

ACT

of 6 September 2001

Pharmaceutical Law

(Journal of Laws from 2008, No. 45, item 271)

Chapter 1

General Provisions

Article 1. 1. This Act shall lay down the following:

- 1) the rules and procedure for authorising medicinal products for marketing, with particular consideration of their quality, efficacy, and safety requirements;
- 1a) ⁽¹⁾ the conditions of conducting clinical trials of medicinal products;
- 2) the manufacturing conditions for medicinal products;
- 3) the requirements for advertising of medicinal products;
- 4) the terms of trade in medicinal products;
- 5) the requirements for pharmacies, pharmaceutical wholesale stores, and points of out-of-pharmacy sale;
- 6) the duties of the Pharmaceutical Inspection and powers of its governing bodies.

2. The provisions of the Act shall also apply to the medicinal products which are narcotic agents, psychotropic substances and their precursors within the meaning of the drug addiction counteracting regulations, to the extent unregulated by those regulations.

Article 2. Within the meaning of this Act:

- 1) biological activity of a medicinal product shall mean the potency of action of its active ingredient(s) expressed in international or biological units;
- 2) a clinical trial shall mean each trial conducted in humans to discover or confirm the clinical, pharmacological, including pharmacodynamic, effects of action of one or more investigational medicinal products, or to identify the adverse reactions to one or more investigational medicinal products, or to monitor absorption, distribution, metabolism and excretion of one or more investigational medicinal products, taking into consideration their safety and efficacy;
- 2a) ⁽²⁾ an investigator shall mean a physician, or a dentist if the clinical trial is related to dentistry, or a veterinarian in the case of a veterinary clinical trial, holding the professional licence in the territory of the Republic of Poland and adequately high professional qualifications, scientific knowledge and experience in work with patients, necessary for the conducted clinical trial or veterinary clinical trial, responsible for conducting these trials at the given site; if the clinical trial or the veterinary clinical trial is conducted by a team of persons, the investigator designated by the sponsor, with consent of the manager of the healthcare establishment where the clinical trial is conducted, shall be the team manager responsible for conducting this trial at the given site;
- 2b) ⁽³⁾ a veterinary clinical trial shall mean each trial, the purpose of which is to confirm the expected efficacy or safety of an investigational veterinary medicinal product, conducted in the target animal species;
- 2c) ⁽⁴⁾ an investigational medicinal product shall mean a substance or a combination of substances, which have been given an active substance or placebo pharmaceutical form, studied or used as a reference product in a clinical trial, including also a product already authorised for marketing but used or prepared differently than the form authorised for marketing, or used in a non-authorised indication, or used to obtain additional information concerning the forms which have already been authorised for marketing;
- 2d) ⁽⁵⁾ an investigational veterinary medicinal product shall mean a substance or a combination of substances, which have been given a pharmaceutical or biological form and which are used in veterinary clinical trials;

- 3) ⁽⁶⁾ an adverse reaction to an investigational medicinal product or investigational veterinary medicinal product shall mean each noxious and unintended effect of these products, which occurs after administration of any dose of these products;
- 3a) ⁽⁷⁾ an adverse reaction to a medicinal product shall mean each noxious and unintended effect of a medicinal product occurring when doses recommended in humans for prophylactic, diagnostic or therapeutic purposes or for modification of physiological functions are used;
- 3b) ⁽⁸⁾ an adverse reaction to a veterinary medicinal product shall mean each adverse and unintended effect of a veterinary medicinal product:
 - a) occurring when doses recommended in animals for prophylactic, diagnostic or therapeutic purposes and to restore, correct or modify physiological functions of an organism are used,
 - b) occurring in a human after exposure to a veterinary medicinal product;
- 3c) ⁽⁹⁾ a serious adverse event after the use of an investigational medicinal product or an investigational veterinary medicinal product shall mean an event that causes, irrespectively of the administered dose of the investigational medicinal product or the investigational veterinary medicinal product, death of a patient, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability, or is a disease, congenital defect or foetal damage;
- 3d) ⁽¹⁰⁾ a serious adverse reaction to a medicinal product shall mean such an effect which irrespectively of the administered dose of the medicinal product results in death of a patient, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, or results in persistent or significant disability or incapacity or in another effect of the medicinal product which is considered severe to the physician's best knowledge, or is a disease, congenital defect or foetal damage;
- 4) Good Distribution Practice shall mean the practice that ensures safe acceptance, transport, storage, and release of medicinal products;
- 5) (repealed);
- 6) ⁽¹¹⁾ Good Clinical Practice shall mean a set of internationally recognised ethical and scientific quality requirements for the conduct of clinical trials, providing assurance that the rights, safety and well being of trial subjects are protected and that the results of the clinical trials are credible;
- 6a) ⁽¹²⁾ Good Veterinary Clinical Practice shall mean a set of internationally recognised ethical and quality requirements for the conduct of veterinary clinical trials, aimed at ensuring the well-being of animals and the safety of the personnel participating in a veterinary clinical trial and protection of the environment and health of the consumer of food of animal origin;
- 7) Good Manufacturing Practice shall mean the practice that guarantees that medicinal products are manufactured and controlled adequately to their intended use and in accordance with the requirements contained in their specifications and documents supporting the marketing authorisation for the medicinal product;
- 7a) ⁽¹³⁾ import of medicinal products shall mean each action involving import of a finished medicinal product from outside the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, including but not limited to the storage, quality control at batch release and distribution of such medicinal products;
- 7b) ⁽¹⁴⁾ parallel import shall mean each action within the meaning of Article 72 (4) involving import of a medicinal product meeting all the following conditions from European Union Member States or European Free Trade Association Member States (EFTA) – parties to the Agreement on the European Economic Area:
 - a) the imported medicinal product has the same active substance or active substances, at least the same indications up to the 3rd level of the ATC/ATCvet code (code of the Anatomical Therapeutic Chemical Classification), the same strength, the same route of administration and the same form as a medicinal product authorised for marketing in the territory of the Republic of Poland or has at least a similar form which does not result in any therapeutic differences as compared to the medicinal product authorised for marketing in the territory of the Republic of Poland,

- b) the imported medicinal product and the medicinal product authorised for marketing in the territory of the Republic of Poland are concomitantly reference medicinal products or concomitantly generic medicinal products in the country from which the product is imported and in the territory of the Republic of Poland, respectively;
- 7c) Inspection – is the control of the conditions of manufacturing and importation of medicinal products and active substances used as input materials used in manufacturing of medicinal products carried out by GMP inspectors from the Main Pharmaceutical Inspectorate in compliance with the provisions of the Act;
- 7d) Control – are activities performed by pharmaceutical inspectors in connection with their supervision over the quality of marketed medicinal products, intended to verify the conditions of marketing of medicinal products;
- 8) a medicinal mineral shall mean an unprocessed mineral raw material forming a deposit in the Earth's shell, used for therapeutic purposes; in particular, medicinal minerals are medicinal waters and medicinal peats;
- 9) initial batch control shall mean the control of each batch of the manufactured medicinal product carried out before such product is placed on the market;
- 10) ⁽¹⁵⁾ an official formula shall mean a medicinal product prepared in a pharmacy in accordance with the prescription of a pharmacopoeia, intended to be dispensed at such pharmacy;
- 11) a proprietary medicinal product shall mean a medicinal product placed on the market under a special name and in a special pack;
- 12) ⁽¹⁶⁾ a magistral formula shall mean a medicinal product prepared in a pharmacy on the basis of a physician's prescription, and in the case of a veterinary medicinal product – on the basis of a prescription issued by a veterinarian;
- 12a) the strength of a medicinal product shall mean the content of active substances expressed as a quantity per dosing, volume or weight unit, depending on the pharmaceutical form;
- 13) ⁽¹⁷⁾ the Maximum Residue Limit shall mean a limit defined in Article 1 (1) (b) of Council Regulation (EEC) No. 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ EC L 224 of 18.08.1990, p. 1; OJ EU Polish special edition, Chapter 3, vol. 10, p. 111), hereinafter referred to as "Regulation No. 2377/90";
- 13a) ⁽¹⁸⁾ a starting material shall mean each substance used for the manufacturing of a medicinal product, except for packaging materials;
- 14) ⁽¹⁹⁾ a name of a medicinal product shall mean the name assigned to a medicinal product which may be a proper name non-confusable with the international non-proprietary name, or the international non-proprietary name or scientific name, bearing the trademark or the responsible person's name;
- 15) a usual common name shall mean the international non-proprietary name recommended by the World Health Organization where such name exists, and failing this – the common name of the medicinal product;
- 16) ⁽²⁰⁾ an adverse event shall mean each event of medical nature causing adverse reactions in a patient or a clinical trial subject having been administered a medicinal product or an investigational medicinal product or an investigational veterinary medicinal product, even if such event is not causatively related to the use of such a product;
- 17) ⁽²¹⁾ an unexpected adverse reaction shall mean each adverse reaction to a medicinal product the nature or severity of which is inconsistent with the data contained in the respective information on the medicinal product, i.e. most often in the investigator's brochure for medicinal products in clinical trials and in the Summary of Product Characteristics for medicinal products authorised for marketing;
- 17a) ⁽²²⁾ an unexpected serious adverse reaction to a medicinal product shall mean each adverse reaction to a medicinal product the nature or severity of which is inconsistent with the data contained in the respective information on the medicinal product:
 - a) most often in the investigator's brochure for medicinal products in clinical trials,
 - b) most often in the Summary of Product Characteristics or the Veterinary Summary of Product Characteristics for medicinal products authorised for marketing

- and which, irrespectively of the dose of the medicinal product used, results in death of a patient, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, or results in persistent or significant disability or incapacity or in another effect of the medicinal product, considered serious to the physician's best knowledge, or is a disease, congenital defect or foetal damage;
- 18) ⁽²³⁾ (repealed);
- 19) ⁽²⁴⁾ the withdrawal period shall mean the period necessary between the last administration of the veterinary medicinal product and the animal slaughter or, in the case of milk, eggs or honey, the collection of such produce for consumption purposes, to ensure that the tissues and products derived from the given animal do not contain residues in quantities in excess of their Maximum Residue Limits;
- 20) an immediate packaging of a medicinal product shall mean the package in direct contact with the medicinal product;
- 21) an outer packaging of a medicinal product shall mean the package in which the immediate packaging is contained;
- 22) labelling of a medicinal product shall mean the information placed on the immediate packaging or outer packaging of the medicinal product;
- 22a) ⁽²⁵⁾ the Reference State shall mean a European Union Member State or a European Free Trade Association (EFTA) Member State – a party to the Agreement on the European Economic Area, which:
 - a) develops the draft assessment report under the decentralised procedure,
 - b) has granted the authorisation constituting the basis for instituting the mutual recognition procedure;
- 23) ⁽²⁶⁾ (repealed);
- 24) ⁽²⁷⁾ a Marketing Authorisation Holder (MAH) shall mean an entrepreneur within the meaning of the Act on Freedom of Business Activity of 2 July 2004 (Journal of Laws No. 173, item 1807) or an entity conducting business in a European Union Member State or a European Free Trade Association (EFTA) Member State – a party to the Agreement on the European Economic Area, which applies for or has obtained the medicinal product marketing authorisation;
- 25) ⁽²⁸⁾ residues of veterinary medicinal products shall mean residues of medicinal products referred to in Article 1 (1) (a) of Regulation No. 2377/90;
- 26) the marketing authorisation shall mean the decision issued by the competent authority and confirming that the specific medicinal product can be traded in the territory of the Republic of Poland;
- 27) a premix for medicated feedingstuff shall mean a veterinary medicinal product that has been prepared, as a result of a technological process, in the form enabling its mixing with animal feed so as to produce the medicated feedingstuff;
- 27a) ⁽²⁹⁾ a medicinal product intended for particular nutritional purposes shall mean a medicinal product intended for nutritional treatment, which is appropriately processed and produced and has a strictly defined composition, used in humans on prescription and under supervision of a physician;
- 28) (repealed);
- 29) ⁽³⁰⁾ a homeopathic medicinal product shall mean a medicinal product prepared from homeopathic primary ingredients or their mixtures, in accordance with the homeopathic manufacturing procedure described in the European Pharmacopoeia or, if such description is lacking, in pharmacopoeias officially recognised by the European Union Member States or the European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area;
- 30) ⁽³¹⁾ an immunological product shall mean a medicinal product that is a serum, a vaccine, a toxin or an allergen, used for the purpose of:
 - a) producing active immunity (vaccines),
 - b) transferring passive immunity (serums),
 - c) diagnosing the state of immunity (in particular tuberculin),

- d) identifying or inducing a specific acquired alteration in the immunological response to an allergising agent (allergens);
- 31) ⁽³²⁾ a blood-derived product shall mean a medicinal product manufactured industrially from blood or its constituents, and in particular albumins, coagulating factors, or immunoglobulins;
- 32) ⁽³³⁾ a medicinal product shall mean any substance or combination of substances presented as able to prevent or treat disease in human beings or animals, or administered with a view to making a medical diagnosis or to restoring, correcting, or modifying physiological functions of an organism through pharmacological, immunological or metabolic action;
- 33) ⁽³⁴⁾ (repealed);
- 33a) a herbal medicinal product shall mean a medicinal product containing as active ingredients one or more herbal substances, or one or more herbal preparations, or one or more herbal substances in combination with one or more herbal preparation, and:
- a) herbal substances shall mean all plants, parts of plants, algae, fungi or lichen, mainly whole, divided into parts or cut, unprocessed and usually dried or sometimes fresh; certain secretions which have not been subjected to the specific treatment can also be considered herbal substances; herbal substances are precisely defined by the plant part and botanical name used,
 - b) a herbal preparation shall mean a preparation obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, condensation and fermentation; preparations are in particular comminuted or powdered herbal substances, tinctures, extracts, essential oils and expressed juices;
- 34) a veterinary medicinal product shall mean a medicinal product used exclusively in animals;
- 35) ⁽³⁵⁾ a radiopharmaceutical product shall mean a medicinal product, except for a veterinary medicinal product, which contains one or more radioactive isotopes intended for medical purposes;
- 35a) ⁽³⁶⁾ a representative of the MAH shall mean a natural or legal person designated by the MAH to perform such person's obligations and rights in the territory of the Republic of Poland;
- 35b) ⁽³⁷⁾ a reference medicinal product shall mean a medicinal product authorised for marketing on the basis of the full dossier;
- 35c) ⁽³⁸⁾ the risk of use of a medicinal product shall mean each threat to the patient's health or public health related to the quality, safety or efficacy of a medicinal product and each threat of an adverse reaction on the environment, and, in the case of veterinary medicinal products, each threat to health of animals or humans related to the quality, safety or efficacy of a veterinary medicinal product and each threat of an adverse reaction on the environment;
- 36) ⁽³⁹⁾ (repealed);
- 37) a batch shall mean a defined quantity of a medicinal product or pharmaceutical raw material, or packaging material, manufactured in the process consisting of one or more operations so that such quantity can be considered homogeneous;
- 37a) ⁽⁴⁰⁾ a sponsor shall mean a natural person, a legal person or an organisational unit without legal personality, responsible for initiating, conducting and financing a clinical trial, with the registered office in the territory of one of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, if the sponsor does not have its registered office in the territory of one of the European Economic Area Member States, it may act solely through its legal representative having its registered office in this territory;
- 37b) ⁽⁴¹⁾ a benefit-to-risk ratio shall mean the assessment of positive therapeutic effects of a medicinal product as related to the risk associated with the use of the medicinal product, except for the threat of an untoward effect on the environment, and in the case of a veterinary medicinal product – the assessment of positive therapeutic effects of the veterinary medicinal product as related to the risk associated with the use of the veterinary medicinal product;
- 38) a substance shall mean any matter which may be:
- a) of human origin, in particular human blood, elements and constituents derived from human blood,

- b) of animal origin, in particular micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, elements and constituents derived from animal blood,
 - c) of plant origin, in particular micro-organisms, whole plants, parts of plants, plant secretions, extracts,
 - d) of chemical origin, in particular chemical elements, chemical compounds naturally occurring in the biological environment or obtained by chemical processes or synthesis;
- 39) ⁽⁴²⁾ (repealed);
- 40) a pharmaceutical raw material shall mean a substance or a combination of substances used for preparation or manufacturing of medicinal products;
- 40a) ⁽⁴³⁾ a clinical trial subject shall mean a person who, having been informed on the nature, significance, implications and risk of a clinical trial, granted the informed consent for participation in the trial; the document acknowledging the granting of informed consent shall be kept together with the clinical trial documentation;
- 41) a leaflet shall mean the information intended for the user, approved in the marketing authorisation process, drawn up as a separate printout, and enclosed to the medicinal product;
- 42) manufacture of medicinal products shall mean any action leading to the creation of a medicinal product, including the manufacturer's purchase and acceptance, at the manufacturing site, of the materials used in production, production, authorisation for subsequent manufacturing stages, including packaging and re-packaging, and storage and distribution of proprietary medicinal products, and also control activities associated with those activities;
- 42a) ⁽⁴⁴⁾ manufacture of active substances used as starting materials intended for the manufacturing of medicinal products shall mean any action leading to the creation of active substances, including import of the active substances used as starting materials intended for manufacturing of medicinal products from outside the territory of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, distribution, packaging, re-packaging and re-labelling;
- 43) ⁽⁴⁵⁾ a manufacturer shall mean an entrepreneur within the meaning of the Act on Freedom of Business Activity of 2 July 2004, which performs at least one of the activities enumerated in paragraph 42, consistently with the manufacturing authorisation granted by the competent authority;
- 44) ⁽⁴⁶⁾ batch release shall mean an attestation by a qualified person that the specific batch of a medicinal product or investigational medicinal product has been manufactured and controlled in accordance with legal regulations and with the marketing authorisation requirements or the clinical trial initiation conditions.

Chapter 2

Authorising Medicinal Product Marketing

Article 3. 1. Subject to paragraph 4 and Article 4, only such medicinal products which have obtained the marketing authorisation, hereinafter referred to as “the authorisation”, shall be authorised for marketing.

2. ⁽⁴⁷⁾ Also the medicinal products which have obtained the authorisation granted by the Council of the European Union or the European Commission shall be authorised for marketing.

3. The authority competent for authorisation granting shall be the minister competent for health matters.

4. The following shall be authorised for marketing without the necessity to obtain the authorisation referred to in paragraph 1:

- 1) magistral formulas;
- 2) officinal formulas;

- 3) radiopharmaceutical products prepared at the time of use at authorised health service establishments from radionuclide generators, kits, radionuclides and precursors authorised for marketing, in accordance with the manufacturer's instructions, and radionuclides in the form of closed radiation sources;
- 4) ⁽⁴⁸⁾ whole blood and whole plasma or blood cells of human or animal origin, except for industrially processed plasma;
- 5) pharmaceutical raw materials not intended for the preparation of magistral or official formulas;
- 6) ⁽⁴⁹⁾ immunological veterinary medicinal products manufactured from pathogens or antigens of animal origin found on the specific farm and used for the treatment of animals found in the same farm.

Article 3a. ⁽⁵⁰⁾ The provisions of this Act shall apply to a product which concomitantly meets the criteria for a medicinal product and criteria for another type of product, in particular a food supplement or a cosmetic, defined in separate regulations.

Article 4. 1. Imported medicinal products, when their use is indispensable for saving a patient's life or health, shall be authorised for marketing without the necessity to obtain the respective marketing authorisation, provided that the specific medicinal product is authorised for marketing in the country from which it is imported and that such medicinal product holds a valid marketing authorisation, subject to paragraphs 3 and 4.

2. The basis for import of the medicinal product referred to in paragraph 1 shall be the requisition document issued by a hospital or by a physician conducting out-of-hospital treatment, confirmed by the consultant in the respective discipline of medicine.

3. The following medicinal products shall not be authorised for marketing as laid down in paragraph 1:

- 1) the medicinal products with respect to which the minister competent for health matters has issued the decision to refuse authorisation or authorisation renewal, or to cancel the authorisation, and
- 2) ⁽⁵¹⁾ the medicinal products containing the same active substances, the same dose and the same form as the medicinal products which have been granted the marketing authorisation, subject to subparagraph 3a.

3a. ⁽⁵²⁾ The provision of subparagraph 2 of paragraph 3 shall not apply to the medicinal products referred to in paragraph 1, the price of which is competitive with the price of the medicinal product holding the authorisation referred to in paragraph 1 or 2 of Article 3, provided that the requisition document confirmed by the consultant in the respective discipline of medicine is issued by a health insurance physician and the minister competent for health matters grants consent for medicinal product import in the respective decision.

4. Furthermore, the medicinal products defined in paragraph 1, which due to the safety of their use and the size of import should be authorised for marketing in accordance with Article 3 (1), shall not be authorised for marketing.

5. Pharmacies, wholesale stores and hospitals trading in the medicinal products referred to in paragraph 1 shall keep records of such products.

6. On the basis of the records kept, the pharmaceutical wholesale store shall submit the list of imported medicinal products to the minister competent for health matters, not later than 10 days after the end of each quarter.

7. The minister competent for health matters shall establish, by way of a Regulation:

- 1) ⁽⁵³⁾ (repealed);
- 2) the detailed procedure and rules for importing the medicinal products referred to in paragraph 1, including in particular the following:
 - a) the form of the requisition document,
 - b) the method of confirming by the minister competent for health matters the circumstances referred to in paragraph 3,

- c) ⁽⁵⁴⁾ the method of confirming the circumstances referred to in Article 36 (4) of the Act on Healthcare Services Funded from Public Funds of 27 August 2004 (Journal of Laws No. 210, item 2135) by the President of the National Health Fund,
- d) the method of keeping by wholesale stores, pharmacies and hospitals the records of imported medicinal products, and
- e) the scope of information transferred by pharmaceutical wholesale store to the minister competent for health matters.

8. In the case of a natural disaster or another hazard to human or animal life or health, the minister competent for health matters may, upon request of the minister competent for agricultural matters with respect to veterinary medicinal products, authorise for marketing, for a specified time, medicinal products that have not been authorised for marketing.

9. ⁽⁵⁵⁾ In the case of a natural disaster or another hazard to human or animal life or health, the minister competent for health matters may, upon request of the minister competent for agricultural matters with respect to veterinary medicinal products, issue a consent for import, upon the conditions defined in paragraphs 2, 3, 5 and 6, of the medicinal product which:

- 1) has been authorised for marketing as referred to in Article 3 (1) or (2), and
- 2) is authorised for marketing in the country from which it is imported, and
- 3) is unavailable in the territory of the Republic of Poland

– provided that no medicinal product containing the same active substance or active substances, and having the same strength and form as the imported medicinal product is available in the territory of the Republic of Poland.

Article 4a. ⁽⁵⁶⁾ Moreover, medicinal products subject to parallel import, which have been granted the parallel import licence, shall be authorised for marketing.

Article 4b. ⁽⁵⁷⁾ The minister competent for health matters may issue a consent for foreign-language content of package labelling for a specific number of packages of orphan drugs defined in Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ EC L 18 of 22.01.2000, p. 1; OJ EU Polish special edition, Chapter 15, vol. 5, p. 21).

