Republic of Slovenia, No. 10/12);

- Rules on clinical testing of medicinal products (Official Gazette of the Republic of Slovenia, No 54/06);

- Rules on radiopharmacological products (Official Gazette of the Republic of Slovenia, No 86/08);

– Regulations on united national naming of medicinal active ingredients and system of arranging treated for round anatomically-therapeutic-chemical classification (Official Gazette of the RS,
no. 86/08),

- – Regulations on determining the prices of medicinal products for human use (Official Gazette of the Republic of Slovenia, Nos 102/10, 6/12 and 16/13);

- – Regulations on more exact demands and procedure for determining interchangeable medicinal products (Official Gazette of the Republic of Slovenia,
no. 102/10),

- – Regulations on the pharmacovigilance of veterinary medicinal products (Official Gazette of the Republic of Slovenia, No 53/06;,

- - Rules on the classification, prescription and administering of veterinary medicinal products (Official Gazette of the Republic of Slovenia, No 91/08);

- – Regulations on analytical, pharmacological-toxicological and clinical testing of veterinary medicinal products (Official Gazette of the Republic of Slovenia, Nos 91/08 and 79/09);

- - Rules on the identification and use instructions of veterinary medicinal products (Official Gazette of the Republic of Slovenia, No 101/09);

- - 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 53/06),

- – Regulations on pricing methodology for testing medicinal products in the quality control of medicinal products (Official Gazette of the Republic of Slovenia,
no. 68/09),

- - Rules on the examination for pharmaceutical inspectors (Official Gazette of the Republic of Slovenia, No 86/08);

- - Rules determining national formulary addition to the European Pharmacopoeia (Official Gazette of the Republic of Slovenia, No 118/06);

- – Rules on the pharmacovigilance of medicinal products for human use (Official Gazette of the Republic of Slovenia, Nos 53/06 and 16/11);

- - Rules on recall of medicines (Official Gazette of the Republic of Slovenia, No 105/08);

- - Rules on the system of reception, storage and traceability of medicines (Official Gazette of the Republic of Slovenia, No 81/09);

- - Rules on the use of potassium iodine (Official Gazette of the Republic of Slovenia, No 59/10);

- – Rules on the authorisation for trade in veterinary medicinal products (Official Gazette of the Republic of Slovenia, No 16/11);

- - Order appointing a legal person for pharmacovigilance and medical devices vigilance (Official Gazette of the Republic of Slovenia, Nos 100/00 and 61/10).

(4) On the day of entry into force of this Act, the following implementing regulations shall cease to apply:

- 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, 86/08);

- Rules on the classification of medical plants (Official Gazette of the Republic of Slovenia, No 103/08).

Article 195

(Procedures following the enforcement of this Act)

(1) All ongoing procedures initiated prior to the date of the implementation of this Act and the implementing regulations adopted on the basis hereof, 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 subject to according to the provisions of the Medicinal Products Act (Official Gazette of the Republic of Slovenia, Nos 31/06 and 45/08), and the implementing regulations issued on the basis thereof, unless the provisions of this Act are more favourable for the client.

(2) Notwithstanding the previous paragraph hereunder, the Agency 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.

Article 196

(Transitional provisions regarding advanced therapy medicinal products prepared on a non-routine basis)

(1) Business entities performing the activity of the preparation of advanced therapy medicinal products prepared on a non-routine basis shall, if such activity is performed without a valid authorisation, submit the application to obtain the authorisation for the preparation of advanced therapy medicinal products prepared on a non-routine basis in accordance with this Act and the implementing regulations relevant for this area within 60 days of the enforcement of the implementing regulations relevant for this area, issued on the basis of this Act. Business entities performing the activity of the preparation of advanced therapy medicinal products prepared on a non-routine basis shall, if such activity is performed with a valid authorisation for the supply of tissues and cells, submit the application to obtain the authorisation for the preparation of advanced therapy medicinal product prepared on a non-routine basis in accordance with this Act within one year of the enforcement of the implementing regulations relevant for this area issued on the basis of this act.

(2) If the business entities fail to submit the application set out in paragraphs one and two of the present Article within the above-specified deadline, they must stop performing the activity of the preparation of advanced therapy medicinal products prepared on a non-routine basis.

Article 197

(Obligations of manufacturing authorisation holders after the implementation of implementing regulations)

(1) The holders of manufacturing authorisations, valid on the day of enforcement hereof, shall be obliged to propose an amendment to the authorisation to perform this activity no later than within 30 days of the enforcement of the implementing regulations, issued on the basis of this Act, regulating the entry in the register of manufacturers of active substances and implementing regulations governing the manufacturing of medicinal products.

(2) If the business entities fail to submit the application within the deadline specified in the previous paragraph hereunder, they must stop performing the activity referred to in the previous paragraph.

Article 198

(Obligations of the holders of the authorisation for wholesaling medicinal products after the implementation of implementing regulations)

(1) The holders of the authorisation for wholesaling medicinal products, valid on the day of enforcement hereof, shall be obliged to propose an amendment to the authorisation for wholesaling medicinal products no later than within 30 days of the day of enforcement of the implementing regulations, issued on the basis of this Act, regulating the field of entry in the register of wholesalers of active substances and implementing regulations, issued on the basis of this Act, governing the wholesaling of medicinal products.