Article 5. ⁽⁵⁸⁾ The following shall not require to be granted an authorisation:

- 1) medicinal products used exclusively for research studies conducted by scientific entities within the meaning of the Act on the State Committee for Scientific Research of 12 January 1991 (Journal of Laws of 2001 No. 33, item 389 and of 2003 No. 39, item 335), conducting medical activities;
- 2) medicinal products used by manufacturers;
- 3) investigational medicinal products used exclusively for clinical trials or veterinary clinical trials entered in the Central Register of Clinical Trials, and
- 4) half-finished products manufactured for the purpose of being used in the further manufacturing process conducted by the manufacturer.

Article 6. ⁽⁵⁹⁾ (repealed).

Article 7. 1. ⁽⁶⁰⁾ The MAH shall submit the applications for authorisation, for variation to the terms of the authorisation, or for changing the expiry date of the authorisation to the minister competent for health matters through the President of the The Office For Registration Of Medicinal Products, Medical Devices And Biocidal Products, hereinafter referred to as “the Office President”.

2. The authorisation shall be granted, refused to be granted, subjected to variations to its terms, renewed, refused to be renewed, subjected to shortening of its period of validity, or cancelled by way of a decision of the minister competent for health matters.

3. ⁽⁶¹⁾ The authorisation shall be granted for 5 years.

4. ⁽⁶²⁾ The authorisation shall be granted for a veterinary medicinal product intended for use in target animal species whose tissues or products are intended for human consumption only in the case when the pharmacologically active substances which it contains appear in Annex I, II or III to Regulation No. 2377/90.

5. (repealed).

6. (repealed).

7. (repealed).

Article 7a. ⁽⁶³⁾ 1. For a veterinary medicinal product containing pharmacologically active substances not included in Annex I, II or III to Regulation No. 2377/90, the authorisation shall be granted if the product does not include the pharmacologically active substances that appear in Annex IV to Regulation No. 2377/90 and is intended for use in registered equidae which are not intended for slaughter for human consumption and which have been granted the identification document (passport).

2. For a veterinary medicinal product referred to in paragraph 1, the authorisation shall not be granted if an authorisation for another veterinary medicinal product intended for the treatment of the specific disease has already been issued.

Article 7b. ⁽⁶⁴⁾ 1. The authorisation for a veterinary medicinal product for use in target animal species whose tissues or products are intended for human consumption, containing pharmacologically active substances not appearing in Annex I, II or III to Regulation No. 2377/90 shall not be granted unless an application for determining the Maximum Residue Limit, containing complete information and with enclosed documentation in accordance with Regulation No. 2377/90 is submitted.

2. The authorisation application shall be submitted not earlier than 6 months after the application for the Maximum Residue Limit is submitted.

Article 8. 1. ⁽⁶⁵⁾ The minister competent for health matters shall grant the marketing authorisation on the basis of the report drawn up by the Office President.

1a. Before drawing up the report, the Office President:

- 1) shall verify the application referred to in Article 10, along with its enclosed documentation;
- 2) ⁽⁶⁶⁾ may request the MAH to submit supplementary information or explanations concerning the documentation referred to in Article 10, and also to present the risk management system for the use of the medicinal product;
- 3) ⁽⁶⁷⁾ in the case of concerns regarding the methods of control referred to in Article 10 (2) (2), and in the case of veterinary medicinal products, regarding the methods of tests referred to in Article 10 (2b) (6) (a), which concerns may be settled only experimentally, may refer to studies the medicinal product, the starting materials and the intermediates or other ingredients of the medicinal product covered by the application; before referring to studies the medicinal product, the starting materials and the intermediates or other ingredients of the medicinal product, the Office President shall inform in writing the MAH on his or her concerns and shall justify the necessity for conducting the trials;
- 4) may consult the Commission for Medicinal Products operating on the basis of separate regulations;
- 5) ⁽⁶⁸⁾ shall draw up the assessment report containing a scientific opinion on the medicinal product.

1b. ⁽⁶⁹⁾ The assessment report shall be updated if any new information important for the assessment of quality, safety or efficacy of the specific medicinal product appears.

1c. ⁽⁷⁰⁾ After the authorisation is granted, the assessment report shall be made available under the regulations on access to public information.

1d. ⁽⁷¹⁾ When submitting the application referred to in Article 7 (1), the MAH may request the Office President not to disclose the information contained in the assessment report, which constitutes business secret within the meaning of Article 11 (4) of the Act on

Counteracting Unfair Competition of 16 April 1993 (Journal of Laws of 2003 No. 153, item 1503, as amended), and in particular the information on supply sources.

2. The Commission must issue its opinion together with the respective rationale within 30 days of reception of the application; the absence of the Commission's opinion shall be considered a positive opinion.

3. ⁽⁷²⁾ The decision to grant the marketing authorisation for a veterinary medicinal product used in animals whose tissues or products are intended for human consumption, other than an immunological product, shall not be made unless at least temporary Maximum Residue Limits accepted in the territory of European Union Member State or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area have been established or it has been decided that for the active substances of such products such limits are not required.

4. ⁽⁷³⁾ The data and documents enclosed to the application, the reports and other documents collected in the procedure of granting, renewal or variation of a marketing authorisation should be kept at the Office for the Registration of Medicinal Products, Medical Devices and Biocides, thereafter referred to as the "Registration Office", for 10 years following the expiry of the marketing authorisation.

5. ⁽⁷⁴⁾ The date of issue of the decision varying the terms of the marketing authorisation and varying the dossier supporting the marketing authorisation and the date of issue of the decision under a separate application for marketing authorisation of a medicinal product, including a medicinal product with an additional strength, form, route of administration, package size, for a different animal species, under a different name or with a different Summary of Product Characteristics or Veterinary Summary of Product Characteristics, for the benefit of the same person who has obtained the first marketing authorisation for the medicinal product or of another person, shall not be considered the date of the first marketing authorisation of a medicinal product within the meaning of Article 15 (1) (2), and with respect to a veterinary medicinal product – within the meaning of Article 15a (1) and (2), subject to the provisions of Article 15a (5), (8) and 9.

Article 8a. ⁽⁷⁵⁾ 1. In the cases justified by reasons of public health protection, the minister competent for health matters may grant the marketing authorisation for a medicinal product not authorised for marketing in the territory of the Republic of Poland, provided that the medicinal product is authorised for marketing in another European Union Member State or European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, in accordance with the requirements defined in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ EC L 311 of 28.11.2001, p. 67, as amended; OJ EU Polish special edition, Chapter 13, vol. 27, p. 69), hereinafter referred to as "Directive 2001/83/EC".

2. The provisions of this Act shall apply accordingly to the authorisations issued under paragraph 1.

3. Before the authorisation referred to in paragraph 1 is granted, the minister competent for health matters:

- 1) shall notify the MAH in the country referred to in paragraph 1 on the minister's intention to grant the marketing authorisation in the territory of the Republic of Poland;
- 2) shall request the competent regulatory authorities referred to in paragraph 1 to send the updated assessment report concerning this medicinal product and a copy of the marketing authorisation for this product.

4. In the case of granting, cancellation or expiry of the authorisation referred to in paragraph 1, the minister competent for health matters shall notify the European Commission, indicating in particular the name of the medicinal product and the name and address of the MAH.

5. In the case when a European Union Member State or a European Free Trade Association (EFTA) Member State – a party to the agreement on the European Economic Area requests the minister competent for health matters, through the Office President, under

Article 126a of Directive 2001/83/EC, for the assessment report and a copy of the marketing authorisation for a medicinal product authorised for marketing in the territory of the Republic of Poland, the dossier of which is consistent with the requirements of this Act, the Office President shall send the updated assessment report and a copy of the authorisation within 120 days.

Article 9. ⁽⁷⁶⁾ 1. In matters referred to in Articles 7, 18a and 19, the procedure shall be initiated upon application submittal.

2. The minister competent for health matters shall establish, by way of a Regulation, the form of marketing authorisation application for a medicinal product, taking into consideration in particular the type of medicinal products and the scope of documentation required.

Article 10. 1. ⁽⁷⁷⁾ Subject to Articles 15 and 16, the marketing authorisation application for a medicinal product should contain in particular the following:

- 1) name and address of the MAH, manufacturer or importer with which the medicinal product batch is released, the manufacturing site, including the manufacturing site where the medicinal product batch control takes place, or the site of conducting import operations where medicinal product batch control takes place, and the numbers of the medicinal product manufacturing or import authorisations;
- 2) name of the medicinal product;
- 3) detailed quantitative and qualitative particulars of the active substance or active substances and other substances, referring to the medicinal product, and their usual common names and if such names do not exist – their chemical names;
- 4) pharmaceutical form, strength and route of administration and shelf-life of the medicinal product, and also the data on environment protection related to the disposal of the medicinal product, if necessary and consequential to the properties of the product.

2. ⁽⁷⁸⁾ The following shall be enclosed to the application referred to in paragraph 1:

- 1) description of the medicinal product manufacturing;
- 2) description of the control methods employed in the manufacturing process;
- 3) information on special requirements for the method of the medicinal product storage and dispensing to patients and of disposing of an expired product, along with the assessment of the environmental risk related to the medicinal product and the description of the methods aiming to limit this risk;
- 4) results, summaries, and reports for:
 - a) pharmaceutical, i.e. physicochemical, biological or microbiological, studies,
 - b) preclinical, i.e. pharmacological and toxicological, studies,
 - c) clinical trials,

– along with the general summary of quality, preclinical overview and summary of preclinical data as well as clinical overview and clinical summary;

- 5) description of the pharmacovigilance system which will be implemented by the MAH;
- 6) description of the risk management system for medicinal product use which will be implemented by the MAH, if required by the European Community guidelines;
- 7) for clinical trials conducted outside the territory of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, statement that these trials meet the ethical requirements defined in the provisions of Chapter 2a;
- 8) statement of the MAH confirming that such person has ensured the services of a person whose duties will include continuous pharmacovigilance for the medicinal product covered by the application and that the MAH has a system ensuring the possibility of prompt reporting of a suspected adverse reaction in the territory of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, or other countries;

- 9) statements signed by experts developing the general summary of quality, preclinical overview and preclinical summary as well as clinical overview and clinical summary referred to in subparagraph 4, on possessing by the experts the necessary technical or professional qualifications described in the enclosed curriculum vitae;
 - 10) in the case referred to in Article 16 (1), the rationale developed by the expert on the use of scientific bibliography consistently with the requirements defined in Annex I to Directive 2001/83/EC;
 - 11) Summary of Product Characteristics;
 - 12) mock-ups of immediate and outer packaging presented in the descriptive and graphic forms, and the leaflet, together with its readability test report;
 - 13) copies of all authorisations, copies of Summaries of Product Characteristics accepted by the respective authorities of the European Union Member States and European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area and copies of leaflets, if applicable;
 - 14) list of the European Union Member States and European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area where the authorisation application is being considered and detailed information on the authorisation granting refusal in any country, if applicable;
 - 15) copy of the manufacturing authorisation for the medicinal product in the country where the product is manufactured.
- 2a. ⁽⁷⁹⁾ Subject to Articles 15a and 16a, the marketing authorisation application for a veterinary medicinal product should contain all the information documenting the quality, safety and efficacy of the specific veterinary medicinal product, including but not limited to:
- 1) name and address of the MAH, manufacturer or importer with which the veterinary medicinal product batch is released, the manufacturing site, including the manufacturing site where the veterinary medicinal product batch control takes place, or the site of conducting import operations where veterinary medicinal product batch control takes place, and numbers of the veterinary medicinal product manufacturing authorisations or import authorisations;
 - 2) name of the veterinary medicinal product;
 - 3) detailed quantitative and qualitative particulars of the active substance or active substances and other substances referring to the veterinary medicinal product and their usual common names and if such names do not exist – their chemical names;
 - 4) pharmaceutical form, strength, route of administration, target animal species and shelf-life of a veterinary medicinal product, storage conditions, including the Maximum Residue Limits data.
- 2b. ⁽⁸⁰⁾ The following shall be enclosed to the application referred to in paragraph 2a:
- 1) description of the veterinary medicinal product manufacturing;
 - 2) information on therapeutic indications, contraindications and adverse reactions to the veterinary medicinal product;
 - 3) information on the dose for individual animal species for which the veterinary medicinal product is intended and on conditions of administration and use of such product;
 - 4) description of the methods of disposal of the veterinary medicinal product and waste of the veterinary medicinal product, and description of the potential risk associated with the use of the veterinary medicinal product for the environment, humans, animals and plants;
 - 5) specification of the withdrawal period for the veterinary medicinal products used in the target animal species whose tissues and products are intended for human consumption, together with the description of the test methods;
 - 6) results, summaries, reports and test methods for:
 - a) pharmaceutical, i.e. physicochemical, biological or microbiological, studies,
 - b) safety and residue studies,
 - c) preclinical and clinical trials,

- d) ecotoxicity studies: specification of the potential environmental risk associated with the use of the veterinary medicinal product,
- along with the expert reports;
- 7) statements signed by the experts developing the reports referred to in subparagraph 6 on possessing by the experts the necessary technical or professional qualifications described in the enclosed curriculum vitae;
- 8) in the case referred to in Article 16a (1), the rationale developed by the expert on the use of scientific bibliography consistently with the requirements defined in Annex 1 to 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 EC L 311 of 28.11.2001, p. 1, as amended; OJ EU Polish special edition, Chapter 13, vol. 27, p. 3), hereinafter referred to as "Directive 2001/82/EC";
- 9) description of the pharmacovigilance system for veterinary medicinal products;
- 10) description of the risk management system for veterinary medicinal product use, which will be implemented by the MAH if required;
- 11) declaration by the MAH confirming that such person has ensured the services of a person whose duties will include continuous pharmacovigilance for the veterinary medicinal product covered by the application and that the MAH has a system ensuring the possibility of prompt reporting of a suspected adverse reaction in the territory of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, or other countries;
- 12) Veterinary Summary of Product Characteristics;
- 13) mock-ups of immediate and outer packaging presented in the descriptive and graphic forms, and the leaflet;
- 14) copies of all authorisations, copies of Veterinary Summaries of Product Characteristics accepted by the respective authorities of the European Union Member States and European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area and copies of leaflets, if applicable;
- 15) list of the European Union Member States and European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area where the authorisation application is being considered, copies of proposed Veterinary Summaries of Product Characteristics and copies of proposed leaflets, if applicable;
- 16) detailed information on the authorisation granting refusal in any country, if applicable;
- 17) copy of the manufacturing authorisation for the veterinary medicinal product in the country where the product is manufactured;
- 18) in the case of veterinary medicinal products referred to in Article 7b, document confirming that the MAH submitted the application for determination of the Maximum Residue Limit in accordance with Regulation No. 2377/90.

3. ⁽⁸¹⁾ When submitting the application referred to in paragraphs 1 and 2a, the MAH shall specify the guidelines of the European Commission, Agency for the Evaluation of Medicinal Products or World Health Organization, which constitute the basis for the documentation prepared.

4. ⁽⁸²⁾ The data and documents referred to in paragraphs 2 and 2b may be presented in English, except for the documents referred to in subparagraphs 11 and 12 of paragraph 2 and in subparagraphs 12 and 13 of paragraph 2b, which shall be presented in Polish.

4a. ⁽⁸³⁾ In the case of a variation to the data referred to in subparagraphs 13 and 14 of paragraph 2 and in subparagraphs 14 and 15 of paragraph 2b, the applicant shall present to the minister competent for health matters, through the Office President, the information on the variations made and the documents including such variations.

5. ⁽⁸⁴⁾ In the case of a justified concern arising from the received documentation on quality of the medicinal product, the minister competent for health matters may request a report on an inspection held at the manufacturing site of the medicinal product manufactured abroad for the purpose of confirming the compliance of the manufacturing conditions with the

authorisation referred to in subparagraph 15 of paragraph 2 and in subparagraph 17 of paragraph 2b.

6. ⁽⁸⁵⁾ The inspection shall be conducted by manufacturing inspectors of the Main Pharmaceutical Inspectorate or by manufacturing inspectors of the competent authorities of European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, or countries which mutually recognise manufacturing inspections, upon request and at the cost of the MAH or upon request and at the cost of the manufacturer, unless the MAH is the manufacturer.

6a. ⁽⁸⁶⁾ The costs of conducting the inspection referred to in paragraph 5 shall include the costs of travel, accommodation and time of work of the inspector.

7. ⁽⁸⁷⁾ The minister competent for health matters shall establish, by way of a Regulation, the detailed method of presenting the documentation referred to in paragraphs 1 and 2, taking into account the provisions of Articles 15, 16, 20, 20a, 21, 23a (3) and (4) and Article 31 (2) (3), as well as the legislation and guidelines of the European Community applicable to the registration procedure for medicinal products.

8. ⁽⁸⁸⁾ The minister competent for health matters shall establish, by way of a Regulation, the detailed method of presenting the documentation referred to in paragraphs 2a and 2b, taking into account the provisions of Articles 15a, 16a, 20, 21, 23a (3) and (4) and Article 31 (2) (3), as well as the legislation and guidelines of the European Community applicable to the registration procedure for veterinary medicinal products.

9. ⁽⁸⁹⁾ The minister competent for health matters shall establish, by way of a Regulation, the method of conducting leaflet readability tests and the criteria for the report on such test, taking into account the European Community guidelines.

Article 11. ⁽⁹⁰⁾ 1. The Summary of Product Characteristics referred to in Article 10 (2) (11) shall contain the following:

- 1) name of the medicinal product along with the specification of the strength and pharmaceutical form of the medicinal product;
- 2) qualitative and quantitative composition of active substances and these excipients in the case of which this information is essential for proper administration of the medicinal product, where the usual common names or the chemical names should be used;
- 3) pharmaceutical form;
- 4) clinical particulars, including:
 - a) therapeutic indications,
 - b) posology and method of administration to adults and to children, if the medicinal product is used in children,
 - c) contraindications,
 - d) special warnings and special precautions for use and, in the case of immunological medicinal products, any special precautions to be taken by persons handling such products and administering them to patients, together with any precautions to be taken by the patient,
 - e) interactions with other medicinal products and other forms of interaction,
 - f) use during pregnancy and lactation,
 - g) effects on ability to drive and use machines,
 - h) undesirable effects,
 - i) overdose, including overdose symptoms, emergency procedures and antidotes;
- 5) pharmacological properties, including:
 - a) pharmacodynamic properties,
 - b) pharmacokinetic properties,
 - c) preclinical safety data;
- 6) pharmaceutical particulars, including:
 - a) list of excipients,
 - b) major incompatibilities,

- c) shelf-life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time,
- d) special precautions for storage,
- e) nature of container and composition of the materials it is made of,
- f) special precautions for disposal of the used medicinal product or waste materials derived from such medicinal product, if applicable;
- 7) name and address of the MAH;
- 8) marketing authorisation number;
- 9) date of the first marketing authorisation or renewal of the marketing authorisation;
- 10) date of revision of the text;
- 11) for radiopharmaceuticals, also the following:
 - a) full details of internal radiation dosimetry,
 - b) instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, the maximum storage time during which the eluate or the ready-to-use radiopharmaceutical product will conform with its specifications.
- 2. The Veterinary Summary of Product Characteristics referred to in Article 10 (2b)
- (12) shall contain the following:
 - 1) name of the veterinary medicinal product along with the specification of the strength and pharmaceutical form of the veterinary medicinal product;
 - 2) qualitative and quantitative composition of active substances and these excipients in the case of which this information is essential for proper administration of the veterinary medicinal product, where the usual common names or the chemical names should be used;
 - 3) pharmaceutical form;
 - 4) clinical particulars, including:
 - a) target species,
 - b) indications for use, specifying the target species,
 - c) contraindications,
 - d) special warnings for each target species,
 - e) special precautions for use, including special precautions to be taken by the person administering the veterinary medicinal product to animals,
 - f) adverse reactions (frequency and seriousness),
 - g) use during pregnancy, lactation or lay,
 - h) interaction with other medicinal products and other forms of interaction,
 - i) amounts to be administered and routes of administration for individual target species,
 - j) overdose, including overdose symptoms, emergency procedures and antidotes,
 - k) withdrawal period;
 - 5) pharmacological properties:
 - a) pharmacodynamic properties,
 - b) pharmacokinetic properties;
 - 6) pharmaceutical particulars, including:
 - a) list of excipients,
 - b) major incompatibilities,
 - c) shelf-life and, when necessary after reconstitution of the veterinary medicinal product or when the immediate packaging is opened for the first time,
 - d) special precautions for storage,
 - e) nature of immediate packaging and composition of the materials it is made of,
 - f) special precautions for disposal of the unused veterinary medicinal products or waste materials derived from such products, if applicable;
 - 7) name and address of the MAH;
 - 8) marketing authorisation number;
 - 9) date of the first authorisation and date of renewal of the authorisation;
 - 10) date of revision of the text.

3. Until the expiry of patent rights for therapeutic indications or pharmaceutical form in the territory of the Republic of Poland, the MAH submitting the application for marketing authorisation of a generic medicinal product or a generic veterinary medicinal product shall not be required to present in the Summary of Product Characteristics or in the Veterinary Summary of Product Characteristics for this product such part of the Summary of Product Characteristics of the reference medicinal product or such part of the Veterinary Summary of Product Characteristics of the reference veterinary medicinal product which refers to the therapeutic indications or dosage forms which will be covered by patent protection in the territory of the Republic of Poland at the time when the generic medicinal product or generic veterinary medicinal product is marketed.

4. In the case referred to in paragraph 3, the MAH shall submit a declaration confirming that therapeutic indication or pharmaceutical form data not entered in the Summary of Product Characteristics or in the Veterinary Summary of Product Characteristics are covered by patent protection.

5. The data contained in the Summary of Product Characteristics and Veterinary Summary of Product Characteristics shall be disclosed to the public.

Article 12. ⁽⁹¹⁾ For radiopharmaceutical products, in addition to the requirements laid down in Articles 10 and 11, in the part concerning the radiopharmaceutical generator, the application should also contain the following information and data:

- 1) general description of the system together with the detailed description of system elements that may affect the composition and quality of the generated radionuclide formulations;
- 2) qualitative and quantitative particulars of the eluate or the sublimate;
- 3) details of internal radiation dosimetry;
- 4) detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, the maximum storage time during which the eluate or the ready-to-use radiopharmaceutical product will conform with its specifications.

Article 13. 1. ⁽⁹²⁾ For a medicinal product derived from human or animal blood, in each document covered by the application referred to in Article 10, the international non-proprietary name and where such name does not exist – the usual common name – of the active ingredients has to be stated at least once. In further parts of the document, the name may be given in the abbreviated form.

2. Quantitative data for a medicinal product derived from human or animal blood should be expressed in weight units or in international units or in biological activity units, depending on what is applicable for the specific product.

3. ⁽⁹³⁾ The application referred to in Article 10 (1), when applies to a medicinal product derived from human or animal blood, should indicate the methods used for the purpose of eliminating viruses and other pathogens which might be transmitted through medicinal products derived from human or animal blood.

Article 14. ⁽⁹⁴⁾ (repealed).

Article 15. ⁽⁹⁵⁾ 1. Irrespectively of the protection arising from the provisions of the Act – Industrial Property Law of 30 June 2000 (Journal of Laws of 2003 No. 119, item 1117, as amended), the MAH shall not be required to provide the results of preclinical or clinical trials, if the MAH evidences that:

- 1) the medicinal product is a generic medicinal product equivalent to a reference medicinal product which has been authorised for marketing in the territory of the Republic of Poland or another European Union Member State or European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, and the MAH – marketing authorisation holder for the reference medicinal product agreed for the use of the results of preclinical or clinical trials

contained in the dossier of the reference medicinal product for assessment of the marketing authorisation application for such generic medicinal product, or

- 2) the medicinal product is a generic medicinal product equivalent to a reference medicinal product which is or was authorised for marketing in the territory of the Republic of Poland or another European Union Member State, or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, and a period of 6 years lapsed between the date of the first marketing authorisation for the reference medicinal product in any of these States and the date the marketing authorisation application was submitted in the territory of the Republic of Poland, unless patent protection for the reference medicinal product in the territory of the Republic of Poland expired earlier.

2. If the reference medicinal product is not or was not authorised for marketing in the territory of the Republic of Poland, the MAH shall specify in the application the European Union Member State or the European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, where the reference medicinal product is or was authorised for marketing. In such a case, the Office President shall request the competent authority of such State to confirm that the reference medicinal product is or was authorised for marketing in such State and to provide the information on at least the composition of such product.

3. Upon request of a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, the Office President shall confirm within 30 days that the reference medicinal product is or was authorised for marketing in the territory of the Republic of Poland and shall provide information on at least the composition of such product.

4. If the medicinal product does not meet the requirements for a generic medicinal product or if it has different therapeutic indications, a different route of administration, a different strength or a different pharmaceutical form as compared with the reference medicinal product, contains different active substances, or when bioequivalence cannot be shown by bioavailability studies, the MAH must present the results of the respective preclinical or clinical trials.

5. Where a biological medicinal product which is similar to a reference medicinal product does not meet the requirements for a generic medicinal product, in particular owing to differences relating to starting materials or manufacturing processes of such products, the MAH must present the results of the clinical or preclinical trials relating to the requirements which have not been met, in accordance with Annex I to Directive 2001/83/EC.

6. A generic medicinal product shall mean a medicinal product having the same qualitative and quantitative composition of active substances and the same pharmaceutical form as a reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

7. Salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance authorised for marketing shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy. In such cases, the MAH shall enclose documentation providing proof of the safety or efficacy of salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of the active substance authorised for marketing.

8. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form.

9. Bioavailability studies need not be required if the applicant can demonstrate that the generic medicinal product meets the criteria as defined in the European Community guidelines.

Article 15a. ⁽⁹⁶⁾ 1. Notwithstanding the protection arising from the provisions of the Act – Industrial Property Law of 30 June 2000, the MAH shall not be required to present the results of safety and residue studies and of preclinical and clinical trials when submitting the marketing authorisation application for a generic medicinal product equivalent to a reference

veterinary medicinal product which is or was authorised for marketing in the territory of the Republic of Poland or another European Union Member State, or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, and a period of at least 8 years (data exclusivity) lapsed between the date of the first marketing authorisation for the reference veterinary medicinal product in any of these States and the date the marketing authorisation application was submitted in the territory of the Republic of Poland.

2. Notwithstanding the granted marketing authorisation, the generic veterinary medicinal product can be marketed by the MAH not earlier than 10 years after the date of the first marketing authorisation for the reference veterinary medicinal product in a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the agreement on the European Economic Area (market exclusivity).

3. If the reference veterinary medicinal product is not or was not authorised for marketing in the territory of the Republic of Poland, the MAH shall specify in the application the European Union Member State or the European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, where the reference veterinary medicinal product is or was authorised for marketing. In such a case, the Office President shall request the competent authority of such State to confirm that the reference veterinary medicinal product is or was authorised for marketing in such a State and to provide the information on at least the full qualitative and quantitative composition of such product and, if necessary, the safety and efficacy documentation enabling the issue of the decision on marketing authorisation of the reference veterinary medicinal product.

4. Upon request of the respective authority of the European Union Member State or the European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, the Office President shall confirm within 30 days that the reference veterinary medicinal product is or was authorised for marketing in the territory of the Republic of Poland and shall provide information on at least full composition of this product and, if necessary, the respective documentation. In such a case, the data exclusivity or market exclusivity period in force in the European Union Member State or the European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area shall apply.

5. The period referred to in paragraph 2 shall be prolonged by no more than 3 years for veterinary medicinal products intended for fish, bees or other animal species determined as per the procedure referred to in Article 5 of Council Decision No. 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ EC L 184 of 17.07.1999, p. 23; OJ EU Polish special edition, Chapter 1, vol. 3, p. 124).

6. If the veterinary medicinal product has different therapeutic indications, a different route of administration, a different strength or a different pharmaceutical form as compared with the reference veterinary medicinal product, or contains different active substances, or when bioequivalence cannot be shown by bioavailability studies, the MAH must present the results of the respective safety and residue studies and preclinical and clinical trials.

7. If a biological veterinary medicinal product which is similar to a reference veterinary medicinal product does not meet the requirements for a generic veterinary medicinal product, in particular owing to differences relating to starting materials or manufacturing processes of such products, the MAH must present the results of the preclinical or clinical trials relating to the requirements which have not been met, in accordance with Annex 1 to Directive 2001/82/EC.

8. For veterinary medicinal products intended for the target animal species whose tissues and products are intended for human consumption and containing a novel active substance non-authorised in European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area up to 30 April 2004, the period referred to in paragraph 2 shall be prolonged by one year in the case of extending the authorisation to other target animal species whose tissues and products are intended for human consumption, within 5 years of the date of granting the

first authorisation. If the authorisation for four or more target animal species whose tissues and products are intended for human consumption is granted, the period referred to in paragraph 2 may be prolonged to 13 years.

9. The period referred to in paragraph 2 shall be prolonged up to one to 3 years, respectively, for a veterinary medicinal product intended for the target animal species whose tissues and products are intended for human consumption, if the MAH submitted earlier the application for determining the Maximum Residue Limits for the target animal species covered by the authorisation.

10. A generic veterinary medicinal product shall mean a medicinal product having the same qualitative and quantitative composition of active substances and the same pharmaceutical form as the reference veterinary medicinal product, and whose bioequivalence with the reference veterinary medicinal product has been demonstrated by appropriate bioavailability studies.

11. Salts, esters, ethers, isomers, isomer mixtures, complexes or derivatives of an active substance authorised for marketing shall be considered the same active substance, unless they differ significantly in properties with regard to safety or efficacy. In such cases, the MAH shall enclose documentation providing proof of the safety or efficacy of salts, esters, ethers, isomers, mixtures of isomers or derivatives of the active substance authorised for marketing.

12. The various immediate-release pharmaceutical oral forms shall be considered the same pharmaceutical form.

13. Bioavailability studies need not be required if the applicant can demonstrate that the generic veterinary medicinal product meets the criteria defined in the European Community guidelines.

Article 16. ⁽⁹⁷⁾ 1. Notwithstanding the protection arising from the provisions of the Act – Industrial Property Law of 30 June 2000, the MAH shall not be required to provide the results of preclinical or clinical trials if the active substance or active substances of the medicinal product has or have a well-established medicinal use in the territory of a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, for at least 10 years counting from the first systematic and documented use of such substance in a medicinal product, with recognised efficacy and an acceptable level of safety. In that event, the results of preclinical or clinical trials shall be replaced or supplemented by scientific literature publications.

2. The well-established medicinal use referred to in paragraph 1 shall mean the well-established medicinal use in the territory of a European Union Member State before it obtained European Union membership or in the territory of a Member State of the European Free Trade Association (EFTA) – party to the Agreement on the European Economic Area before it entered into the Agreement on the European Economic Area.

3. For a combined medicinal product containing a combination of known active substances found in medicinal products authorised for marketing but not used so far in the specified composition for medicinal purposes, the MAH shall present the results of new preclinical or clinical trials on the combined medicinal product. In such a case, the MAH shall not be required to present the results of such trials separately for each active substance.

4. For a homeopathic medicinal product with therapeutic indications, containing a combination of homeopathic stocks which have not been used in therapy so far or which are not described in scientific literature, the MAH shall present the results the respective preclinical or clinical trials on the combined homeopathic medicinal product and on each of its ingredients.

5. The MAH shall not be required to present the documentation referred to in Article 10 (2) (1) – (4), if such MAH has obtained the consent of another MAH for the use of the documentation referred to in Article 10 (2) (1) – (4) for a medicinal product with the same qualitative and quantitative composition of active substances and the same pharmaceutical form, and authorised earlier for marketing in the territory of the Republic of Poland, for application assessment purposes.

Article 16a. (98) 1. Notwithstanding the protection arising from the provisions of the Act – Industrial Property Law of 30 June 2000, the MAH shall not be required to present results of studies contained in the safety and residue documentation or preclinical or clinical documentation, if the MAH evidences that the active substance of the veterinary medicinal product has well-established efficacy and acceptable level of safety and has been used in the territory of European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area for at least 10 years. In this case, the MAH shall present the respective scientific literature data. Reports published by the European Agency for the Evaluation of Medicinal Products on assessment of the applications for determination of the Maximum Residue Limits may be included as data in scientific literature, especially in the safety documentation.

2. If the MAH submits the marketing authorisation application for a veterinary medicinal product defined in paragraph 1 for the target animal species whose tissues and products are intended for human consumption, and the application for the same veterinary medicinal product but for another target animal species whose tissues and products are intended for human consumption, containing new results of residue tests consistently with Regulation No. 2377/90 and new clinical trial results, then such trial results cannot be used for assessment of the veterinary medicinal product for which the application was submitted as per Article 15a, for a period of 3 years from the date of issuing the authorisation for such other target animal species whose tissues and products are intended for human consumption.

3. The MAH shall not be required to present the documentation referred to in Article 10 (2b) (6) if such MAH has obtained the consent of another MAH for the use of the documentation referred to in Article 10 (2b) (6) for a veterinary medicinal product with the same qualitative and quantitative composition of active substances and the same pharmaceutical form and authorised earlier for marketing in the territory of the Republic of Poland, for application assessment purposes.

4. For a veterinary medicinal product containing active substances authorised in veterinary medicinal products but not used so far in the specified composition for therapeutic purposes, the MAH must present the results of the respective safety and residue studies and preclinical and clinical trials with respect to the combined veterinary medicinal product; the MAH shall not be required to present the results of such trials on each ingredient separately.

5. For immunological veterinary medicinal products, the MAH shall not be required to present the results of trials conducted in non-laboratory conditions if such trials cannot be performed.

Article 17. 1. ⁽⁹⁹⁾ The trials referred to in Article 10 (2) (4) (b), aimed to assess the safety of the medicinal product, or the trials referred to in Article 10 (2b) (6) (b), aimed to assess the safety of the veterinary medicinal product, shall be conducted in accordance with Good Laboratory Practice principles within the meaning of the Act on Chemical Substances and Preparations of 11 January 2001 (Journal of Laws No. 11, item 84, as amended).

1a. ⁽¹⁰⁰⁾ The medicinal product trials referred to in Article 10 (2) (4) (c) shall be conducted in accordance with the Good Clinical Practice requirements, and the veterinary medicinal product trials referred to in Article 10 (2b) (6) (c) shall be conducted in accordance with the Good Veterinary Clinical Practice requirements.

2. ⁽¹⁰¹⁾ The requirements concerning the documentation of the results of the trials referred to in Article 10 (2) (4), on medicinal products, including radiopharmaceutical products, herbal medicinal products other than those referred to in Article 20a, homeopathic medicinal products other than those referred to in Article 21 (1), shall be defined in Annex I to Directive 2001/83/EC.

2a. ⁽¹⁰²⁾ In the case of veterinary medicinal products, including homeopathic medicinal products intended solely for animals, other than those referred to in Article 21 (4), the requirements for the documentation of the results of the trials referred to in Article 10 (2b) (6) shall be defined in Annex 1 to Directive 2001/82/EC.

3. ⁽¹⁰³⁾ The minister competent for health matters shall establish, by way of a Regulation, the requirements concerning the documentation of the results of trials on medicinal products indicated for particular nutritional purposes and antiseptics, taking into consideration in particular the specific nature of individual products and the necessity to present expert reports.

Article 18. 1. ⁽¹⁰⁴⁾ The procedure for granting the medicinal product marketing authorisation should be completed not later than within 210 days, subject to the time limits laid down in Articles 18a and 19.

1a. ⁽¹⁰⁵⁾ Within 30 days of application submittal, the Minister of Health shall perform the formal examination of the application. The formal examination shall mean checking whether the application contains all the necessary elements and whether all the additional documents provided for in this Chapter have been submitted. If any formal deficiencies are found, the Minister of Health requests the applicant to supplement them.

1b. ⁽¹⁰⁶⁾ If the applicant is requested to supplement the deficiencies, the time limit referred to in paragraph 1 shall be counted from the date of their supplementation.

2. ⁽¹⁰⁷⁾ The time limit referred to in paragraph 1 shall be counted from the day of submittal of the medicinal product marketing authorisation application containing the complete information with the required documentation enclosed.

3. ⁽¹⁰⁸⁾ The procedure for granting the medicinal product marketing authorisation referred to in Article 4a, should be completed at the latest within 45 days of submission of the application for issuing the parallel import licence containing the complete information and with the required documentation enclosed.

4. The course of the time limit referred to in paragraph 1 shall be suspended if the documentation has to be supplemented or explanations have to be submitted.

5. In the case referred to in paragraph 4, the minister competent for health matters shall issue the decision to suspend the course of the time limit.

Article 18a. ⁽¹⁰⁹⁾ 1. If marketing authorisation applications for the same medicinal product which has not been authorised in any European Union Member State or European Free Trade Association (EFTA) Member State – party to the agreement on the European Economic Area are submitted in parallel to the minister competent for health matters through the Office President and in another European Union Member State or European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, the minister competent for health matters shall initiate the procedure for issuing the marketing authorisation for the medicinal product hereinafter referred to as the “decentralised procedure”.

2. In the case when in the application referred to in paragraph 1 the MAH indicates the Republic of Poland as the Reference State, within 120 days of receiving the complete application, the Office President shall develop the draft assessment report and shall send it to the competent authorities of the concerned European Union Member States and European Free Trade Association (EFTA) Member State – parties to the Agreement on the European Economic Area and to the MAH along with the enclosed draft Summary of Product Characteristics or Veterinary Summary of Product Characteristics, draft package labelling and draft leaflet.

3. Within 90 days of the date of transferring the draft assessment report as per paragraph 2, the Office President shall inform the MAH on:

- 1) approval of the draft assessment report, draft Summary of Product Characteristics or Veterinary Summary of Product Characteristics, draft package labelling and draft leaflet by the States participating in the decentralised procedure, or
- 2) refusal to approve the draft assessment report, draft Summary of Product Characteristics or Veterinary Summary of Product Characteristics, draft package labelling or draft leaflet by the States participating in the decentralised procedure and initiation of the explanatory procedure referred to in paragraph 6.

4. The minister competent for health matters shall grant the authorisation consistently with the assessment report, the Summary of Product Characteristics or Veterinary Summary of Product Characteristics, the package labelling and the leaflet approved under the decentralised procedure, within 30 days of the date of their approval.

5. Upon request of the Office President, within 90 days of the date of receipt of the assessment report developed by the competent authority of the Reference State, along with the Summary of Product Characteristics or Veterinary Summary of Product Characteristics, the package labelling and the leaflet, the minister competent for health matters shall accept such report and inform on this the competent authority of the Reference State. The provision of paragraph 4 shall apply per analogy.

6. If in the course of the decentralised procedure reasonable concerns arise that marketing authorisation of the medicinal product concerned might pose a risk to public health, and in the case of a veterinary medicinal product might pose a risk for human or animal health, or for the environment within the meaning of the European Community guidelines, the Office President shall initiate the explanatory procedure and shall send the respective rationale to the competent authorities of the Reference State, the concerned European Union Member States and European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, and to the applicant.

7. The application referred to in paragraph 1 shall be submitted by the MAH or the MAH which is a subsidiary or parent entity of the MAH within the meaning of the Act on Public Offering and Conditions of Introducing Financial Instruments into the Organised Trade System and on Public Companies of 29 July 2005 (Journal of Laws No. 184, item 1539 and of 2006 No. 157, item 1119) or a MAH's licensor or licensee or an entity which aims to cooperate with the MAH at medicinal product marketing, except for the entity referred to in Article 16 (5) and Article 16a (3).

8. The same medicinal product referred to in paragraph 1 shall be considered the medicinal product with the identical qualitative and quantitative composition of active substances, identical pharmaceutical form and essentially consistent package labelling, leaflet and Summary of Product Characteristics or Veterinary Summary of Product Characteristics in the sections of indications, posology, method of administration, contraindications, warnings and precautions, and for which the potential differences do not affect the medicinal product safety or efficacy.

Article 19. ⁽¹¹⁰⁾ 1. If a marketing authorisation application for a medicinal product which has received an authorisation granted by the competent authority of a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area is submitted to the minister competent for health matters through the Office President, the minister competent for health matters shall initiate the medicinal product marketing authorisation procedure hereinafter referred to as the "mutual recognition procedure".

2. In the case when the authorisation has been granted for the medicinal product in the territory of the Republic of Poland, the MAH may submit the application for developing the assessment report on the medicinal product or for updating the existing report to the minister competent for health matters, through the Office President. The Office President shall develop or update the assessment report within 90 days of the date of receipt of the application and shall transfer the assessment report, the Summary of Product Characteristics or Veterinary Summary of Product Characteristics, the package labelling and the leaflet to the competent authorities of the concerned European Union Member States and European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, and to the applicant.

3. Within 90 days of the date of receipt of the assessment report developed by the competent authority of the Reference State, along with the Summary of Product Characteristics or Veterinary Summary of Product Characteristics, the package labelling and the leaflet, the minister competent for health matters shall accept such report and inform on

this the competent authority of the Reference State. The provision of Article 18a (4) shall apply per analogy.

4. If in the course of the mutual recognition procedure reasonable concerns arise that marketing authorisation of the medicinal product concerned might pose a risk to public health, and in the case of a veterinary medicinal product might pose a risk for human or animal health, or for the environment within the meaning of the European Community guidelines, the Office President shall initiate the explanatory procedure and shall send the respective rationale to the competent authorities of the Reference State, the concerned European Union Member States and European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, and to the applicant.

5. The application referred to in paragraph 1 shall be submitted by the MAH or the MAH which is a subsidiary or parent entity within the meaning of the Act on Public Offering and Conditions of Introducing Financial Instruments into the Organised Trade System and on Public Companies of 29 July 2005 with respect to the MAH or being the MAH's licensor or licensee, or an entity which aims to cooperate with the MAH at medicinal product marketing, except for the entity referred to in Article 16 (5) and Article 16a (3).

6. The application referred to in paragraph 1 may be applicable to a medicinal product with the identical qualitative and quantitative composition of active substances, identical pharmaceutical form and essentially consistent package labelling, leaflet and Summary of Product Characteristics or Veterinary Summary of Product Characteristics in the sections of indications, posology, method of administration, contraindications, warnings and precautions as a product holding the authorisation granted by the competent authority of a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, and for which the potential differences do not affect the medicinal product safety or efficacy.

Article 19a. ⁽¹¹¹⁾ The mutual recognition procedure and decentralised procedure shall not apply in the case of:

- 1) submitting an application for variation to the terms of the authorisation and variation to the documentation in the case of variations which require submittal of the application referred to in Article 10, if the authorisation was not granted consistently with Article 18a or Article 19 or if the documentation, including the Summary of Product Characteristics or Veterinary Summary of Product Characteristics, the package labelling and the leaflet, for this product was not harmonised under the provision of Article 31 (1);
- 2) homeopathic medicinal products other than those referred to in Article 21 (1) and (4);
- 3) traditional herbal medicinal products for which no Community monograph referred to in Article 16h (3) of Directive 2001/83/EC, hereinafter referred to as "Community monograph", has been developed, and traditional herbal medicinal products which do not consist of herbal substances, preparations or their combination, found in the Community list of traditional herbal medicinal products referred to in Article 16f (1) of Directive 2001/83/EC;
- 4) medicinal products whose documentation has not been supplemented and made consistent with the requirements of the Act referred to in Annex XII to the Treaty between the Kingdom of Belgium, the Kingdom of Denmark, the Federal Republic of Germany, the Hellenic Republic, the Kingdom of Spain, the French Republic, Ireland, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the Republic of Austria, the Portuguese Republic, the Republic of Finland, the Kingdom of Sweden and the United Kingdom of Great Britain and Northern Ireland (Member States of the European Union), and the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic concerning the accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the

Republic of Poland, the Republic of Slovenia and the Slovak Republic to the European Union, which was signed in Athens on 16 April 2003 (Journal of Laws of 2004 No. 90, item 864), if the MAH indicates the Republic of Poland as the Reference State.

Article 19b. ⁽¹¹²⁾ 1. The applications referred to in Articles 18a and 19 shall contain the data referred to in Article 10 (1) and (2), and for veterinary medicinal products – in Article 10 (2a) and (2b), and the declaration of consistency of the documentation submitted with the documentation covered by the assessment report.

2. The applications and documents referred to in paragraph 1 may be presented in Polish or in English, except for the Summary of Product Characteristics and Veterinary Summary of Product Characteristics, immediate and outer packaging labelling and leaflet, which shall be presented in Polish and English.

Article 19c. ⁽¹¹³⁾ If after the medicinal product marketing authorisation application is submitted, the Office President finds out that the marketing authorisation application for the medicinal product covered by the first application is being considered in another European Union Member State or European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, or that the competent authority of another European Union Member State or European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area has granted the marketing authorisation for such product, then the Office President shall inform the MAH on the necessity to apply the procedure laid down in Article 18a or Article 19, respectively, and shall discontinue the procedure.

Article 19d. ⁽¹¹⁴⁾ If the explanatory procedure referred to in Article 18a (6) or in Article 19 (4) is initiated and the Member States fail to reach an understanding within 60 days, upon request of the MAH the minister competent for health matters may grant the authorisation before the closure of the explanatory procedure, provided that the minister competent for health matters has already accepted the assessment report, the Summary of Product Characteristics or Veterinary Summary of Product Characteristics, the package labelling and the leaflet.

Article 19e. ⁽¹¹⁵⁾ The minister competent for health matters shall establish, by way of a Regulation, the scope of and the method of conducting the explanatory procedure referred to in Article 18a (6) and Article 19 (4), taking into account the legal regulations and the European Community guidelines as related to authorising medicinal products for marketing.