(2) If the business entities fail to submit the application within the deadline specified in the previous paragraph hereunder, they must stop performing the activity referred to in the previous paragraph.

Article 199

(Transitional period for the activity of manufacturing, marketing and importing active substances)

(1) Business entities performing the activity of manufacturing, marketing and importing active substances perform such activity on the basis of valid authorisations, issued by the Agency; however, they can only perform it on this basis until the completion of the process of entry in the register of manufacturers, wholesalers and importers of active substances under this Act.

(2) The application for the entry in the registers from the previous paragraph must be submitted by the business entities no later than within 60 days of the enforcement of the implementing regulations, issued on the basis of this Act, regulating the entry in the register of manufacturers, wholesalers and importers of active substances.

(3) Up to the establishment of mechanisms specified in the third and the fourth paragraph of Article 119 hereof are set up, the importers of active substances may import active substances intended for manufacture of medicinal products for human use, based on an inspection conducted in the exporting country by another European Union Member State in the last three years, whereby it was established that the manufacture complied with the good manufacturing practice for active substances, or on the basis of a declaration made by the person responsible for the release of manufacturer medicinal products stating that the active substance being imported has been manufactured in accordance with the good manufacturing practice for active substances.

Article 200

(Transitional period for experts in advertising medicinal products)

(1) Experts for advertising medicinal products, that on the day of enforcement hereof meet the conditions listed in Article 88 of the Medicinal Products Act (Official Gazette of Republic of Slovenia, Nos 31/08 and 45/08) and the data of whom holders of authorisation for marketing of medicinal products report to the Agency in accordance with the Rules on advertising of medicines (Official Gazette of Republic of Slovenia, Nos 105/08, 98/09 - ZMedPri and 105/10) and with the enforcement hereof no longer fulfil the conditions regarding education, but have at least two years of experience in the field of advertising of medicinal products, which include a documented program of training in the field of knowledge on the operation of the human or animal organism, may continue to perform their activities.

(2) The holders of manufacturing authorisations shall be obliged to submit the application for the entry in the experts' register for these experts for advertising medicinal products referred to in the previous paragraph hereunder no later than within 30 days following the enforcement of the regulations, issued on the basis of this Act, regulating the area of entry in the experts' register for advertising medicinal products.

Article 201

Authorisations for the import and/or entry of medicinal products pursuant to the Medicinal Products Act (Official Gazette of the RS, no.

Authorisations for the entry or import of medicinal products issued on the basis of the Medicinal Products Act (Official Gazette of the Republic of Slovenia, No 31/06 and 45/08) valid on the day of enforcement hereof shall be valid until the expiry of the deadline, specified in the relevant authorisation issued by the Agency.

Article 202

(Validity of authorisations for the labelling of medicinal products in foreign packaging with a label in the Slovene language)

Authorisations for the labelling of medicinal products in foreign packaging with a label in Slovenian and authorisations for alternative marking of medicinal products granted pursuant to the Medicinal Products Act (Official Gazette of the Republic of Slovenia, No 31/06 and 45/08) valid on the day of enforcement hereof shall be valid until the expiry of the deadline, specified in the relevant authorisation.

Article 203

(Transitional provisions on pharmacovigilance)

(1) For medicinal products for which marketing authorisation had been issued prior to 21 July 2012, the obligation to keep the master file on the pharmacovigilance system and the Agency's access to it shall be valid from the extension of marketing authorisation or from 21 July 2015, whichever is earlier.

(2) The holders of marketing authorisations issued prior to 21 July 2012 need not implement the system of risk management for each medicinal product, unless there exist any security restrictions that could affect the risk-to-benefit ratio and if required by the Agency.

(3) The procedure stipulated in Articles 107m through 107p of Directive 2001/83/EC is used for the studies from paragraph three of Article 58 hereof, ordered after 21 July 2012.

(4) The obligation of electronic reporting, as stipulated in the third paragraph of Article 107 of the Directive 2001/83/EC, shall enter into force six months after the notice by the EMA on the establishment of functionality of the EudraVigilance database, as specified in Article 24 of the Regulation (EC) 726/2004.

(5) Until the deadline specified in the previous paragraph hereunder, the marketing authorisation holder shall report to the Agency in 15 days of the day of acknowledgement of a suspected serious adverse reaction that occurred in the territory of the Republic of Slovenia.

The suspected serious adverse reaction occurring on the territory of third countries shall be reported by the medicinal product marketing authorisation holder directly to the EudraVigilance database.

The medicinal product marketing authorisation holder shall report on any suspected adverse reactions that are not serious and occur on the territory of the Republic of Slovenia to the Agency based on its previously published request within 90 days of acknowledging them.

(6) A marketing authorisation holder shall set up electronic forwarding of regularly updated reports on safety of medicinal products, as specified in the first paragraph of Article 107b of the Directive 2001/83/EC, to the EMA within 12 months after the EMA has set up the electronic archive and publishes it.