Article 20. 1. The marketing authorisation application for:

- 1) unprocessed pharmaceutical raw material used for therapeutic purposes,
- 2) herbal crude drug in the comminuted form,
- 3) therapeutic mineral,
- 4) medicinal product manufactured by industrial methods in accordance with the prescriptions of the Polish Pharmacopoeia,
- 5) pharmaceutical raw material intended for the preparation of officinal and magistral formulas,
- 6) ⁽¹¹⁶⁾ veterinary medicinal product intended solely for ornamental animals, in particular aquarium fish, cage birds, homing pigeons, terrarium animals, small rodents, and ferrets and rabbits, kept exclusively as pets.

2. The application referred to in paragraph 1 should contain:

- 1) name of medicinal product and name of active substance together with the specification of the pharmaceutical form and mode of dose administration, if applicable;
- 2) package size;

- 3) name and permanent address of the MAH filing the application and particulars of the manufacturer or manufacturers, if the MAH is not the manufacturer of the medicinal product;
- 4) list of documents enclosed to the application.

3. The minister competent for health matters, in consultation with the minister competent for agricultural matters with respect to veterinary medicinal products, shall establish, by way of a Regulation, the detailed list of the data and documents encompassed by the application referred to in paragraph 2 and of the products and raw materials defined in subparagraphs 1–5 of paragraph 1, and the list of medicinal products manufactured by industrial methods in accordance with the prescriptions of the Polish Pharmacopoeia, of unprocessed pharmaceutical raw materials used for therapeutic purposes, and of herbal crude drugs in the comminuted form that can be authorised for marketing pursuant to subparagraphs 1–5 of paragraph 1 and to paragraph 2.

4. The minister competent for health matters, in consultation with the minister competent for agricultural matters with respect to veterinary medicinal products, shall establish, by way of a Regulation, the detailed list of data and documents encompassed by the application referred to in paragraph 2 and of the products defined in subparagraph 6 of paragraph 1, including the composition of these products and taking into consideration the necessity to prevent their use in other animal species.

Article 20a. ⁽¹¹⁷⁾ 1. Traditional herbal medicinal products shall be the herbal medicinal products which meet all the following conditions:

- 1) they have indications exclusively appropriate to traditional herbal medicinal products which, due to their composition and purpose, can be used without the supervision of a physician for therapeutic, diagnostic or therapy monitoring purposes, and meet the criteria for a medicinal product dispensed without a physician's prescription;
- 2) they are intended exclusively for administration at the specific strength and with a specific posology;
- 3) they are intended exclusively for oral or external use, or for inhalation;
- 4) they were traditionally used in the period referred to in subparagraph 6 of paragraph 5;
- 5) the data on their traditional use are sufficient, in particular with respect to their safety of use in accordance with the method of use referred to in subparagraph 2 and their adequate pharmacological effects and efficacy have been established on the basis of long-standing use and experience in therapy.

2. Traditional herbal medicinal products shall be subjected to a simplified marketing authorisation procedure.

3. The provision of paragraph 2 shall not apply if the traditional herbal medicinal product can be authorised for marketing under Article 10 or Article 21.

4. A traditional herbal medicinal product may contain an addition of minerals or vitamins with well-documented safety of use in the given composition, provided that the action of vitamins or minerals is ancillary to that of the herbal active ingredients regarding the specified indications.

5. The marketing authorisation application of traditional herbal medicinal products should contain in particular:

- 1) name and address of the MAH;
- 2) name of the medicinal product;
- 3) quantitative and qualitative particulars for the medicinal product and all of its ingredients and their usual common names, if any;
- 4) pharmaceutical form, strength, route of administration and shelf-life of the medicinal product, and also the environmental protection data associated with the use and disposal of the medicinal product, if necessary and consequential to the properties of the product;
- 5) therapeutic indications, contraindications and adverse reactions;

- 6) literature data, including scientific literature data, or experts' opinions finding out that the herbal medicinal product or the corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years in a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area;
 - 7) results of the pharmaceutical tests defined in Article 10 (2) (4) (a).
6. In the case of combinations of herbal substances or herbal preparations, or a traditional herbal medicinal product, the data referred to in subparagraph 6 of paragraph 5 should refer to the combinations, and if the individual herbal substances or herbal preparations are not sufficiently known the data should also refer to these ingredients.
7. The following shall be enclosed to the application:
- 1) Summary of Product Characteristics except for the data referred to in Article 11 (1) (4);
 - 2) copies of documents confirming marketing authorisation in European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area or in other countries, or the detailed information on the refusal to grant the authorisation in any country, if applicable;
 - 3) safety overview of literature, including scientific literature, along with the expert report and, upon request of the Office President, the data necessary for assessing the safety of the medicinal product.
8. The Office President may request the Committee on Herbal Medicinal Products of the European Agency for the Evaluation of Medicinal Products to issue the opinion on considering the presented documentation adequate for establishing the traditional use of the traditional herbal medicinal product or corresponding product, enclosing the documentation for the traditional herbal medicinal product to the request for opinion.
9. A corresponding product is a traditional herbal medicinal product which contains the same herbal substances or herbal preparations, irrespectively of the excipients used, and having the same or similar intended purpose, equivalent strength and posology and the same or similar route of administration as the traditional herbal medicinal product covered by the application referred to in paragraph 5.

Article 20b. ⁽¹¹⁸⁾ 1. If the application referred to in Article 20a (5) is submitted, the MAH shall not be required to present the marketing authorisation for the traditional herbal medicinal product in the period referred to in Article 20a (5) (6). The requirement of 30 years of use of the traditional herbal medicinal product shall likewise be satisfied if the number or quantity of ingredients of the herbal medicinal product was reduced during that period.

2. If a marketing authorisation application is submitted for a traditional herbal medicinal product used in a European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area for less than 15 years, the Office President shall submit to the Committee on Herbal Medicinal Products of the European Agency for the Evaluation of Medicinal Products the documentation for this product for the purpose of determining by the Committee whether the remaining conditions necessary for acknowledging the traditional use of the traditional herbal medicinal product have been met. When considering the marketing authorisation application for the traditional herbal medicinal product, the Office President shall take into account the Community monograph.

3. If for the traditional herbal medicinal product covered by the application referred to in Article 20a (5) a Community monograph has been developed or the ingredients of this product are contained in the Community list of substances of traditional herbal medicinal products referred to in Article 16f (1) of Directive 2001/83/EC, the provisions of Articles 18a and 19 shall apply.

4. If the application referred to in Article 20a (5) is submitted, the Office President shall take into account the marketing authorisation of the given traditional herbal medicinal product granted in other European Union Member States or European Free Trade

Association (EFTA) Member States – parties to the Agreement on the European Economic Area.

Article 21. 1. ⁽¹¹⁹⁾ Homeopathic medicinal products:

- 1) which are administered orally or externally,
- 2) whose labelling and leaflet do not include therapeutic indications,
- 3) which are characterised by the sufficient degree of dilution to guarantee the safety of their use; i.e. which do not contain either more than 1/10,000 parts of the mother tincture or more than 1/100th of the smallest dose of the active substance contained in the medicinal product dispensed on prescription

– shall be subjected to a simplified marketing authorisation procedure.

2. The marketing authorisation application for the products referred to in paragraph 1 should contain in particular:

- 1) ⁽¹²⁰⁾ name and address of the MAH, manufacturer or importer with which the medicinal product batch is released, the manufacturing site, including the manufacturing site where the medicinal product batch control takes place, or the site of conducting import operations where medicinal product batch control takes place, and the numbers of the medicinal product manufacturing authorisations or import authorisations;
- 2) ⁽¹²¹⁾ name and address of the manufacturer of the mother tincture from which the homeopathic medicinal product is to be manufactured;
- 3) scientific or pharmacopoeial name of the product consistent with the name of the homeopathic stock contained in the European Pharmacopoeia or other respective pharmacopoeias recognised in the European Union Member States, and if such names do not exist – the common name, along with the specification of the route of administration, the pharmaceutical form and the degree of dilution;
- 4) product composition, including the excipients;
- 5) storage and transport conditions;
- 6) ⁽¹²²⁾ size and type of the packaging and content of the homeopathic medicinal product in the immediate packaging.

3. The following shall be enclosed to the application referred to in paragraph 2:

- 1) ⁽¹²³⁾ description of the method of obtaining and controlling the homeopathic stocks and justification of their homeopathic use on the basis of literature, including scientific literature;
- 2) description of the manufacturing process, including the description of dilution and potentisation methods;
- 3) description of control methods for each pharmaceutical form, including stability and microbiological quality tests;
- 3a) ⁽¹²⁴⁾ results, summaries and reports of quality, biological and pharmacological studies, along with the expert report;
- 4) ⁽¹²⁵⁾ original or authenticated copy of the manufacturing authorisation for the homeopathic medicinal product;
- 5) copies of authorisations granted in other countries;
- 6) commitment by the MAH to supply, for analytical testing, a sample of the mother tincture from which the product is to be manufactured, and a sample of the final product;
- 7) draft label or leaflet;
- 8) ⁽¹²⁶⁾ immediate packaging data, with specification of the quality requirements, and mock-ups of the immediate or outer packaging, package size, along with the information on the contents of the homeopathic medicinal product in the immediate packaging;
- 9) ⁽¹²⁷⁾ expiry date of the homeopathic medicinal product;
- 10) data and warning concerning:
 - a) storage and transport conditions,
 - b) method of administration.

4. ⁽¹²⁸⁾ Homeopathic veterinary medicinal products are also subjected to the simplified marketing authorisation procedure in the case when:

- 1) their labelling does not include therapeutic indications,
- 2) they are characterised by the sufficient degree of dilution to guarantee the safety of their use which means that they do not contain either more than 1/10,000 parts of the mother tincture or more than 1/100th of the smallest dose of the active substance contained in the medicinal product dispensed on prescription,
- 3) they are administered by the route described in the European Pharmacopoeia or in other pharmacopoeias officially recognised by European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area

– except for immunological homeopathic veterinary medicinal products.

5. The marketing authorisation application for the products referred to in paragraph 4 should contain in particular:

- 1) name and address of the MAH or the manufacturer, if the manufacturer is not the MAH, the manufacturing sites and the manufacturing authorisation number;
- 2) ⁽¹²⁹⁾ name and address of the manufacturer of the mother tincture from which the homeopathic medicinal product is to be manufactured;
- 3) ⁽¹³⁰⁾ scientific or pharmacopoeial name of the product consistent with the name of the homeopathic stock contained in the European Pharmacopoeia or other respective pharmacopoeias recognised in the European Union Member States, and if such names do not exist – the common name, along with the specification of the route of administration, the pharmaceutical form and the degree of dilution;
- 4) product composition, including the excipients;
- 5) storage and transport conditions;
- 6) size and type of the package and product content in the immediate packaging.

6. The following should be enclosed to the application referred to in paragraph 5:

- 1) ⁽¹³¹⁾ description of the manner of obtaining and controlling the homeopathic stocks and confirmation of their homeopathic use on the basis of literature, including scientific literature;
- 2) ⁽¹³²⁾ description of the manufacturing process of the homeopathic veterinary medicinal product, including the description of dilution and potentisation method;
- 3) description of the control method of the finished product for each pharmaceutical form, including stability and microbiological quality testing;
- 4) original or authenticated copy of the manufacturing authorisation for the product;
- 5) copies of authorisations granted in other countries;
- 6) commitment by the MAH to supply, for analytical testing, a sample of the mother tincture from which the product is to be manufactured, and a sample of the final product;
- 7) draft label or leaflet;
- 8) immediate packaging data, with specification of the quality requirements, and mock-ups of the immediate or outer packaging, package size and product content in the immediate packaging;
- 9) ⁽¹³³⁾ expiry date of the homeopathic medicinal product;
- 10) data and warning concerning:
 - a) storage and transport conditions,
 - b) method of administration,
 - c) ⁽¹³⁴⁾ withdrawal period, with full rationale.

7. ⁽¹³⁵⁾ The homeopathic medicinal products defined in paragraphs 1 and 4 shall not require evidence of their therapeutic efficacy.

7a. ⁽¹³⁶⁾ The marketing authorisation application referred to in paragraphs 2 and 5 may include a list of homeopathic medicinal products originating from the same homeopathic stock(s).

8. The minister competent for health matters shall establish, by way of a Regulation, the detailed method of presenting the documentation referred to in paragraphs 2, 3, 5 and 6, taking into consideration in particular the nature of the documentation presented.

9. The minister competent for health matters shall establish, by way of a Regulation, the model forms of the applications referred to in paragraphs 2 and 5, and other types of documents than those listed in paragraphs 3 and 6, taking into account the data contained in paragraphs 2 and 5.

Article 21a. ⁽¹³⁷⁾ 1. The application for the parallel import licence or application for variation to such licence shall be submitted to the minister competent for health matters through the Office President.

2. The parallel import licence shall be granted, licence granting shall be refused, and the licence shall be amended or cancelled through the decision issued by the minister competent for health matters on the basis of the report of the Office President.

3. The parallel import licence shall be granted for a period of 5 years.

3a. ⁽¹³⁸⁾ The parallel import licence shall expire one year after the expiry of the marketing authorisation in the territory of the Republic of Poland, and in the case of expiration of the marketing authorisation for the medicinal product in a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, from which the medicinal product is imported in parallel, the parallel import licence shall expire upon the date of expiry of this authorisation.

3b. ⁽¹³⁹⁾ Cancellation of the marketing authorisation in the territory of the Republic of Poland or in a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, from which the medicinal product is imported in parallel, due to reasons related to its life-threatening or health of humans or animals, in particular those referred to in subparagraphs 1, 2, 4 and 7 of paragraph 1 of Article 33 shall result in cancellation of the parallel import licence.

4. ⁽¹⁴⁰⁾ The provisions of Article 23 (1)–(2), Article 29 (1)–(2a), Article 33 and Article 37 shall apply to the parallel import licences and to the cancellation of such licences, per analogy.

5. If the minister competent for health matters is unable to find out on the basis of the documentation in his or her possession whether the differences between the medicinal product imported in parallel and the medicinal product authorised for marketing in the territory of the Republic of Poland could be considered significant from the point of view of the safety or efficacy of this product, such minister shall request additional documentation other than that defined in paragraphs 7 and 8 from the respective authorities of the European Union Member State or the European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, from which the medicinal product is imported.

6. If the minister competent for health matters considers that the differences between the medicinal product from parallel import and the medicinal product holding the marketing authorisation in the territory of the Republic of Poland are important and might constitute a life and health hazard to humans or animals, such minister shall refuse granting the parallel import licence for such medicinal product or making variations to the parallel import licence.

7. The parallel import licence application shall contain the following:

- 1) basic data contained in the authorisation granted by a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, from which the medicinal product is imported;
- 2) particulars of the parallel importer.

8. The following shall be enclosed to the parallel import licence application:

- 1) model forms of the package labelling and leaflet;
- 2) copy of the manufacturing authorisation granted by the competent authority of a European Union Member State or a European Free Trade Association (EFTA)

Member State – party to the Agreement on the European Economic Area, including as related to re-packaging;

- 3) receipt for payment of the fee for application submittal.

8a. ⁽¹⁴¹⁾ Having obtained the parallel import licence, at least 30 days before the planned market placement date, the parallel import licence holder shall inform the following persons on the anticipated date of market placement of the medicinal product in the territory of the Republic of Poland:

- 1) the Main Pharmaceutical Inspector;
- 2) the Office President;
- 3) the MAH holding the marketing authorisation for the territory of the Republic of Poland.

9. ⁽¹⁴²⁾ The parallel import licence holder can place the imported product on the market in parallel:

- 1) under the name used in the territory of the Republic of Poland, or
- 2) under the name used in the European Union Member State or the European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, from which the medicinal product is imported, or
- 3) under the usual common name or the scientific name bearing the trademark, or the name of the parallel import licence holder.

9a. ⁽¹⁴³⁾ The parallel import licence holder shall promptly notify the minister competent for health matters on the expiry of the marketing authorisation of the medicinal product in the European Union Member State or the European Free Trade Association (EFTA) Member State – party to the agreement on the European Economic Area, from which the medicinal product is imported in parallel.

10. In consultation with the minister competent for agricultural matters, the minister competent for health matters shall establish, by way of a Regulation, the form of the parallel import licence application and the detailed list of data and documents encompassed by the application for variation to the authorisation, including the data and documents referred to in paragraphs 7 and 8 and taking into consideration the type of the medicinal product and the scope of the terms of the parallel import licence.

Article 22. 1. In the course of the authorisation granting procedure, the medicinal product shall be subjected, in accordance with Article 8 (1a) (3), to quality tests, at the MAH's cost.

2. (repealed).

3. The minister competent for health matters shall establish, by way of a Regulation:

- 1) the entities testing medicinal products and veterinary medicinal products, taking into account in particular the scope of tests which should be performed to assess the quality of the medicinal product, qualifications of the personnel of the entity, experience in analysis of medicinal products;
- 2) the price list of payments charged for the quality tests referred to in paragraph 1, taking into account in particular the scope of tests performed, the expenses related to the test and the type of the tested product.

Article 23. 1. The authorisation shall specify:

- 1) the MAH;
- 2) ⁽¹⁴⁴⁾ name and address manufacturer or importer with which the medicinal product batch is released, the manufacturing site or the site of conducting import operations where medicinal product batch control takes place;
- 3) name of the medicinal product and their usual common name of the medicinal product, if exists, and the form, route of administration, strength, active substance dose, full qualitative composition and size and type of packaging of the medicinal product;
- 4) dispensing category of the medicinal product;
- 4a) ⁽¹⁴⁵⁾ category of use, for a veterinary medicinal products;
- 5) shelf-life of the medicinal product;

- 6) date of expiry of the authorisation;
- 7) withdrawal period for veterinary medicinal products;
- 8) species in which the given medicinal product can be used;
- 9) storage and transport requirements;
- 10) code consistent with the EAN UCC system;
- 11) authorisation number and date;
- 12) ⁽¹⁴⁶⁾ parallel import licence holder;
- 13) ⁽¹⁴⁷⁾ limit date authorising for marketing of a generic veterinary medicinal product, in the case referred to in Article 15a (2);
- 14) ⁽¹⁴⁸⁾ conditions arising from assessment of the documentation referred to in Article 23b, if applicable.

1a. The terms of the authorisation shall be non-confidential.

2. Issuing the authorisation shall mean the approval of the Summary of Product Characteristics, the leaflet and the packages of the medicinal product, including its labelling, quality requirements and quality testing methods for the medicinal product and the quality requirements for their packaging.

3. ⁽¹⁴⁹⁾ The minister competent for health matters shall establish, by way of a Regulation, the criteria for categorising the medicinal product in individual dispensing categories, taking into consideration in particular the nature of individual dispensing categories and the safety of medicinal product use.

3a. ⁽¹⁵⁰⁾ In consultation with the minister competent for health matters, the minister competent for agricultural matters shall establish, by way of a Regulation, the categories of veterinary medicinal product use, the criteria for assigning to individual categories of use and the criteria for assigning to individual dispensing categories, taking into consideration in particular the nature of individual categories and the safety of veterinary medicinal product use.

4. ⁽¹⁵¹⁾ The authorisation may include the list of homeopathic medicinal products without therapeutic indications, meeting the requirements defined in Article 21 (1) and (4).

Article 23a. ⁽¹⁵²⁾ 1. Medicinal products authorised for marketing shall be assigned one of the following dispensing categories:

- 1) dispensed without physician's prescription (over-the-counter) – OTC;
- 2) dispensed on physician's prescription – Rp;
- 3) dispensed on physician's prescription for restricted use – Rpz;
- 4) dispensed on physician's prescription, containing narcotic agents or psychotropic substances defined in separate regulations – Rpw;
- 5) only for hospital use – Lz.

2. The provisions of subparagraphs 1 and 2 of paragraph 1 shall apply per analogy to veterinary medicinal products.

3. If the MAH submits an application for changing the dispensing categories for a medicinal product, referring to the results of significant preclinical or clinical trials conducted previously for the medicinal product by another MAH and on the basis of which the dispensing categories have been changed, the Office President shall not take into account the results of these trials for one year after the decision on a change to the dispensing category was issued.

4. If the application referred to in paragraph 3 is submitted before the lapse of one year after the decision on a change to the dispensing category was issued, the minister competent for health matters shall suspend the procedure until one year elapses after the date of issue of such decision.

Article 23b. ⁽¹⁵³⁾ 1. In exceptional circumstances, taking into account the safety of medicinal product use, the minister competent for health matters may grant the marketing authorisation for the medicinal product under the proviso of meeting by the MAH, on the basis of Annex I to Directive 2001/83/EC, and in the case of a veterinary medicinal product – on the basis of Annex 1 to Directive 2001/82/EC, the specific conditions, in particular concerning the safety

of medicinal product use, reporting adverse reactions related to such a product, and undertaking in such cases the specific actions, along with the indication of the time limits for meeting these conditions.

2. The authorisation referred to in paragraph 1 shall be revised every 12 months starting from the date of its granting.

Article 24. 1. ⁽¹⁵⁴⁾ The MAH which has obtained the authorisation must:

- 1) indicate the person whose duties shall include pharmacovigilance;
- 2) keep the register of reported adverse reactions;
- 3) present to the Office President:
 - a) reports on single cases of adverse reactions reported by a physician, a dentist, a veterinarian, a pharmacist or a medical representative; the reports on serious adverse reactions shall be presented promptly but not later than 15 days following the receipt of the information,
 - b) Periodic Safety Update Reports for the medicinal products, consistent with the data contained in the register of reported adverse reactions:
 - every 6 months between the date of obtaining the first authorisation in the world by the given medicinal product and the date of placing the product on the market,
 - every 6 months during the first 2 years following the placing on the market,
 - every 12 months for the subsequent 2 years starting from the third year following the placing on the market, and then every 3 years,
 - in justified cases, on each request of the Office President;
- 4) present reports on safety trials conducted after the authorisation was obtained;
- 5) present the studies on the benefit-to-risk ratio.

2. ⁽¹⁵⁵⁾ Upon request of the MAH, the Office President may define other time limits for the presentation of Periodic Safety Update Reports than those indicated in subparagraph 3.b) of paragraph 1; such reports should be presented not less frequently than once in 3 years.

3. ⁽¹⁵⁶⁾ The MAH must also:

- 1) report the necessity to make urgent variations to the Summary of Product Characteristics or the Veterinary Summary of Product Characteristics;
- 2) report promptly all variations related to the medicinal product authorised for marketing and approved in another European Union Member State or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, which may affect the benefit-to-risk ratio;
- 3) report to the Office President the first date of medicinal product marketing;
- 4) report to the Office President temporary or permanent suspension of trade in the medicinal product, not later than within 60 days of the date when marketing of the medicinal product was ceased;
- 5) upon request of the Office President, present the information on the volume of sales of the medicinal product;
- 6) implement continuous scientific and technical progress related to the methods of manufacturing and control of medicinal products, consistently with the recognised scientific methods;
- 7) deliver the medicinal products exclusively:
 - a) to entities authorised to conduct wholesale trade,
 - b) for healthcare establishments to hospital pharmacies,
 - c) to research and development units, scientific departments of the Polish Academy of Sciences and the basic organisational units of public universities for the purpose of conducting scientific research,
 - d) within the framework of export outside the territory of the Republic of Poland conducted by the MAH on its own or contracted with another entity.

3a. ⁽¹⁵⁷⁾ The MAH granted the authorisation cannot disclose to the public any pharmacovigilance concerns with respect to such person's medicinal products without transferring this information earlier or concomitantly to the Office President.

3b. ⁽¹⁵⁸⁾ If the Office President learns about the new risks related to the safety of medicinal product use, the Office President shall make the MAH commit to make changes in the documentation for the medicinal product, specifying the time limit for submittal of the variation application.

3c. ⁽¹⁵⁹⁾ The MAH and the wholesale traders in medicinal products must ensure, to satisfy the patients' needs, adequate and continuous meeting of the needs of the entities authorised to conduct retail trade in medicinal products and the wholesale traders in medicinal products.

4. The minister competent for health matters shall establish, in consultation with the minister competent for agricultural matters with respect to a veterinary medicinal product, by way of a Regulation, the method and procedure pharmacovigilance, taking into consideration in particular:

- 1) creation and maintenance of a system ensuring that all information regarding suspected adverse reactions to medicinal products transferred to the MAH and to the medical representatives shall be collected so as to make such information easily available at one place;
- 2) development of the reports referred to in subparagraph 3 of paragraph 1;
- 3) ensuring that prompt and full responses are given to each request of the Office President for submittal of additional information indispensable for the assessment of benefits and risk involved with the use of the medicinal product, and that such responses shall include the information on the volume of sales of the specific medicinal product;
- 4) physicians' and pharmacists' obligations in the area of adverse reaction reporting as well as the manner and procedure for such reporting and the forms of reports;
- 5) detailed scope and procedure of and the method of reporting by the MAH the adverse reactions to the medicinal product, taking into consideration in particular the type of effect reported.

Article 24a. ⁽¹⁶⁰⁾ 1. The Office President shall conduct the control of the pharmacovigilance system, which may in particular:

- 1) control the MAHs with respect to the pharmacovigilance system;
- 2) request presentation of the documentation related to ensuring the operation of the pharmacovigilance system;
- 3) request explanations concerning the assurance of functioning of the pharmacovigilance system.

2. The minister competent for health matters shall establish, by way of a Regulation, the method of conducting and the scope of control of the pharmacovigilance system, taking into account the reliability of data collecting and analysis and the reliability of data transfer into the system.

Article 25. ⁽¹⁶¹⁾ 1. The basic quality requirements and methods of testing medicinal products and their packages and pharmaceutical raw materials shall be laid down by the European Pharmacopoeia or its translation into Polish contained in the Polish Pharmacopoeia.

2. If the European Pharmacopoeia does not contain the monograph, the requirements referred to in paragraph 1 shall be determined by the Polish Pharmacopoeia or the respective pharmacopoeias recognised in European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area.

Article 26. 1. The package, its labelling and the contents of the information leaflet for a medicinal product should be consistent with the data included in the documents as per Article 23 (2).

1a. ⁽¹⁶²⁾ The name of the medicinal product shall be expressed in the Braille format on the outer packaging of the medicinal product.

1b. ⁽¹⁶³⁾ The provision of paragraph 1a shall not be applicable to medicinal products with the dispensing category as referred to in Article 23a (1) (5) and to veterinary medicinal products.

1c. ⁽¹⁶⁴⁾ The MAH shall ensure that the content of the leaflet is made available on the patient's request via patients' organisations in the format appropriate for the blind and partially-sighted.

1d. ⁽¹⁶⁵⁾ The minister competent for health matters may discharge the MAH from the duty to place some information on the package and may allow the introduction of the leaflet in another language than Polish if the product is intended for administration solely by a veterinarian. The Office President shall inform the Chief Veterinary Officer on such decision.

1e. ⁽¹⁶⁶⁾ The minister competent for health matters may establish, by way of a Regulation, the category of medicinal products the name of which shall not be expressed on the outer packaging in the Braille format, taking into account the safety of medicinal product use, the method of medicinal product administration, or the size of the medicinal product package.

2. ⁽¹⁶⁷⁾ The minister competent for health matters shall establish, by way of a Regulation, the requirements for package labelling of a medicinal product and the content of the leaflet, and the scope of availability of the content of the leaflet in the form appropriate for the blind and partially-sighted, taking into consideration in particular the special requirements for the appropriate use of medicinal products, including radiopharmaceutical products, homeopathic medicinal products and traditional herbal medicinal products.

3. ⁽¹⁶⁸⁾ In consultation with the minister competent for agricultural matters, the minister competent for health matters shall establish, by way of a Regulation, the requirements for package labelling of a veterinary medicinal product and content of the leaflet, taking into consideration in particular special requirements concerning the appropriate use of veterinary medicinal products.

Article 27. 1. Medicinal products may contain preservative agents, sweeteners, colorants, antioxidants, and with respect to veterinary medicinal products – also labelling substances, subject to paragraph 2.

2. The minister competent for health matters shall establish, in consultation with the minister competent for agricultural matters with respect to veterinary medicinal products, by way of a Regulation, the list of substances referred to in paragraph 1 which can be contained in medicinal products, the basic quality requirements for these substances and the method of their describing in the dossier supporting the medicinal product marketing authorisation application, taking into consideration in particular the safety of medicinal products and the procedure harmonised with the European Union Member States.

Article 28. 1. The medicinal product authorised for marketing shall have to be entered into the Register of Medicinal Products Authorised for Marketing in the Territory of the Republic of Poland, hereinafter referred to as "the Register".

2. The Register referred to in paragraph 1 shall be kept by the Office President.

3. The minister competent for health matters shall establish, by way of a Regulation, the method and procedure for keeping the Register, taking into consideration in particular the established practices of making entries, changes and deletions in the Register as well as the procedure for making the Register available.

Article 29. 1. ⁽¹⁶⁹⁾ The term of the authorisation may be prolonged or shortened upon request of the MAH.

2. ⁽¹⁷⁰⁾ The term of the authorisation may be prolonged for an unlimited period on the basis of an application filed by the MAH at least 6 months before the end of the authorisation period. The application should contain the consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced in the period of validity of the

authorisation, except for the variations referred to in Article 31 (2) (3), and the pharmacovigilance data collected by the MAH in the manner defined in Article 24 (4), together with the assessment of those data.

2a. ⁽¹⁷¹⁾ When considering the application for the renewal of the marketing authorisation for the given medicinal product, the minister competent for health matters may, in justified cases, taking into account the data on safety of medicinal product use, issue a one-off decision to renew the authorisation for subsequent 5 years.

3. Issuance of the decision to renew the authorisation shall result in release of the updated text of the authorisation including its variations made in the authorisation validity period.

3a. ⁽¹⁷²⁾ The MAH shall submit the applications for renewal of an authorisation granted under the mutual recognition procedure or decentralised procedure in all countries in which the medicinal product was authorised for marketing in this procedure. The provisions of Article 18a and 19 shall apply per analogy.

4. The minister competent for health matters shall establish, by way of a Regulation, the model form of the application referred to in paragraph 1, taking into account the data contained in the application and the pharmacovigilance data.

5. ⁽¹⁷³⁾ The medicinal product which has not been granted authorisation renewal may be produced and marketed for 6 months counting from the date of issue of the final decision and may remain in the market until the date of expiry of the medicinal product, unless the renewal refusal decision is immediately enforceable.

6. ⁽¹⁷⁴⁾ The medicinal product the authorisation of which has expired in connection with MAH's failure to submit an application for authorisation renewal may remain in the market until the date of expiry of the medicinal product.

7. ⁽¹⁷⁵⁾ If the application referred to in paragraph 1 submitted within the time limit referred to in paragraph 2 is not considered, the medicinal product can still be manufactured and marketed after the authorisation expiry, until such application is considered.

Article 30. 1. The minister competent for health matters shall issue the decision refusing to grant the authorisation if:

- 1) the application and the dossier submitted in support of the application do not comply with the requirements laid down in the Act;
- 2) the results of tests and studies demonstrate that the medicinal product is characterised by risk of use unbalanced by the expected therapeutic effect within the framework of the indications, contraindications and prescribed dosing stated in the application;
- 3) the results of tests and studies demonstrate that the medicinal product does not have the declared therapeutic efficacy or the therapeutic efficacy is insufficient;
- 4) the results of tests and studies demonstrate that the qualitative or quantitative composition or another qualitative characteristic of the product is not as declared;
- 5) the withdrawal period specified by the MAH is not long enough to ensure that the foodstuffs derived from the treated animals do not contain products posing a potential risk to human health or such period is not sufficiently evidenced.

2. Moreover, subject to paragraph 3, the minister competent for health matters shall issue the decision refusing to grant the authorisation for an immunological medicinal product used solely in animals when:

- 1) administration of such product to animals would collide with the implementation of the national infectious disease diagnosis, control or elimination programme or would preclude the monitoring of infection prevalence;
- 2) the disease against which the product is to immunise does not occur in the territory of the Republic of Poland.

3. The provision of paragraph 2 shall not be applied to veterinary inactivated immunological medicinal products made from pathogens and antigens derived from an animal or animals in a farm and used for the treatment of such animal or animals on the specific farm, at the same place.

4. The minister competent for health matters shall issue the decision refusing to renew the authorisation due to the reasons specified in paragraph 1 or paragraph 2.

5. ⁽¹⁷⁶⁾ If in the course of the marketing authorisation procedure conducted as per Article 19 (1) the minister competent for health matters considers that the medicinal product should not be authorised for marketing due to the reasons listed in paragraph 1, the minister competent for health matters shall apply to the European Union authorities for taking up of the appropriate procedure.

6. ⁽¹⁷⁷⁾ If the case of issuing the decision refusing to grant the marketing authorisation for a traditional herbal medicinal product minister competent for health matters shall notify the European Commission, indicating the cause of such refusal.

Article 31. 1. Any variation to the terms of the authorisation and variations of the dossier supporting the authorisation shall be made by the minister competent for health matters on the MAH's request.

1a. ⁽¹⁷⁸⁾ The minister competent for health matters may define in a decision on variation to the terms of the marketing authorisation and variation to the dossier supporting the authorisation the date of entry into effect of the variations as proposed by the MAH, unless such decision concerns the safety of medicinal product use or is issued on the basis of the decision of the European Commission notified to the Republic of Poland. The date defined in the decision of the minister competent for health matters shall not be longer than 6 months after the date of the decision.

1b. ⁽¹⁷⁹⁾ In the case of variation to the terms of the authorisation and variation of the dossier supporting the authorisation under mutual recognition procedure or decentralised procedure, the MAH shall submit the applications in all European Union Member States and European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area where the medicinal product has been authorised for marketing. The provisions of Article 18a (6) and Article 19 (4) shall apply per analogy.

2. The minister competent for health matters, in consultation with the minister competent for agricultural matters with respect to veterinary medicinal products, shall establish by way of a Regulation:

- 1) the form of application for variations to the authorisation and to the marketing authorisation dossier;
- 2) the type and scope of variations introduced and the scope of required documents, tests and studies justifying the change introduced;
- 3) the types of variations that require filing of the application referred to in Article 10, taking into consideration in particular the data subject to changes, the manner of documenting the changes, and the scope of tests and studies confirming that the change introduced is justified;
- 4) the method and procedure for making the variations referred to in paragraph 1.

Article 32. 1. ⁽¹⁸⁰⁾ In the case of change of the MAH, the minister competent for health matters shall issue a new authorisation upon request of the person entering into the rights and obligations of the hitherto MAH. The decision issued for the new MAH shall enter into effect not later than 6 months after the date of its issue. The new authorisation shall be granted not later than within 30 days of the date the request is filed and shall retain the existing number and code consistent with the EAN UCC system.

2. The new MAH should enclose to the application referred to in paragraph 1 the agreement on assignment of rights and obligations and the declaration that other elements of the authorisation and the dossier supporting the authorisation have not changed.

Article 33. 1. The minister competent for health matters shall revoke the authorisation when any of the following circumstances occur:

- 1) an unexpected serious adverse reaction to the medicinal product, constituting a hazard to human life or health, and with respect to veterinary medicinal products – constituting a hazard to animal life or health, is observed;

- 2) the medicinal product does not have the declared therapeutic efficacy or the risk of its use is unbalanced by its therapeutic effect;
 - 3) ⁽¹⁸¹⁾ the medicinal product is found to be marketed in breach of the authorisation or provisions of the Act;
 - 3a) ⁽¹⁸²⁾ the payment referred to in Article 36 (2) is not paid when due;
 - 4) the recommended withdrawal period is found to be inadequate to ensure that the foodstuffs obtained from the treated animals will not contain residues which might constitute a health hazard to the consumer;
 - 5) new information covered by the documentation referred to in Article 10, which might result in the limitation of use of a medicinal product, is not notified to the Office President;
 - 6) ⁽¹⁸³⁾ removal from the Community list of traditional medicinal products referred to in Article 16f (1) of Directive 2001/83/EC, unless within 3 months of the date of such removal the MAH supplements the dossier referred to in Article 20a (5) (6) and Article 20a (7) (2) and (3), and the minister competent for health matters issues a positive decision concerning the application referred to in Article 20a (5);
 - 7) ⁽¹⁸⁴⁾ incompliance with the conditions referred to in Article 23b;
 - 8) ⁽¹⁸⁵⁾ removal of the pharmacologically active substance from Annexes I, II or III to Regulation No. 2377/90;
 - 9) ⁽¹⁸⁶⁾ in the case of lapse of the time limit referred to in Article 24 (3b).
2. If the authorisation is cancelled, the competent authority deletes the medicinal product from the Register.
 3. ⁽¹⁸⁷⁾ The minister competent for health matters informs the Council of Europe or the European Commission that the authorisation has been cancelled.
 4. ⁽¹⁸⁸⁾ In the case referred to in subparagraph 6 of paragraph 1, the provisions of Article 31 shall apply per analogy.
 5. ⁽¹⁸⁹⁾ The minister competent for health matters shall inform on the decision referred to in paragraph 1 the Main Pharmaceutical Inspector, and in the case of veterinary medicinal products also the Chief Veterinary Officer.

Article 33a. ⁽¹⁹⁰⁾ 1. The authorisation shall expire in the case when:

- 1) the MAH does not market the medicinal product within 3 years of the date of obtaining the authorisation;
- 2) the medicinal product was not marketed in a period of 3 subsequent years.

2. In view of protection of public health, and in the case of veterinary medicinal product – in view of protection of human or animal health or environment protection, and in the case of occurrence of exceptional circumstances, in particular in the case of issuing by a court the temporary order prohibiting medicinal product marketing, the minister competent for health matters may establish, upon request of the MAH and by way of the minister's decision, that the authorisation referred to in paragraph 1 does not expire.

Article 34. The Register and the documents submitted within the marketing authorisation procedure shall be accessible to persons who have the respective legal interest, subject to the regulations on secret information and intellectual property protection.

Article 35. ⁽¹⁹¹⁾ The provisions of the Code of Administrative Procedure shall apply to the matters of medicinal product marketing authorisation granting and of clinical trials, unregulated in the Act.

Article 36. ⁽¹⁹²⁾ 1. The MAH shall pay a fee for granting the marketing authorisation for a medicinal product, including the payments for filing the application for:

- 1) issuing the authorisation referred to in Articles 7, 18a, 19, 20, 20a, 21, 21a and 32;
- 2) renewal of the authorisation referred to in Articles 7, 18a, 19, 20, 20a, 21 and 21a;
- 3) variation to the data supporting the authorisation referred to in Articles 7, 18a, 19, 20, 20a, 21 and 21a;

- 4) other variations resulting from the administrative activities connected with the granted authorisation referred to in Articles 7, 18a, 19, 20, 20a, 21 and 21a;
- 5) developing the assessment report referred to in Article 18a (2) and Article 19 (2);
- 6) updating the assessment report referred to in Article 19 (2);
- 7) preparing the documents constituting the basis for initiating the explanatory procedure;
- 8) referred to in Article 33a (2).

2. The MAH who obtained authorisation renewal for an unlimited period, as referred to in Article 29 (2), shall pay the fee within the period of validity of such authorisation, for each year of its validity.

3. In the case of the application including the list of homeopathic medicinal products referred to in Article 21 (1) and (4), a single fee shall be collected.

4. The fees referred to in paragraphs 1 and 2 shall constitute the revenue of the State budget.

Article 36a. ⁽¹⁹³⁾ The minister competent for health matters, in consultation with the minister competent for agricultural matters with respect to veterinary medicinal products, shall establish, by way of a Regulation, the detailed method of determining the fees referred to in Article 36 (1) and (2) and the method of their payment, taking into consideration the levels of the respective fees in European Union Member States having a similar Gross Domestic Product per capita, as well as the labour connected with the performance of the specific activity and the level of costs borne by the Registration Office.

Article 37. ⁽¹⁹⁴⁾ 1. Authorisation obtaining and designating by the MAH the representative of the MAH shall not discharge the MAH from penal or civil liability arising from the use of the medicinal product, including under the provisions concerning responsibility for the product.

2. The representatives of the MAH shall be designated in a dated written agreement determining the scope of powers and duties of the MAH's representative.

3. The MAH shall promptly communicate the agreement referred to in paragraph 2 to the Office President and the Main Pharmaceutical Inspector.

4. The MAH, the manufacturer, the entity authorised to conduct wholesale or retail trade, the physician or other persons authorised to prescribe and dispense the medicinal product under separate regulations, shall not bear any civil or disciplinary liability for the effects of use of the medicinal product otherwise than in its therapeutic indications covered by the authorisation or the effects of use of a medicinal product which is not authorised for marketing, if such use is related to authorising the medicinal product for marketing for the time defined by the minister competent for health matters under Article 4 (8).

Chapter 2a ⁽¹⁹⁵⁾

Clinical Trials of Medicinal Products

Article 37a. 1. Clinical trials shall be conducted consistently with the rules defined in Articles 37b – 37ag, and veterinary clinical trials shall be conducted consistently with the rules defined in Articles 37ah – 37ak.

2. A clinical trial of a medicinal product is a medical experiment conducted in humans with the use of the medicinal product, within the meaning of the provisions of the Physician's Profession Act of 5 December 1996 (Journal of Laws of 2002 No. 21, item 204, No. 76, item 691, No. 152, item 1266 and No. 153, item 1271 and of 2003 No. 90, item 845), hereinafter referred to as "the Physician's Profession Act".

Article 37b. 1. Clinical trials, including the bioavailability and bioequivalence trials, shall be planned and conducted and the report on the clinical trials shall be presented in accordance with the Good Clinical Practice.

2. The clinical trial shall be conducted bearing in mind that the patient's interest prevails over the interest of science or society, if in particular:

- 1) the foreseeable risks and discomforts were compared to the expected benefits for individual clinical trial subjects and for the existing and future patients, and the Bioethics Committee referred to in Article 29 of the Physician's Profession Act and the minister competent for health matters have considered that the expected therapeutic benefits and benefits for public health justify the permission of the risks, and the clinical trial can be continued only when its compliance with the trial protocol is constantly monitored,
- 2) the clinical trial subject, and if such person is unable to grant the informed consent – the statutory representative of such person, learned about the objectives, risks and discomforts related to the clinical trial and the conditions in which it is to be conducted, and were informed on their right to withdraw from the clinical trial at any time, in the conversation with the investigator or a member of the investigator's staff conducted before the clinical trial;
- 3) the right of the clinical trial subject to ensure his/her physical and mental integrity, privacy and personal data protection is complied with;
- 4) having been informed on the nature, significance, implications and risks of the clinical trial, the clinical trial subject, and if such person is unable to grant the informed consent – the statutory representative of such person, granted the informed consent for participation in the trial; the document confirming informed consent granting shall be kept along with the clinical trial documentation;
- 5) the procedure ensuring that the subject's withdrawal from the clinical trial shall not cause any harm to such subject;
- 6) the sponsor and the investigator have signed the agreement of mandatory third-party liability insurance for the damage caused in connection with the clinical trial conduct.

3. In consultation with the minister competent for health matters and having consulted the Polish Insurance Chamber, the minister competent for financial institutions shall establish, by way of a Regulation, the detailed scope of the mandatory insurance referred to in subparagraph 6 of paragraph 2, the date of commencement of the insurance duty and the minimum sum insured, taking into account in particular the specific nature of the clinical trial.

Article 37c. Clinical trial conduct shall not release the sponsor and the investigator from criminal or civil liability arising from the clinical trial conducted.

Article 37d. 1. The clinical trial subject may withdraw from the clinical trial at any time, without any harm to such subject.

2. The entity indicated in the Good Clinical Practice requirements shall inform the clinical trial subject on the possibility to obtain additional information on the rights of such subject.

Article 37e. Except for clinical trials conducted in adult and healthy clinical trial subjects, no incentives or financial gratifications except for reimbursement of costs can be used in clinical trials.

Article 37f. 1. Informed consent granting shall be considered written, dated and signed declaration of will to take part in the clinical trial, made voluntarily by the person able to make such a declaration, and in the case of a person unable to make such a declaration, made by such person's statutory representative; such declaration also contains a mention that it was submitted after the appropriate information on the nature, significance, implications and risks related to the clinical trial had been obtained.

2. If the informed consent referred to in paragraph 1 cannot be granted in writing, the consent expressed orally in the presence of at least two witnesses shall be considered equivalent. Such consent shall be recorded in the clinical trial documentation.

Article 37g. The minister competent for health matters shall establish, by way of a Regulation, the detailed requirements of Good Clinical Practice, taking into consideration in particular the method of planning, conducting, monitoring, documenting and reporting the results of the clinical trials, on the basis of Good Clinical Practice regulations in force in the European Union.

Article 37h. 1. A clinical trial on minors may be undertaken only if the following conditions are additionally met:

- 1) the informed consent of the statutory representative and of the minor has been obtained upon the rules defined in Article 25 of the Physician's Profession Act;
- 2) the investigator or the person indicated by the investigator, having experience in dealing with minors, have granted to the minor the information on the clinical trial and the related risks and benefits, understandably to such minor;
- 3) the investigator assures to consider at any time the wish of the minor who is capable of forming an opinion and assessing the above information to refuse participation in the clinical trial or to be withdrawn from the clinical trial;
- 4) some direct benefit for the group of patients will potentially be obtained from the clinical trial and only where such research is essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods;
- 5) the clinical trial relates directly to a clinical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;
- 6) the clinical trial has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and patient's developmental stage.

2. The minister competent for health matters shall establish, by way of a Regulation, the method of conducting clinical trials on minors, taking into account in particular the justification for participation of minors in the clinical trial, methods of minimising the risk in such clinical trials, the sequence of conducting clinical trials with consideration of the patients' age, classification of clinical trials by the type and nature of the disease, the timetable of conducting clinical trials on minors taking into account the advancement stage of the clinical trials on the investigational medicinal product, the type of conducted trials, the type of clinical documentation required before initiating clinical trials on minors, guided by the European Union regulations on the rules of conducting clinical trials on minors.