Article 204

(Transitional period regarding quantitative requirements for medicinal products)

The collection of quantity needs for medicinal products in accordance with the sixth and the seventh paragraph of Article 116 hereof shall be started by the Agency within three months after the entry into force of the regulation governing the area, with it starting the issuing of certificates and authorisations under the fifth and the eighth paragraph of Article 116 hereof for entry and import of medicinal products within nine months after the collection of quantity needs has begun.

Article 205

(Transitional period for the continuation of the work of supervisors and dispensation of medicinal products via the Internet and establishment of central medicinal product database)

(1) With the implementation of this act pharmaceutical supervisors under Articles 101., 102. and 104. of the Medicinal Products Act (Official Gazette of RS, no. 31/06 and 45/08), supervisors under Article 7 of the Supply of Blood Act and

supervisors under Article 9 of the Act on Quality and Safety of Human Tissues and Cells for the Purposes of Medical Treatment (Official Gazette of the Republic of Slovenia, No 61/07), who have a valid professional certification examination for the position of inspector and pharmaceutical supervisor in accordance with the Rules on professional certification examination for pharmaceutical supervisors (Official Gazette of RS, no. 86/08), and are performing the tasks of pharmaceutical supervisors or supervisors on the day of implementation of the present Act, shall continue their work as pharmaceutical inspectors.

(2) Pharmaceutical inspectors referenced in the prior paragraph shall acquire additional expert knowledge within 60 days of enforcement of the regulations under paragraph two of Article 166 hereof.

(3) Positions, method of work, measures and powers of pharmaceutical inspectors referred to in first paragraph of the present Act shall be subject to the provisions of Articles 166, 167 and 173 hereof.

(4) The Minister shall issue the regulation detailed under paragraph twentythree of Article 126 hereof, pertaining to more detailed conditions for designing and use of a common logo and more detailed procedure of issuing and revocation of authorisation for sale of medicinal products via the Internet within six months of publication of implementing measures of the European Commission pursuant to Directive 2011/62/EU regarding the common logo.

(5) Business subjects that dispense medicinal products via the Internet on the day of implementation of this Act shall coordinate their operations with the provisions of Article 126 hereof within one year of enforcement of provisions of the prior paragraph.

(6) The central medicinal product database under Article 163 hereof shall be established within one year of the implementation of the present Act.

Article 206

(Initiation of operations of the official control laboratory within NLHEF)

(1) NLHEF and the Agency shall commence the procedure for inclusion of NLHEF into the European network of control laboratories with EDQM within one month of the implementation of this Act.

(2) NLHEF shall commence performing the tasks of an official control laboratory pursuant hereto after inclusion into the European network of control laboratories with EDQM, no sooner than six months from the implementation of this Act, but no later than within one year.

(3) Tasks of the official control laboratory shall be performed by the Agency until the commencement of tasks listed in the prior paragraph.

Article 207

(Premises, equipment and materials of the official control laboratory within NLHEF)

(1) NLHEF shall assume business premises, equipment, materials for performing analytical testing of medicinal products, documentation, records and unfinished matters pertaining to the tasks of an official control laboratory from the Agency.

(2) Agency employees that are up to the commencement of duties of the official control laboratory at NLHEF employed at the Agency and are performing the tasks of an official control laboratory, shall continue their employment at the Agency and shall be offered another position at the Agency that corresponds to the type and degree of education required for the performance of tasks that relevant Agency employees were employed for prior to the day that NLHEF commenced performing the tasks of an official control laboratory.

Article 208

(Transitional period for the prices of services of official quality control of medicinal products)

Until first publication of a pricelist of the services of official control of the quality of medicinal products at the website of NLHEF, NLHEF shall invoice such services based on the pricelist published on the website of the Agency on the day of commencement of tasks of official control laboratory pursuant to the second paragraph of Article 206 hereof.

Article 209

(Entry into force of provisions on safety features and notification to the European Commission)

The provisions of Article 88 hereof relating to the affixing, covering and removing safety features shall enter into force three years from the publication of the delegated acts of the European Commission, stipulating on the basis of Directive 2011/62/EC amending Directive 2001/83/EC on the Community code related to medicinal products for human use regarding prevention of entry of counterfeit medicinal products into the legal delivery chain (Official Gazette no. 174 of 1 July 2011, p. 74) the characteristics and technical specifications for protective elements and lists of medicinal products or categories of medicinal products that must or need not be equipped with a safety feature.

Article 210

(Initiation of use of provisions regarding reporting of the body competent for veterinary medicine)

Provisions of paragraph thirteen of Article 24 hereof shall enter into force three years after enforcement of the present Act.

Article 211

(Termination of validity)

On the day this Act enters into force the Medicinal Products Act - ZZdr (Official Gazette of the Republic of Slovenia Nos. 9/96 and 19/96) and the Medicinal Products Act - ZZdr-1 (Official Gazette of the Republic of Slovenia Nos. 31/06 and 45/08) shall cease to be valid.

Article 212

(Effective date)

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

No. 520-01/13-4/62
Ljubljana, 24 February 2014
EPA 1508-VI

National Assembly of the
Republic of Slovenia **Janko**
Veber l.r. Predsednik