Article 37i. 1. In the case of a clinical trial on:

- 1) a totally incapacitated person – the informed consent for such person's participation in clinical trials shall be granted by such person's statutory representative, and if the person is capable of forming an informed opinion on such person's participation in the clinical trial, it is also necessary to obtain the written consent of such person;
- 2) a person with full legal capacity who is incapable to express an opinion on participation in the clinical trial – the informed consent for such person's participation in the clinical trial shall be granted by the guardianship court having jurisdiction on the basis of the place of conduct of the clinical trial.

2. The persons referred to in subparagraph 2 of paragraph 1 shall not be subjected to clinical trials if such persons, having full legal capacity, have consciously refused to participate in such clinical trials.

3. The clinical trial on persons referred to in paragraph 1 may be undertaken only if the following conditions are additionally met:

- 1) such person has received information on the clinical trial and the related risks and benefits, according to his/her capacity of understanding;
- 2) the investigator assures to consider at any time the wish of such person who is capable of forming an opinion and assessing the above information to refuse participation in the clinical trial or to be withdrawn from the clinical trial investigator;
- 3) the clinical trial is essential to validate data obtained in clinical trials on persons able to give informed consent and relates directly to a life-threatening or debilitating clinical condition from which the person concerned suffers;

- 4) the clinical trial has been designed to minimise pain, fear and any other foreseeable risk in relation to the disease and the patient's age;
- 5) there are grounds for expecting that administering the medicinal product to be tested will produce a benefit to the patient outweighing the risks or produce no risk at all.

Article 37j. The sponsor and investigator shall be liable for damage caused in connection with clinical trial conduct.

Article 37k. 1. The sponsor shall supply free of charge to clinical trial subjects the investigational medicinal products and devices for their administration.

2. The investigational medicinal products referred to in paragraph 1 must meet the Good Manufacturing Practice requirements with respect to their manufacture.

3. ⁽¹⁹⁶⁾ Import of investigational medicinal products and equipment necessary for conducting clinical trials shall require the Office President's certificate attesting that the clinical trial has been entered in the Central Register of Clinical Trials and that the product or equipment concerned is imported for the purposes of such trial.

4. ⁽¹⁹⁷⁾ The provision of paragraph 3 shall not concern the import of investigational medicinal products and equipment necessary for conducting clinical trials from a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area.

Article 37l. 1. A clinical trial can be commenced if the Bioethics Committee has issued a positive opinion on the trial conduct and the minister competent for health matters has issued the authorisation for clinical trial conduct.

2. ⁽¹⁹⁸⁾ A clinical trial can also be commenced if the minister competent for health matters did not request the information referred to in Article 37n (2), within the time limit defined in Article 37p (1).

3. The provision of paragraph 2 shall not apply to clinical trials on investigational medicinal products intended for gene therapy or somatic cell therapy or investigational medicinal products containing genetically modified organisms.

4. The authorisation referred to in paragraph 1 shall be granted or refused by way of an administrative decision.

5. The Office President shall enter the clinical trial into the Central Register of Clinical Trials; the entry shall include also the information on refusal to grant the authorisation for clinical trial.

Article 37m. 1. The request for clinical trial commencement shall be submitted by the sponsor or investigator to the minister competent for health matters through the Office President.

2. The following shall be enclosed in particular to the request referred to in paragraph 1:

- 1) particulars of the investigational medicinal product;
- 2) clinical trial protocol which is a document describing the objectives, plan, methodology, statistical issues and organisation of the clinical trial;
- 3) patient information sheet and informed consent form;
- 4) document confirming the entry into the insurance agreement referred to in Article 37b (2) (6);
- 5) case report form;
- 6) particulars of the investigators and of the sites participating in the clinical trial;
- 7) receipt confirming that the fee for request submittal has been paid;
- 8) signed and dated description of the scientific and professional activity of the investigator;
- 9) clinical trial agreements between the parties participating in the clinical trial.

3. A fee shall be charged for submitting the request referred to in paragraph 1.

Article 37n. 1. If the submitted documentation referred to in Article 37m must be supplemented, the minister competent for health matters shall designate to the sponsor or investigator the time limit for such supplementation, with instruction that failure to provide the supplementation shall result in leaving the request without consideration.

2. During the procedure for issuing the clinical trial authorisation, the minister competent for health matters may once request the sponsor or the investigator to provide supplementary information necessary for authorisation granting. The time limit for supplementary information submittal shall not exceed 90 days.

Article 37o. (199) The minister competent for health matters shall issue the decision refusing to grant the clinical trial authorisation if:

- 1) the request or the documentation does not comply with the requirements laid down in the Act;
- 2) the basic concepts of the clinical trial are incompatible with the public order or with the rules of social conduct;
- 3) the basic concepts of the clinical trial do not meet the Good Clinical Practice requirements.

Article 37p. 1. The minister competent for health matters shall grant or refuse granting the clinical trial authorisation within not more than 60 days.

2. The time limit referred to in paragraph 1 shall be counted from the day of submittal of the documentation defined in Article 37m.

3. The time limit referred to in paragraph 1 may be extended by not more than 30 days, and if an expert is consulted – by another 90 days, with respect to clinical trials on investigational medicinal products intended for gene therapy or somatic cell therapy or investigational medicinal products containing genetically modified organisms.

4. The course of the time limit referred to in paragraph 1 shall be suspended until the information referred to in Article 37n (2) is received but by not more than 90 days.

5. The provisions of paragraphs 1 – 4 shall not apply to clinical trials on xenogenic therapy.

Article 37r. 1. The Bioethics Committee shall give its opinion on the clinical trial upon request of the sponsor or investigator submitted along with the supporting documentation.

2. In preparing its opinion referred to in paragraph 1, the Bioethics Committee shall consider, in particular:

- 1) the relevance, feasibility and plan of the clinical trial;
- 2) the analysis of the anticipated benefits and risks;
- 3) the correctness of the clinical trial protocol;
- 4) the suitability of the investigator and supporting staff members;
- 5) the quality of the investigator's brochure;
- 6) the quality of the site;
- 7) the level and completeness of the written information to be given to the clinical trial subject;
- 8) the correctness of the procedure to be followed for the purpose of obtaining informed consent and the justification for the research on persons incapable of giving informed consent, as regards the specific restrictions laid down in Articles 37h and 37i;
- 9) the level of the indemnity or compensation in the event of injury or death attributable to participation in the clinical trial;
- 10) the amounts rewarding or compensating the persons conducting the clinical trial and clinical trial subjects and the clinical trial agreements between the sponsor and the site;
- 11) the arrangements for the recruitment of clinical trial subjects;
- 12) the agreement referred to in Article 37b (2) (6).

Article 37s. 1. If clinical trials are conducted by different investigators on the basis of a single protocol and at many research centres situated in the territory of the Republic of Poland or other countries (multi-centre clinical trials), the sponsor shall select a clinical trial coordinator among all the investigators conducting the clinical trial in the territory of the Republic of Poland.

2. In the case of clinical trials referred to in paragraph 1, conducted in the territory of the Republic of Poland, the sponsor or coordinator of a clinical trial shall submit the request to the Bioethics Committee competent on the basis of the basic location of the clinical trial coordinator.

3. The Committee's opinion referred to in paragraph 2 shall be binding for all the sites on whose behalf the sponsor or coordinator of a clinical trial issued the request for opinion.

4. The Bioethics Committee referred to in paragraph 2 shall inform on the planned clinical trial participation by the site considered all the Bioethics Committees competent on the basis of the place of conduct of the clinical trial in the territory of the Republic of Poland. Within 14 days such Committees may submit reservations concerning the participation of the investigator or site in the clinical trial; failure to submit any reservations within the above-designated time limit shall be interpreted as acceptance of participation by the investigator or site in the clinical trial.

Article 37t. 1. Within not more than 60 days, the Bioethics Committee shall present its opinion to the sponsor or investigator and to the minister competent for health matters through the Office President.

2. The provisions of Article 37n and Article 37p shall apply per analogy.

3. If the Bioethics Committee issuing an opinion on the clinical trial:

- 1) on a minor – does not include a physician being a paediatrics specialist, the Bioethics Committee shall consult such a specialist;
- 2) on persons incapable of giving informed consent – does not include a physician being a specialist in the domain of medicine to which the clinical trial applies, the Bioethics Committee shall consult such a specialist.

Article 37u. The sponsor or investigator shall have the right to appeal against a negative opinion of the Bioethics Committee to the Bioethics Committee of Appeal referred to in Article 29 of the Physician's Profession Act.

Article 37w. The minister competent for health matters shall establish, by way of a Regulation:

- 1) ⁽²⁰⁰⁾ the form of the request to the Bioethics Committee for an opinion on the clinical trial referred to in Article 37r (1) and of the request to the minister competent for health matters for clinical trial commencement, referred to in Article 37m (1),
- 2) ⁽²⁰¹⁾ the documentation referred to in Article 37r (1),
- 2a) ⁽²⁰²⁾ the documentation referred to in Article 37m (2),
- 2b) ⁽²⁰³⁾ the form of request for opinion to the Bioethics Committee and for consent for the amendments referred to in Article 37x (1) to the minister competent for health matters,
- 2c) ⁽²⁰⁴⁾ the form of notification to the Bioethics Committee and to the minister competent for health matters on termination of the clinical trial, referred to in Article 37ab,
– taking into account in particular guidelines of the Agency for the Evaluation of Medicinal Products and the necessity to submit requests and notifications in Polish and English, and in the case of requests and notifications to the minister competent for health matters, also in the electronic form;
- 3) the level of fees referred to in Article 37m (3) and the methods of their payment – taking into account in particular the clinical trial phase, the labour related to the performance of the given activity and the level of cost borne by the Registration Office and the level of the fee in the European Union Member States having a similar Gross Domestic Product per capita.

Article 37x. 1. ⁽²⁰⁵⁾ Making amendments to the clinical trial protocol or to the investigational medicinal product documentation supporting the trial authorisation, if such amendments are substantial and are likely to have an impact on the safety of the clinical trial subjects, shall require obtaining the respective positive opinion of the Bioethics Committee which has issued an opinion on such trial and the consent of the minister competent for health matters.

2. The consent referred to in paragraph 1 shall be issued within a maximum of 35 days of the date of request submittal.

3. ⁽²⁰⁶⁾ The amendments referred to in paragraph 1 may also be introduced if the minister competent for health matters has not submitted, within the time limit defined in paragraph 2 reservations as to the permissibility of such amendments.

Article 37y. 1. If any event which is likely to affect the safety of the clinical trial subjects occurs, the sponsor or investigator shall abstain from conducting the clinical trial in accordance with the existing clinical trial protocol. In such a case, the sponsor and investigator shall be required to take appropriate urgent safety measures to protect the clinical trial subjects.

2. The sponsor shall forthwith inform the Office President and the Bioethics Committee which has issued an opinion on the clinical trial on the above circumstances and on the safety measures taken.

Article 37z. 1. The duties of the investigator conducting the clinical trial at the site shall include in particular:

- 1) providing medical care to clinical trial subjects;
- 2) monitoring the compliance of the clinical trial with the Good Clinical Practice rules;
- 3) reporting to the sponsor the serious adverse event related to the investigational medicinal product, except for such event that the protocol or investigator's brochure identifies as not requiring immediate reporting.

2. Along with reporting the event as referred to in subparagraph 3 of paragraph 1, the investigator must draw up a written report containing a description of the serious adverse event, in which clinical trial subjects are identified with code numbers.

3. The adverse events and laboratory abnormalities other than those referred to in subparagraph 3 of paragraph 1 shall be reported to the sponsor as specified in the clinical trial protocol.

4. For reported death of a trial subject, the investigator shall supply, upon request of the sponsor or the Bioethics Committee, all the necessary information not included in the report referred to in paragraph 2.

5. The sponsor shall keep the documentation referred to in paragraphs 2 – 4 in accordance with the Good Clinical Practice rules and shall make it available upon request of European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area in whose territories the specific clinical trial is conducted, subject to Article 37aa.

Article 37aa. 1. ⁽²⁰⁷⁾ If it is suspected that the adverse event referred to in Article 37z (1) (3) is an unexpected serious adverse reaction to the medicinal product that was fatal or life-threatening for a clinical trial subject, the sponsor shall forthwith, but in any case not later than 7 days after receiving such information by the sponsor on such a case, report the information to the competent authorities of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area in whose territories the specific clinical trial is conducted, and to the Bioethics Committee which has issued an opinion on the clinical trial, and shall report the information in the electronic form to the European database of adverse reactions.

2. ⁽²⁰⁸⁾ The sponsor shall report the additional information containing the description of the unexpected serious adverse reaction to the medicinal product to the authorities referred to in paragraph 1 within 8 days of the date of reporting the information referred to in

paragraph 1 and shall report the additional information in the electronic form to the European database of adverse reactions.

3. ⁽²⁰⁹⁾ If it is suspected that the adverse event is an unexpected serious adverse reaction to the medicinal product, other than specified in paragraph 1, the sponsor shall forthwith but in any case not later than 15 days after receiving such information report the information to the competent authorities of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, in whose territories the specific clinical trial is conducted, and to the Bioethics Committee which has issued an opinion on the clinical trial, and shall report the information in the electronic form to the European database of adverse reactions.

4. Notwithstanding the information forwarded as defined in paragraphs 1 – 3, the sponsor shall also inform on the suspected unexpected serious adverse reaction all the investigators conducting the clinical trial in the territory of the Republic of Poland.

5. ⁽²¹⁰⁾ In each year the clinical trial is conducted, the sponsor shall submit to the competent authorities of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area in whose territories the clinical trial is conducted, and to the Bioethics Committee which has issued an opinion on the clinical trial, the list containing all the suspected serious adverse reactions which occurred in the year concerned and an annual report on the subjects' safety.

6. ⁽²¹¹⁾ The Office President shall collect the information on the unexpected serious adverse reactions to the medicinal product, which occurred in relation to the clinical trials conducted in the territory of the Republic of Poland.

7. The minister competent for health matters shall establish, by way of a Regulation, the procedure for reporting the unexpected serious adverse reaction to the medicinal product, the data included in the documentation referred to in Article 37z (5), and the forms of unexpected serious adverse reaction reports, taking into account in particular the method of collection, verification and presentation of the information on the unexpected serious adverse reaction to the medicinal product and unexpected event.

Article 37ab. 1. The sponsor shall inform on termination of a clinical trial conducted in the territory of the Republic of Poland the Bioethics Committee which has issued an opinion on the trial and the minister competent for health matters, through the Office President, within 90 days of the date of clinical trial termination.

2. If the clinical trial is terminated earlier than declared, the sponsor shall notify the Bioethics Committee which has issued an opinion on the clinical trial and the minister competent for health matters through the Office President, within 15 days of the date of clinical trial termination, and shall specify the reasons for early termination of the clinical trial.

Article 37ac. 1. Where there are reasonable grounds for considering that the conditions in the clinical trial authorisation are no longer met or the information obtained raise doubts about the safety or scientific validity of the clinical trial, the minister competent for health matters may:

- 1) issue a decision suspending the clinical trial,
- 2) cancel the clinical trial authorisation,
- 3) specify the actions which are to be undertaken to enable trial continuation.

2. Except where there is imminent risk to the safety of clinical trial subjects, before issuing the decision referred to in paragraph 1 the minister competent for health matters shall ask the sponsor and the investigator for their opinion to be delivered within 7 days.

3. The minister competent for health matters shall inform on the decision referred to in paragraph 1 the sponsor, the countries participating in the clinical trial, the Bioethics Committee which has issued an opinion on the clinical trial, the European Agency for the Evaluation of Medicinal Products and the European Commission.

Article 37ad. 1. The Office President shall enter the information on the clinical trial into the European database of clinical trials.

2. The information referred to in paragraph 1 shall include in particular:

- 1) required data from the request for authorisation for clinical trial commencement,
- 2) any amendments made in the submitted documentation,
- 3) the date of receipt of the opinion of the Bioethics Committee,
- 4) the declaration of the end of the clinical trial,
- 5) the information on control of a clinical trial conducted in accordance with the Good Clinical Practice rules.

3. At the substantiated request of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, the European Agency for the Evaluation of Medicinal Products or the European Commission, the Office President shall supply additional information concerning the clinical trial in question, other than the data already in the European database.

Article 37ae. 1. The Clinical Trial Inspection shall carry out the inspection of clinical trials for compliance with the Good Clinical Practice requirements.

2. The inspection referred to in paragraph 1 shall be carried out by a person authorised by the Office President, hereinafter referred to as “the inspector”.

3. The inspector may in particular:

- 1) inspect centres conducting the clinical trial, the sponsor’s registered office, the contractual research organisation or other places considered relevant for clinical trial conduct;
- 2) demand presentation of documentation related to the conducted clinical trial;
- 3) demand explanations concerning the conducted clinical trial and the presented documentation.

4. The Office President shall inform the European Agency for the Evaluation of Medicinal Products on inspection results and shall make available to the European Agency for the Evaluation of Medicinal Products, other European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area or the Bioethics Committee which has issued an opinion on the clinical trial, at their substantiated request, the report on the completed inspection.

5. The Clinical Trial Inspection may conduct an inspection also upon request of the European Commission.

6. The outcomes of the clinical trial inspection conducted on the territory of another European Union Member State shall be recognised by the Office President.

7. The minister competent for health matters shall establish, by way of a Regulation, the procedure and scope of conducting clinical trial inspections, taking into account in particular the nature of the trials and being guided by the Good Clinical Practice requirements.

Article 37af. The minister competent for health matters shall cooperate with the European Commission, the European Agency for the Evaluation of Medicinal Products and the competent authorities of European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area at clinical trial inspections; upon request of the Office President, the minister competent for health matters may submit to the European Commission a request for conducting an inspection in a country outside the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area.

Article 37ag. To the extent unregulated in this Chapter, the regulations on medical experiment referred to in Chapter IV of the Physician’s Profession Act shall apply to clinical trials of investigational medicinal products.

Article 37ah. 1. The sponsor or investigator shall submit a request for authorisation for a veterinary clinical trial to the minister competent for health matters through the Office President.

2. The provision of paragraph 1 shall also apply to veterinary clinical trials on residues of investigational veterinary medicinal product in tissues and to other veterinary clinical trials on animals whose tissues or products are intended for consumption.

3. Fees shall be charged for submitting the request referred to in paragraph 1.

4. Veterinary clinical trial can be commenced or conducted after the authorisation of the minister competent for health matters is obtained, if the minister finds the proposed clinical trial to be compliant with the Good Veterinary Clinical Practice requirements. The minister competent for health matters shall grant or refuse to grant the authorisation by way of a decision.

5. The Office President shall enter the veterinary clinical trial which has been authorised or refused by the minister competent for health matters into the Central Register of Clinical Trials.

6. Import of investigational veterinary medicinal products and equipment necessary for conducting veterinary clinical trials shall require the Office President's certificate attesting that the veterinary clinical trial has been entered in the Central Register of Clinical Trials and that the product or equipment concerned is imported for the purposes of such trial.

Article 37ai. 1. The Clinical Trial Inspection shall carry out the inspection of veterinary clinical trials for compliance with the Good Veterinary Clinical Practice requirements.

2. The inspector, authorised by the Office President, may in particular:

- 1) inspect centres conducting the veterinary clinical trial, the sponsor's registered office, the contractual research organisation or other places considered relevant for veterinary clinical trial conduct;
- 2) demand presentation of documentation related to the conducted veterinary clinical trial;
- 3) demand explanations concerning the conducted veterinary clinical trial and the presented documentation.

3. If the clinical trial on the investigational veterinary medicinal product constitutes a hazard to life or health of the animals subjected to the veterinary clinical trial or is conducted inconsistently with the protocol of veterinary clinical trials, or is of low scientific value, upon request of the Office President the minister competent for health matters shall order, by way of a decision, to suspend or discontinue the veterinary clinical trial; the Office President shall issue a request for inspection of the veterinary clinical trials.

Article 37aj. In consultation with the minister competent for agricultural matters, the minister competent for health matters shall establish, by way of a Regulation:

- 1) the form of the request referred to in Article 37ah (1),
- 2) the method and the scope of conducting an inspection of veterinary clinical trials for compliance of such trials with Good Veterinary Clinical Practice requirements, taking into account the type and intended purpose of the investigational veterinary medicinal product and the scope of the veterinary clinical trials conducted,
- 3) the procedure and rules for keeping the Central Register of Clinical Trials on investigational veterinary medicinal products, taking into account in particular the registered data,
- 4) the amounts of the fees referred to in Article 37ah (3) and the method of their payment, taking into account the labour connected with the performance of the specific activity,
- 5) the specific requirements of Good Veterinary Clinical Practice, taking into account in particular the method of planning, conducting, monitoring, documenting and reporting the results of veterinary clinical trials and the duties of the entities participating in or requesting the conduct of clinical trials.

Article 37ak. To the extent unregulated in this Act, the regulations of the Act on Animal Protection of 27 August 1997 (Journal of Laws of 2003 No. 106, item 1002) shall apply to veterinary clinical trials.

Article 37al. The provisions of this Chapter shall not apply to non-interventional trials in which:

- 1) medicinal products are used as defined in the marketing authorisation,
- 2) the patient is assigned to the group where the specified treatment method is used not on the basis of the trial protocol but depends on the actual practice, and the decision to administer the drug is clearly separated from the decision to enrol the patient to the trial,
- 3) the patients are not subjected to any additional diagnostic procedures or monitoring and epidemiological methods are used for the analysis of the collected data.

Chapter 2b ⁽²¹²⁾

General Provisions on Activities Subject to Authorisations

Article 37am. Before making the decision to grant the authorisation, the authority granting the authorisation, hereinafter referred to as "the authorising authority":

- 1) may require the applicant to supplement, within the designated time, the deficient documentation confirming that the applicant meets the legal conditions required for performing the specific business activity;
- 2) may verify the facts specified in the authorisation application for the purpose of finding whether the entrepreneur meets the conditions for conducting the business activity covered by the authorisation.

Article 37an. 1. Entrepreneur intending to take up business activity in the area covered by the authorisation may request an authorisation promise, hereinafter referred to as "the promise". In the promise, authorisation granting may be made conditional upon meeting the conditions for conducting the business activity covered by the authorisation.

2. In the promise granting procedure, the regulations applying to granting the authorisations defined in the provisions of this Act shall apply.

3. The period of validity of the promise, not shorter than 6 months, shall be specified in such promise.

4. Authorisation for the business activity defined in the promise shall not be refused in the period of validity of the promise unless:

- 1) the data contained in the promise application have changed or
- 2) the applicant has not met all the conditions specified in the promise, or
- 3) the applicant does not meet the conditions for conducting the business activity covered by the authorisation, or
- 4) this is justified by threat to defence or safety of the country or to another important public interest.

Article 37ao. 1. The authorisation shall be granted for an indefinite time.

2. The authorisation may be granted for a specified time on entrepreneur's request.

Article 37ap. 1. The authorising authority shall cancel the authorisation if:

- 1) a legally binding award prohibiting the entrepreneur to conduct the business activity covered by the authorisation has been issued;
- 2) the entrepreneur no longer meets the conditions laid down in legal regulations, required for conducting the business activity specified in the authorisation;
- 3) the entrepreneur has not remedied, within the time limit designated by the authorising authority, the factual or legal status violating the legal regulations governing the business activity covered by the authorisation.

2. Authorising authority may cancel the authorisation in the cases specified in the provisions of this Act.

Article 37ar. The entrepreneur must report to the authorising authority all changes to the data specified in the authorisation.

Article 37as. The entrepreneur was cancelled due to the reasons referred to in Article 37ap (1) may reapply for the authorisation with the same coverage not earlier than 3 years after the decision on authorisation cancellation is issued.

Article 37at. 1. The authorising authority shall have the right to inspect the business activity for which the authorisation was granted.

2. The inspection activities shall be carried out on the basis of an authorisation issued by the authorising authority.

3. The persons authorised by the authorising authority to carry out the inspection shall have in particular the right to:

1) enter the real property, site, premises or their part, where the business activity covered by the authorisation is carried out, on days and at times when the business is or should be carried out;

2) demand oral or written explanations, presentation of documents or other information carriers and making available data related to the inspection object.

4. The authorising authority may require the entrepreneur to remedy within the designated time the deficiencies found in the course of the inspection.

5. The authorising authority may authorise for conducting the inspection referred to in paragraph 1 another administrative authority specialised in the inspection of the type of business concerned. The provisions of paragraphs 2 – 4 shall apply per analogy.

Article 37au. Business activity of the entrepreneur referred to in Articles 38, 70, 74 and 99 shall be governed by the provisions of Chapter 5 of the Business Activity Act of 3 July 2004;

Chapter 3

Manufacturing and Import of Medicinal Products ⁽²¹³⁾

Article 38. 1. Taking up business activity of medicinal product manufacture shall require, subject to paragraph 4, manufacturing authorisation.

1a. ⁽²¹⁴⁾ Taking up business activity of medicinal product import shall require, subject to paragraph 4, import authorisation.

2. ⁽²¹⁵⁾ The Main Pharmaceutical Inspector shall be the authority competent for granting, refusing to grant and cancelling, and also amending the manufacturing authorisation or import authorisation.

3. ⁽²¹⁶⁾ (repealed).

3a. ⁽²¹⁷⁾ The provisions of Article 40 (2), Article 41, Article 42, Article 43 (2) and (4), Article 46 and Articles 48 – 51 shall apply per analogy to business activity of medicinal product import.

4. ⁽²¹⁸⁾ The Main Pharmaceutical Inspector shall issue an opinion on compliance of the conditions of manufacturing of a medicinal product manufactured abroad with Good Manufacturing Practice requirements referred to in Article 39 (4) if:

1) the MAH submits an application for the authorisation referred to in Article 10 (1) and (2a), or

2) the medicinal product is imported into the territory of the Republic of Poland for the purpose of further processing,

– having found, on the basis of an inspection conducted by manufacturing inspectors of the Main Pharmaceutical Inspectorate or of the report on inspection conducted in the last 3 years by the competent authority of a European Union Member State or a European Free Trade

Association (EFTA) Member State – party to the Agreement on the European Economic Area or country which has signed an agreement on the mutual recognition of inspections with a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, that the requirements necessary for obtaining a medicinal product of the declared quality have or have not been met and after being presented the authenticated copy of the manufacturing authorisation issued by the competent authority in the country where the product is manufactured.

5. ⁽²¹⁹⁾ In the case referred to in subparagraph 1 of paragraph 4, Main Pharmaceutical Inspector shall present the opinion to the minister competent for health matters.

6. ⁽²²⁰⁾ The inspection referred to in paragraph 4 shall be conducted by the manufacturing inspector of the Main Pharmaceutical Inspectorate at the cost of the applicant for the opinion referred to in paragraph 4.

7. ⁽²²¹⁾ The provisions of paragraphs 4 – 6 shall not apply to European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area other than the Republic of Poland and countries which possess equivalent Good Manufacturing Practice requirements and inspection system to those in force in the European Union.

8. ⁽²²²⁾ (repealed).

9. ⁽²²³⁾ The Main Pharmaceutical Inspector shall forward the copies of the decisions referred to in paragraphs 1 and 1a to the European Agency for the Evaluation of Medicinal Products.

Article 39. 1. The manufacturing authorisation applicant should:

- 1) ⁽²²⁴⁾ submit the authorisation application containing the applicant's corporate name along with the tax identification number (NIP) and defining the type and name of the medicinal product, its pharmaceutical form, the manufacturing site, the scope of manufacturing and the control points;
- 2) supply detailed information on quality assurance, including the compliance with the Good Manufacturing Practice requirements referred to in subparagraph 1 of paragraph 4;
- 3) have at its disposal suitable and sufficient premises, technical equipment and control facilities necessary for the manufacture, control and storage of the medicinal products referred to in the application;
- 4) employ a qualified person responsible for ensuring that before market placement each batch of the medicinal product has been manufactured and controlled in accordance with the provisions of the Act and the requirements contained in the specifications and documents supporting the marketing authorisation of such product.

1a. ⁽²²⁵⁾ The applicant for an import authorisation should:

- 1) submit an authorisation application containing the applicant's corporate name along with the tax identification number (NIP) and defining the type and name of the medicinal product, its pharmaceutical form, the sites of conducting import business activity, and the control points;
- 2) supply detailed information on quality assurance, including the compliance with the Good Manufacturing Practice requirements referred to in subparagraph 1 of paragraph 4;
- 3) have at its disposal suitable and sufficient premises, technical equipment and control facilities necessary for the import, control and storage of the medicinal products referred to in the application;
- 4) employ a qualified person responsible for ensuring that before market placement each batch of the medicinal product has been controlled in accordance with the provisions of the Act and the requirements contained in the specifications and documents supporting the marketing authorisation of such product.

2. ⁽²²⁶⁾ The manufacturing authorisation and the import authorisation shall be granted for an unlimited time after the Pharmaceutical Inspection finds that the authorisation applicant adequately complies with the requirements referred to in paragraph 1 or 1a.

3. If the authorisation application concerns several medicinal products, the names of the medicinal products included in the application may be specified in an appendix to the application.

4. ⁽²²⁷⁾ The minister competent for health matters shall establish, by way of a Regulation:

- 1) ⁽²²⁸⁾ the Good Manufacturing Practice requirements, taking into account the respective European Community guidelines;
- 2) the requirements which should be met by the person referred to in subparagraph 4 of paragraph 1 and in subparagraph 4 of paragraph 1a, taking into account in particular the education and professional experience, in view of correct performance of duties by such person;
- 3) the form of application for the medicinal product manufacturing authorisation and the form of application for the medicinal product import authorisation, taking into account the documents confirming the data referred to in paragraphs 1 and 1a and the types of document enclosed to the application as well as the type of the medicinal product and the scope of manufacture and import covered by the authorisation;
- 4) the form of application for variation to the medicinal product manufacturing authorisation and the form of application for variation to the medicinal product import authorisation, taking into account the variation data.

Article 40. 1. ⁽²²⁹⁾ The manufacturing authorisation shall include:

- 1) name and address of the manufacturer;
- 2) specification of the manufacturing and control sites;
- 3) type and name of the medicinal product;
- 4) detailed scope of manufacture covered by the authorisation;
- 5) authorisation number and date.

1a. ⁽²³⁰⁾ The import authorisation shall include:

- 1) name and address of the importer;
- 2) specification of the sites of conducting the business activity of import;
- 3) type and name of the medicinal product;
- 4) detailed scope of import covered by the authorisation;
- 5) authorisation number and date.

2. If the authorisation several medicinal products, the names of the medicinal products included in the authorisation may be specified in an appendix to the authorisation.

3. ⁽²³¹⁾ The minister competent for health matters shall establish, by way of a Regulation, the form of medicinal product manufacturing authorisation and the form of the medicinal product import authorisation, taking into account in particular the data defined in paragraphs 1 and 1a.

Article 41. 1. The decision granting or refusing to grant the medicinal product manufacturing authorisation shall not be issued later than 90 days after the date the applicant submitted the application.

2. The time limit referred to in paragraph 1 shall be suspended if the application must be supplemented.

3. The decision on variation to the manufacturing authorisation shall be granted within 30 days of the date the application is submitted; in justified cases, this time limit may be extended, by the maximum of subsequent 60 days; the provision of paragraph 2 shall apply per analogy.

4. ⁽²³²⁾ Fees which shall constitute the revenue of the State budget shall be charged for granting the manufacturing authorisation, for granting the import authorisation, for variation to the manufacturing authorisation and for variation of the import authorisation.

5. ⁽²³³⁾ The minister competent for health matters shall establish, by way of a Regulation, the level and the method of collecting the fees referred to in paragraph 4, taking into account in particular that the fees cannot exceed more than seven times the minimum

wages determined on the basis of the minimum wage regulations, and also shall establish the scope of manufacturing and import.

Article 42. 1. The manufacturer's duties shall include:

- 1) manufacturing only medicinal products covered by the authorisation referred to in Article 38 (1), subject to Article 50;
- 1a) ⁽²³⁴⁾ sale of the manufactured medicinal products:
 - a) to an entrepreneur manufacturing medicinal products or conducting wholesale trade in medicinal products,
 - b) to hospitals and similar institutions as related to medicinal products used at granting healthcare services performed under agreements entered into with the National Health Fund;
- 2) notifying in writing the Main Pharmaceutical Inspector, at least 30 days in advance, on an intended variation to manufacturing conditions, which especially includes forthwith notification on the necessary change of the qualified person;
- 3) storage of retained samples of medicinal products in conditions specified in the authorisation, for not more than one year after the date of expiry of the medicinal product, not for less than three years;
- 4) ⁽²³⁵⁾ making accessible rooms at the manufacturing site, documentation and other manufacturing data to manufacturing inspectors of the Main Pharmaceutical Inspectorate, for the purpose of conducting an inspection, and also enabling them to collect samples of medicinal products for quality tests, including retained samples;
- 5) enabling the qualified person employed with the manufacturing site to make independent decision within the framework of the competencies granted to such a person;
- 6) ⁽²³⁶⁾ applying the Good Manufacturing Practice requirements to medicinal products and using as starting materials intended for manufacturing of medicinal products exclusively the active substances which have been manufactured in accordance with the Good Manufacturing Practice requirements for active substances intended for medicinal product manufacturing;
- 7) ⁽²³⁷⁾ applying the Good Manufacturing Practice requirements to excipients specified in the regulations issued on the basis of paragraph 3.

2. When manufacturing the medicinal product with the use of human blood as the starting product, the manufacturer must:

- 1) take all the necessary measures for the purpose to prevent transmission of infectious diseases;
- 2) comply with the provisions adopted in the Polish Pharmacopoeia or in pharmacopoeias recognised in European Union Member States;
- 3) when selecting and examining blood donors, comply with the guidelines of the Council of Europe and the World Health Organization;
- 4) use only the blood originating from persons whose good health status was confirmed in accordance with separate regulations.

3. ⁽²³⁸⁾ The minister competent for health matters shall establish, by way of a Regulation, the list of excipients to which the Good Manufacturing Practice requirements apply and the scope of application of such requirements, taking into account the European Community legislation.

Article 43. 1. ⁽²³⁹⁾ The Main Pharmaceutical Inspector shall cancel the manufacturing authorisation, by way of a decision, when the manufacturer no longer meets the requirements defined in Article 39 (1) (2) and (3), Article 42 (1) (1) and Article 42 (2) and in the authorisation referred to in Article 40 (1).

2. The authorisation may be cancelled in the case of violation of the provisions of Article 42 (1) (2) – (6).

3. ⁽²⁴⁰⁾ The Main Pharmaceutical Inspector shall cancel the import authorisation, by way of a decision, when the importer no longer meets the requirements defined in Article 39 (1a) (2) and (3), Article 42 (1) (1) and in the authorisation referred to in Article 40 (1a).

4. ⁽²⁴¹⁾ The Main Pharmaceutical Inspector shall notify the minister competent for health matters on manufacturing authorisation cancellation.

Article 44. ⁽²⁴²⁾ (repealed).

Article 45. ⁽²⁴³⁾ (repealed).

Article 46. ⁽²⁴⁴⁾ 1. Notwithstanding the inspections referred to in paragraph 3, the manufacturing pharmaceutical inspector of the Main Pharmaceutical Inspectorate shall verify not less frequently than once every 3 years whether the manufacturer performs the duties arising from the Act; the manufacturing pharmaceutical inspector shall inform the manufacturer on the date and time of inspection commencement at least 30 days before the planned inspection date.

2. A report shall be drawn out on the completed inspection, on the basis of which an opinion shall be issued on meeting by the manufacturer the Good Manufacturing Practice requirements; the report shall be delivered to the manufacturer.

3. Where there are reasonable grounds to suspect manufacturer's deficiencies which may negatively affect the quality, safety of use or efficacy of the medicinal products manufactured by such manufacturer, the Main Pharmaceutical Inspector shall order an ad-hoc inspection of the manufacturing site without prior announcement.

4. Where there are reasonable grounds to suspect deficiencies which may negatively affect the quality or safety of active substances, the Main Pharmaceutical Inspector shall order an ad-hoc inspection of the manufacturer of the active substances or of the MAH.

5. The inspection referred to in paragraph 4 shall be ordered by the Main Pharmaceutical Inspector also upon request of the competent authority of a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, of the European Agency for the Evaluation of Medicinal Products, or of the European Commission.

6. The competent authority of the European Union Member State or the European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, the European Agency for the Evaluation of Medicinal Products or the European Commission may request the Main Pharmaceutical Inspector to conduct an inspection of the manufacturing conditions with a manufacturer of medicinal products or a manufacturer of active substances.

7. The Main Pharmaceutical Inspector may request a manufacturer of medicinal products or manufacturer of active substances established in a country which is not a member of the European Union or a country which is not a member of the European Free Trade Association (EFTA) – party to the Agreement on the European Economic Area to subject itself to the inspection of manufacturing conditions.

8. On the basis of the findings of the inspection referred to in paragraphs 1 and 3, for the purpose of protecting humans and animals against medicinal products not complying with the established requirements of quality, safety of use or efficacy or for the purpose of ensuring that the medicinal products are manufactured in accordance with the Act, the Main Pharmaceutical Inspector may, by way of a decision:

- 1) impose on the manufacturer an order to remedy the deficiencies found in the report within the designated time, failure to perform which may result in cancellation of the authorisation;
- 2) discontinue manufacturing of the medicinal product permanently or until the deficiencies found are remedied.

Article 47. 1. Manufacturer, exporter, or authority competent for granting marketing authorisations in the importer's country may request the Main Pharmaceutical Inspector to

grant an attestation certifying that the manufacturer of the medicinal product holds the manufacturing authorisation for the medicinal product concerned.

2. The attestation referred to in paragraph 1 should be consistent with the forms adopted by the World Health Organization.

3. The following should be enclosed to the request referred to in paragraph 1:

- 1) the Summary of Product Characteristics, if the manufacturer is the MAH;
- 2) ⁽²⁴⁵⁾ explanations of the lack of the marketing authorisation if the manufacturer does not hold it.

Article 47a. ⁽²⁴⁶⁾ 1. The manufacturer may request the Main Pharmaceutical Inspector to conduct an inspection for the purpose of granting the attestation which constitutes the certificate confirming the compliance of the manufacturing conditions with the Good Manufacturing Practice requirements.

2. The manufacturer of active substances may request the Main Pharmaceutical Inspector to conduct an inspection for the purpose of granting the attestation which constitutes the certificate confirming the compliance of the manufacturing conditions with the Good Manufacturing Practice requirements.

3. Within 90 days of the day of completion of the inspection referred to in paragraphs 1 and 2 and in Article 46 (1) and (6), the Main Pharmaceutical Inspector shall issue the attestation referred to in paragraph 1 if the results of the inspection conducted by the manufacturing inspector of the Main Pharmaceutical Inspectorate confirm compliance of manufacturing conditions with the Good Manufacturing Practice requirements.

4. The Main Pharmaceutical Inspector shall provide information on granting or refusal to grant the attestation referred to in paragraph 1 to the European manufacturing database.

5. If as a result of the inspection referred to in paragraphs 1 and 2 and in Article 46 (1) and (6) it is found out that the manufacturer of medicinal products or manufacturer of active substances does not comply with the Good Manufacturing Practice requirements, the Main Pharmaceutical Inspector shall forward such information to the European manufacturing database.

Article 47b. ⁽²⁴⁷⁾ 1. The inspections referred to in Article 46 (6) and Article 47a (1) and (2) shall be conducted at the cost of the medicinal product manufacturer or active substance manufacturer requesting the attestation.

2. The costs of conducting the inspection referred to in Article 46 (6) and Article 47a (1) (2) shall include in particular the costs of travel, accommodation and actions of the manufacturing inspector of the Main Pharmaceutical Inspectorate.

3. The minister competent for health matters shall establish, by way of a Regulation, the amounts and the method of covering the costs of conducting the inspections referred to in Article 10 (5), Article 38 (4), Article 46 (6) and Article 47a (1) and (2), taking in particular into account the labour related to the performance of the action concerned, the level of costs borne by the Main Pharmaceutical Inspectorate and the level of the fee in the European Union Member States having a similar Gross Domestic Product per capita.

Article 47c. ⁽²⁴⁸⁾ 1. The Office President shall keep a register of manufacturers of the active substances used for manufacturing of veterinary medicinal products with anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties.

2. The Register shall include:

- 1) the name and address of the registered office and place of business in the territory of the Republic of Poland, referred to in Article 2 (42a), related to the manufacturing of active substances with anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties;
- 2) the scope of active substance manufacturing activity;
- 3) the trade name and the usual common name of the active substance in Latin and English, and if the usual common name does not exist – one of the following names:

the name in accordance with the European Pharmacopoeia, the Polish Pharmacopoeia, common name or scientific name.

3. The entrepreneur conducting the manufacturing of active substances referred to in paragraph 1 shall be required to submit a request for entry into the register, variation to the register or deletion from the register.

4. The Office President shall make a deletion from the register upon request of the entrepreneur or upon being informed that the entrepreneur has ceased to manufacture the active substances referred to in paragraph 1.

5. The Office President shall charge fees for entry into the register, variation to the register or deletion from the register being made upon request.

6. The entrepreneurs entered in the register must store their documents, in particular invoices, bills and agreements on trade in active substances referred to in paragraph 1, for 3 years.

7. The minister competent for health matters shall establish, by way of a Regulation:

- 1) the register keeping method,
- 2) the procedure for making entries into the register, variations to the register or deletions from the register, and also the procedure for making the register available,
- 3) the form of the request for entry into the register, variation to the register or deletion from the register,
- 4) the level and the method of payment of the fees referred to in paragraph 5, taking into account labour connected with the performance of the specific activity and the level of costs borne by the Registration Office

– taking into account in particular the following data defined in paragraph 2.

Article 48. 1. The qualified person shall be responsible for finding and certifying that:

- 1) for medicinal products manufactured in the territory of the Republic of Poland, each medicinal product batch has been manufactured and controlled in accordance with the legal regulations and with the requirements specified in the marketing authorisation;
- 2) ⁽²⁴⁹⁾ for a medicinal product originating from import, notwithstanding its manufacture in the European Union Member State or the European Free Trade Association (EFTA) Member State – party to the agreement on the European Economic Area – each medicinal product batch has undergone full qualitative or quantitative analysis in the territory of the Republic of Poland, at least with respect to all active substances and underwent other tests and examinations necessary for ensuring the quality of medicinal products in accordance with the requirements specified in the marketing authorisation.

2. ⁽²⁵⁰⁾ The medicinal product batches which have undergone control in one of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, are excluded from the control referred to in subparagraph 2 of paragraph 1 if they are available in the market of one of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area and if the batch release certificate signed by the qualified person was presented.

3. ⁽²⁵¹⁾ In the case of medicinal products imported from other countries with which the European Union made the appropriate arrangements ensuring that the manufacturer of medicinal products meets at least the same Good Manufacturing Practice requirements as the requirements in force in the European Union and that the controls referred to in subparagraph 2 of paragraph 1 have been performed in the exporting country, the qualified person may abstain from conducting such controls.

4. In all cases, and in particular when the medicinal product batch is released to the market, the qualified person must certify that each manufactured batch meets the requirements defined in paragraph 1.

5. The document referred to in paragraph 4 must be kept until one year lapses after the date of expiry of the medicinal product but not shorter than five years and must be made available to the Pharmaceutical Inspection on each demand.

Article 49. Upon request of the Main Pharmaceutical Inspector, the qualified person employed with the manufacturing site may be suspended in the performance of the activities defined in Article 48 (1) if action was brought against such person due to negligence of duties by such person.

Article 50. 1. The MAH or the manufacturer may enter into a contract for medicinal product manufacturing with another manufacturer meeting the requirements defined in the Act, subject to paragraph 2, and shall notify the Main Pharmaceutical Inspector on entry into such a contract.

2. The medicinal product manufacturing contract should be signed in writing, otherwise being null and void, and should define the quality assurance duties of both parties and specify the qualified person responsible for batch release.

3. (repealed).

4. The manufacturer who accepts an order for manufacture of a medicinal product on the basis of a medicinal product manufacturing contract cannot order the manufacture of such products to other sub-contractors without the client's consent granted in writing. The provision of paragraph 1 shall apply per analogy.

Article 51. Receiving the manufacturing authorisation shall not exempt the manufacturer from the penal or third-party liability arising from the use of the medicinal product or of the veterinary medicinal product.

Article 51a. ⁽²⁵²⁾ The provisions of this Chapter shall also apply to medicinal products intended exclusively for export, intermediate products and investigational medicinal products.

Chapter 4

Advertising of Medicinal Products

Article 52. 1. ⁽²⁵³⁾ Medicinal product advertising is an activity of informing on or encouraging to the use of the medicinal product with an aim to increase the number of prescriptions, delivery, sale or consumption of medicinal products.

2. ⁽²⁵⁴⁾ Advertising referred to in paragraph 1 shall include in particular:

- 1) the advertising of medicinal products addressed to the general public;
- 2) the advertising of medicinal products addressed to persons qualified to prescribe them or to persons trading in them;
- 3) visits by medical and sales representatives to persons qualified to prescribe medicinal products or to persons trading in medicinal products;
- 4) the supply of samples of medicinal products;
- 5) sponsorship of promotional meetings for persons qualified to prescribe medicinal products or for persons trading in medicinal products;
- 6) sponsorship of conferences, meetings and scientific congresses for persons qualified to prescribe medicinal products or for persons trading in medicinal products.

3. ⁽²⁵⁵⁾ The following activities shall not be considered advertising of medicinal products:

- 1) information placed on packaging or enclosed to packaging of medicinal products provided that it is in accordance with the marketing authorisation;
- 2) correspondence, accompanied by information materials of non-promotional nature, needed to answer questions about a particular medicinal product;

- 3) announcements of informative nature not addressed to the public, relating, for example, to pack changes, adverse reaction warnings, provided that such announcements do not include any medicinal product claims;
- 4) trade catalogues and price lists, containing exclusively the trade name, the usual common name, the dose, the dosage form and the price of the medicinal product, and in the case of a reimbursable medicinal product, the official retail price, provided that the contents do not include any medicinal product claims, including therapeutic indications;
- 5) information relating to human or animal health or diseases, provided that there is no reference, even indirect, to medicinal products;
- 6) making available the Summary of Product Characteristics or Veterinary Summary of Product Characteristics.
4. ⁽²⁵⁶⁾ (repealed).

Article 53. ⁽²⁵⁷⁾ 1. Medicinal product advertising shall not be misleading, should present the medicinal product objectively and should inform on its reasonable use.

2. Medicinal product advertising shall not involve offering or promising any indirect benefits for purchasing the medicinal product or for delivery of evidence that the medicinal product has been purchased.

3. Medicinal product advertising shall not be addressed to children or contain any element addressed to children.

4. Medicinal product advertising which is a remainder of a full advertisement shall contain, apart from the proprietary name and the usual common name, only the trademark without any references to therapeutic indications, pharmaceutical form, dose, advertising slogans or other advertising contents.

Article 54. ⁽²⁵⁸⁾ 1. Medicinal product advertising addressed to persons qualified to prescribe medicinal products or to persons trading in medicinal products should contain the information consistent with the Summary of Product Characteristics or Veterinary Summary of Product Characteristics and the information on assigning the dispensing category, and in the case of medicinal products entered in the lists of reimbursed drugs, also the information on the official retail price and the maximum amount of supplementary payment made by the patient.

2. The documentation supplied to the persons referred to in paragraph 1 should contain the information which is accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned, and the information on the date of its development or last revision. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works should be faithfully reproduced and the precise sources indicated.

3. Advertising of the medicinal product involving free-of-charge delivery of product samples shall be addressed exclusively to persons qualified to prescribe medicinal products, provided that:

- 1) the person qualified to prescribe medicinal products submitted a written request for the supply of a medicinal product sample to a medical or sales representative;
- 2) the person supplying the sample maintains records of the samples supplied;
- 3) each supplied sample shall not be larger than one smallest medicinal product presentation authorised for marketing in the territory of the Republic of Poland;
- 4) each supplied sample shall be marked "free sample – not for sale";
- 5) each supplied sample shall be accompanied by the Summary of Product Characteristics or Veterinary Summary of Product Characteristics;
- 6) the number of samples of the same medicinal product delivered to the same person shall not exceed five packs per year.

4. The provision of paragraph 3 shall be applicable also to samples supplied to a physician and used in treatment of patients in healthcare establishments referred to in Article 2 (1) (1) of the Act on Healthcare Establishments of 30 August 1991 (Journal of Laws z 2007 No. 14, item 89). These samples must be recorded by the hospital pharmacy referred to in

Article 87 (1) (2), the onsite pharmacy referred to in Article 87 (1) (3) or the hospital pharmacy department referred to in Article 87 (4).

5. Advertising of the medicinal product involving free of charge supply of its samples shall not apply to medicinal products containing narcotic agents or psychotropic substances.

Article 55. (259) 1. The advertising of medicinal products addressed to the general public shall not involve:

- 1) presenting the medicinal product by celebrities, scientists, healthcare professionals or by persons suggested to be healthcare professionals;
- 2) referring to recommendations by celebrities, scientists, healthcare professionals or by persons suggested to be healthcare professionals.

2. Furthermore, the advertising of medicinal products addressed to the general public shall not include contents which:

- 1) suggest that:
 - a) a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail,
 - b) even a healthy person taking the medicinal product can enhance such person's health,
 - c) failure to take the medicinal product may deteriorate the health of the specific person; this reservation shall not apply to vaccines referred to in Article 57 (2),
 - d) the medicinal product is a foodstuff, cosmetic or represents other consumer goods,
 - e) the efficacy or safety of use of the medicinal product arises from its natural origin;
- 2) ensure that taking the medicinal product guarantees the appropriate effect, is unaccompanied by adverse reactions or that the effect is better than or equivalent to, that of another treatment or medicinal product;
- 3) may lead to erroneous self-diagnosis due to giving detailed descriptions of case histories and disease symptoms;
- 4) contain improper, alarming or misleading terms referring to graphically represented pathologies, human body injuries or actions of the medicinal product on the human body or its parts;
- 5) justify the use of the medicinal product by the fact of its marketing authorisation.

Article 56. ⁽²⁶⁰⁾ It shall be prohibited to advertise medicinal products:

- 1) which have not been authorised for marketing in the territory of the Republic of Poland;
- 2) providing the information inconsistent with the Summary of Product Characteristics or Veterinary Summary of Product Characteristics.

Article 57. 1. It shall be prohibited to address to the general public the advertising related to medicinal products:

- 1) dispensed exclusively on the basis of a prescription;
- 2) containing narcotic agents and psychotropic substances;
- 3) entered in the lists of reimbursed drugs in accordance with separate regulations or authorised for dispensing without prescription, if their name is identical with that entered in these lists.

1a. ⁽²⁶¹⁾ The provision of paragraph 1 shall also apply to advertising of the medicinal product whose name is identical with the name of the medicinal product dispensed exclusively on the basis of a prescription.

2. ⁽²⁶²⁾ The provision of paragraph 1 shall not apply to protective vaccines defined in the communication of the of the Chief Sanitary Inspector issued on the basis of Article 14 (9) of the Act of on Infectious Diseases and Infections of 6 September 2001 (Journal of Laws No. 126, item 1384, as amended).

Article 58. 1. It shall be prohibited to address to persons qualified to prescribe medicinal products and to persons trading in medicinal products the advertising of medicinal products

involving the supply, offering or promising of pecuniary advantages, gifts and various types of facilitation, prizes, trips, and organising and financing medicinal product promotional meetings at which hospitality manifestations are not limited to the main purpose of the meeting.

2. It shall be prohibited to accept the advantages and benefits referred to in paragraph 1.

3. ⁽²⁶³⁾ The provisions of paragraphs 1 and 2 shall not apply to giving or accepting the objects of value not exceeding the amount of 100 zlotys, related to medical or pharmaceutical practice, bearing the mark advertising the specific company or medicinal product.

Article 59. ⁽²⁶⁴⁾ The minister competent for health matters, in consultation with the minister competent for agricultural matters with respect to veterinary medicinal products, shall establish, by way of a Regulation:

- 1) the conditions and forms of the advertising of medicinal products addressed to the general public, to persons qualified to prescribe medicinal products and to persons trading in medicinal products,
- 2) the necessary data which are to be contained in the advertising,
- 3) the method of conveying the advertising,
- 4) the documentation constituting the basis for introducing in the territory of the Republic of Poland the samples of medicinal products intended to be delivered within the framework of advertising

– taking into account in particular the duty to present objectively the medicinal product and the safety of its use.

Article 60. 1. Advertising of the medicinal product may be conducted exclusively by the MAH or on order of the MAH.

2. The MAH shall establish within the framework of its business the person whose duties will include informing others on medicinal products marketed by the MAH.

3. The duties of the MAH shall include ensuring that:

- 1) advertising complies with the regulations in force;
- 2) advertising specimens are retained for 2 years after the end of the calendar year in which the advertising was distributed;
- 3) decisions made by the authority referred to in Article 62 (2) are enforced immediately.

4. The MAH shall employ as medical and sales representatives the person who have sufficient scientific knowledge to grant possibly most comprehensive and accurate information on the advertised medicinal product.

5. ⁽²⁶⁵⁾ The provisions of paragraphs 1 – 4 shall apply to the person authorised to parallel import.

Article 61. 1. The MAH shall ensure that such person's medical representatives collect and transfer to such person all information on medicinal products, and especially on adverse reactions to them reported by visited persons.

2. The MAH shall ensure a system of training for such person's medical representatives.

3. ⁽²⁶⁶⁾ In the course of performing the activities described in Article 52 (2) (3), the medical or sales representative must supply or make available Summary of Product Characteristics or Veterinary Summary of Product Characteristics, and in the case of medicinal products entered in the lists of reimbursed drugs – also the information on the official retail price and the maximum amount of supplementary payment made by the patient.

Article 62. 1. The Main Pharmaceutical Inspector, or the Chief Veterinary Officer for veterinary products, shall supervise the compliance with the advertising-related provisions of this Act.

2. ⁽²⁶⁷⁾ The authorities referred to in paragraph 1 may order, by way of a decision:

- 1) cessation of appearance or conduct of medicinal product advertising incompliant with the regulations in force;
 - 2) publication of the issued decision at places where advertising incompliant with the regulations in force appeared and publication of an erratum to erroneous advertising;
 - 3) remedying the deficiencies found.
3. ⁽²⁶⁸⁾ The decisions referred to in paragraph 2 (1) and (3) shall be immediately enforceable.

Article 63. Upon request of the Pharmaceutical Inspection bodies, the MAH must make available:

- 1) the specimen of each advertising addressed to the general public, along with the information on the method and data of its distribution;
- 2) information on each advertising addressed to persons qualified to prescribe medicinal products and to persons supplying medicinal products.

Article 64. The provisions of Articles 62 and 63 shall not prejudice the Act on Counteracting Unfair Competition of 16 April 1993 (Journal of Laws of 2003 No. 153, item 1503).

Chapter 5

Trade in Medicinal Products

Article 65. 1. Trade in medicinal products shall be conducted exclusively upon the rules laid down in this Act.

1a. Trade in medicinal products for the purposes of State reserves shall not be considered trade in medicinal products for the purposes of this Act.

2. Import of samples of the medicinal product by the MAH for advertising purposes shall not be considered trade in medicinal products.

3. The medicinal products referred to in paragraph 4 may be traded provided that they have undergone initial batch control at the cost of the MAH.

4. ⁽²⁶⁹⁾ The following shall undergo initial batch control:

- 1) immunological medicinal products for human use which constitute:
 - a) live vaccines,
 - b) vaccines intended for neonates or other groups at risk,
 - c) vaccines used in public health immunisation programmes,
 - d) new immunological medicinal products or immunological medicinal products manufactured using new or altered kinds of technology or new for a particular manufacturer, during a period specified in the marketing authorisation;
- 2) veterinary immunological medicinal products;
- 3) blood-derived products;
- 4) raw materials used for preparing magistral or officinal formulas, before their distribution for this purpose.

5. Research and development units and drug quality control laboratories shall perform the initial batch control referred to in paragraph 4.

6. ⁽²⁷⁰⁾ The Main Pharmaceutical Inspector may request a manufacturer of an immunological medicinal product to present quality control certificates for each batch, attested by the person referred to in Article 39 (1) (4).

7. ⁽²⁷¹⁾ Research and development units authorised to conduct the initial batch control shall exempt from the initial batch control the specific batch of the medicinal product referred to in subparagraphs 1 – 3 of paragraph 4 if such batch was submitted to such control by the competent authorities in one of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area and if the document confirming such tests was issued.

8. ⁽²⁷²⁾ (repealed).

9. ⁽²⁷³⁾ The time limit for the initial batch control for the products referred to in subparagraphs 1 – 3 of paragraph 4 shall be 60 days and for the products referred to in subparagraphs 4 of paragraph 4 shall be 30 days.

10. The minister competent for health matters, in consultation with the minister competent for agricultural matters with respect to veterinary medicinal products, shall establish, by way of a Regulation:

- 1) conditions of and procedure for performing the initial batch control, taking into account in particular the number of samples collected for testing, specification of the documents necessary for reporting batch control, the method of transferring samples for testing;
- 2) ⁽²⁷⁴⁾ the research and development units and drug quality control laboratories for testing the medicinal products referred to in subparagraphs 1 – 3 of paragraph 4 and in 7, taking into account in particular complying by these establishments with Good Laboratory Practice rules within the meaning of the Act on Chemical Substances and Preparations of 11 January 2001;
- 2a) ⁽²⁷⁵⁾ drug quality control laboratories specialised in testing the products referred to in subparagraph 4 of paragraph 4, taking into account in particular complying by these establishments with Good Laboratory Practice within the meaning of Act on Chemical Substances and Preparations of 11 January 2001;
- 3) the form of the certificate issued by the units referred to in subparagraph 2.

Article 66. Medicinal products shall be traded exclusively until the expiry date established for them.

Article 67. 1. It shall be prohibited to trade in and use medicinal products incompliant with the established quality requirements and medicinal products which have expired.

2. ⁽²⁷⁶⁾ The medicinal products referred to in paragraph 1 shall be destroyed, subject to Article 122 (1) (2).

3. The cost of destruction of the medicinal product which does not meet the quality requirements shall be borne by the person specified in the decision issued on the basis of Article 122, and for medicinal products which have expired such cost shall be borne by the person on whose premises the cause of the necessity of market recall of the medicinal product arose.

Article 68. 1. Retail trade in medicinal products shall be conducted in generally accessible pharmacies, subject to the provisions of paragraph 2, Article 70 (1) and Article 71 (1).

2. ⁽²⁷⁷⁾ Retail trade in veterinary medicinal products purchased in pharmaceutical wholesale store of veterinary medicinal products shall be conducted within the framework of the business of the animal treatment centre.

2a. ⁽²⁷⁸⁾ The manager of the animal treatment centre or the veterinarian designated by such manager shall be responsible for the trade referred to in paragraph 2.

3. ⁽²⁷⁹⁾ It shall be permissible to conduct mail order sale of medicinal products dispensed without physician's prescription by generally accessible pharmacies and pharmacy outlets.

3a. ⁽²⁸⁰⁾ The minister competent for health matters shall establish, by way of a Regulation, the conditions mail order sale of medicinal products dispensed without physician's prescription and the method of delivery of such products to the recipients, so as to ensure the appropriate quality of such products.

4. Direct use of medicinal products and of medicinal products included in shock treatment kits, when the necessity of their use arises from the type of health service provided, in the patient by a physician, *dentist* ⁽²⁸¹⁾ or another healthcare professional, shall not be considered retail trade.

4a. ⁽²⁸²⁾ Direct use of veterinary medicinal products and of medicinal products the necessity of use of which arises from the type of the therapeutic veterinary service provided, in an animal by a veterinarian, shall not be considered retail trade.

5. Import of not more than five smallest packs of medicinal product for the patient's own therapeutic purposes shall not require consent of the minister competent for health matters.

6. ⁽²⁸³⁾ The provisions of paragraph 5 shall not apply to narcotic agents and psychotropic substances whose import is governed by the provisions of the Act on Drug Prevention of 29 July 2005 (Journal of Laws No. 179, item 1485, z 2006 No. 66, item 469 and No. 120, item 826 and of 2007 No. 7, item 48), and of veterinary medicinal products intended for animals whose tissues or products are intended for human consumption.

7. The minister competent for health matters shall establish, by way of a Regulation:

- 1) the list of medicinal products which may be supplied ad hoc in connection with the provided healthcare service, taking into account the type of such healthcare service;
- 2) the list of medicinal products in life-saving shock treatment kits.

Article 69. ⁽²⁸⁴⁾ 1. The veterinarian who provides therapeutic veterinary services at an animal treatment centre must:

- 1) keep the documentation on each transaction in veterinary medicinal products dispensed on prescription, in the form of:
 - a) retail trade documentation,
 - b) therapeutic veterinary documentation as defined in the provisions of the Act on Animal Health Protection and Infectious Disease Management of 11 March 2004 (Journal of Laws No. 69, item 625, as amended);
- 2) conducting at least once per year a check inventory of veterinary medicinal products in stock, recording all the inconsistencies.

2. The veterinarian shall use medicinal products for the purpose of saving life or health of animals, and in particular for the purpose of alleviating animal suffering.

3. If animal tissues and products are intended for human consumption, the owners of such animals or persons responsible for such animals must possess the documentation in the form of the records of purchase, possession and use of veterinary medicinal products and treatment of animals conducted in accordance with the provisions of the Act on Animal Health Protection and Infectious Disease Management of 11 March 2004.

4. The documentation referred to in paragraphs 1 and 3 shall be kept by the veterinarian, animal holder and the person responsible for animals for 5 years after the date of its development.

5. The minister competent for agricultural matters shall establish, by way of a Regulation, the method of keeping the documentation of retail trade in veterinary medicinal products and the model form of such documentation, so as to ensure uniformity of such documentation and protection of health of humans or animals or protection of environment, and also the respective legislation of the European Community.

6. In consultation with the minister competent for agricultural matters, the minister competent for health matters shall establish, by way of a Regulation, the procedure for using medicinal products where there is no appropriate veterinary medicinal product authorised for marketing for the animal species concerned, taking into account in particular the necessity to ensure that the food obtained from the treated animals does not contain residues harmful for the consumer.

Article 70. 1. Apart from pharmacies, retail trade in medicinal products may be conducted by pharmacy outlets, subject to Article 71 (1) and (3) (2).

2. The points referred to in paragraph 1 may be managed by a natural person, legal person and a company without legal personality.

2a. At a pharmacy outlet there should be an appointed person responsible for managing such an outlet, who shall be the manager of the pharmacy outlet.

2b. A pharmacist with one year's experience in this profession or a pharmacy technician with three years' experience in generally accessible pharmacies can be the manager of the pharmacy outlet.

3. ⁽²⁸⁵⁾ Pharmacy outlets created after the date of entry into effect of this Act can be situated exclusively in rural areas if there is no generally accessible pharmacy run in the given village.

4. Operation of pharmacy outlets shall require an authorisation. The regulations of Article 99 (2) and (3), Article 100 (1) – (3), Articles 101 – 104 and Article 107 shall apply per analogy.

5. ⁽²⁸⁶⁾ The regulations concerning pharmacies shall apply per analogy to the storage and keeping the documentation of the purchased and sold medicinal products and the method and procedure for conducting the inspections of accepting medicinal products and the conditions and procedure for reporting the turnover and status of possession of individual medicinal products.

6. ⁽²⁸⁷⁾ Fees which shall constitute the revenue of the State budget shall be charged for granting an authorisation for operation of a pharmacy outlet and for variation to the authorisation for operation of a pharmacy outlet.

7. ⁽²⁸⁸⁾ The minister competent for health matters shall establish, by way of a Regulation, the level of the fees referred to in paragraph 6, taking into account in particular the type of conducted business activity, and such fees cannot exceed more than twice the minimum wages determined on the basis of the minimum wage regulations.

Article 71. 1. ⁽²⁸⁹⁾ Apart from pharmacies and pharmacy outlets the retail trade in medicinal products issued without a physician's prescription, except for of veterinary medicinal products, may be conducted by:

- 1) herbal medicine stores,
- 2) specialised stores with medical supplies,
- 3) generally accessible stores

– hereinafter referred to as "points of out-of-pharmacy sale".

1a. ⁽²⁹⁰⁾ The entrepreneurs may conduct retail trade in veterinary medicinal products dispensed without physician's prescription outside animal treatment centres upon reporting such activity to the Voivodeship Veterinary Officer 7 days before its commencement.

2. The stores referred to in subparagraph 1 of paragraph 1 may be operated only by a pharmacist, a pharmacy technician, a graduate of the second-degree course in herbal commodity science or by entrepreneurs employing the above-listed persons as managers of such stores.

3. ⁽²⁹¹⁾ The minister competent for health matters shall establish, by way of a Regulation:

- 1) the criteria of determining eligibility of medicinal products to the lists referred to in subparagraph 2,
- 2) the lists of medicinal products which can be authorised for marketing at points of out-of-pharmacy sale and pharmacy outlets,
- 3) the qualifications of persons dispensing medicinal products at points of out-of-pharmacy sale,
- 4) the requirements which should be met by the premises and facilities of points of out-of-pharmacy sale and pharmacy outlet referred to in Article 70

– taking into account safety of use of medicinal products and requirements for the storage and distribution of medicinal products at these points of sale.

4. ⁽²⁹²⁾ The minister competent for agricultural matters shall establish, by way of a Regulation:

- 1) the criteria of enrolment of veterinary medicinal products to the list referred to in subparagraph 2,
- 2) the list of veterinary medicinal products which may be traded by the persons referred to in paragraph 1a,
- 3) the conditions which should be met by the persons referred to in paragraph 1a

– so as to ensure the safety of retail trade in veterinary medicinal products and hygienic and taking into account the sanitary conditions, and in particular so as to ensure proper separation of such products from the remaining products and proper storage.

5. ⁽²⁹³⁾ The lists referred to in subparagraph 2 of paragraph 3 and in subparagraph 2 of paragraph 4 shall be updated every 12 months.

Article 72. 1. ⁽²⁹⁴⁾ Subject to paragraph 8 (2), wholesale trade in medicinal products can be carried out solely by pharmaceutical wholesale stores as well as by bonded and consignment warehouses of medicinal products.

2. The respective provisions concerning a pharmaceutical wholesale store shall apply to bonded and consignment warehouses of medicinal products per analogy.

3. ⁽²⁹⁵⁾ Wholesale trade shall mean all activities of procurement, storage, delivery or export of medicinal products or of veterinary medicinal products, holding marketing authorisation issued in a European Union Member State or a European Free Trade Association (EFTA) Member State – party to the agreement on the European Economic Area or the authorisation referred to in Article 3 (2), conducted with manufacturers or importers with respect to the medicinal products manufactured or imported by them, or with wholesale traders, or with pharmacies or animal treatment centres, or with other authorised persons, except for direct supplies to the public.

3a. ⁽²⁹⁶⁾ A medicinal product shall be introduced into wholesale trade in the territory of the Republic of Poland only upon prior notification of:

- 1) the MAH on the intended import of the medicinal product;
- 2) the Office President.

4. ⁽²⁹⁷⁾ Wholesale trade within the meaning of paragraph 3 shall include export of medicinal products from the territory of the Republic of Poland and import of medicinal products from the territory of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area.

5. Pharmaceutical wholesale stores may also carry out wholesale trade in:

- 1) medical devices,
- 1a) ⁽²⁹⁸⁾ medicinal products intended exclusively for export, holding marketing authorisation other than defined in paragraph 3;
- 2) ⁽²⁹⁹⁾ feedingstuffs intended for particular nutritional purposes,
- 2a) ⁽³⁰⁰⁾ food supplements within the meaning of the regulations on the safety of food and nutrition,
- 3) cosmetics within the meaning of Article 2 of the Act on Cosmetics of 30 March 2001 (Journal of Laws No. 42, item 473 and of 2003 No. 73, item 659, No. 189, item 1852 and No. 208, item 2019), except for the cosmetics intended for perfuming and beauty cosmetic products,
- 4) hygiene articles,
- 5) articles intended for the care of infants and patients,
- 6) foodstuffs containing pharmacopoeial natural plant-derived ingredients,
- 7) disinfectants used in medicine

– complying with the requirements laid down in separate regulations.

6. Pharmaceutical wholesale stores may carry out wholesale trade in technical supplies useful in the work of hospitals, pharmacies, and institutions referred to in Articles 70 and 71.

7. ⁽³⁰¹⁾ Pharmaceutical wholesale stores of veterinary medicinal products may also carry out wholesale trade in:

- 1) feedingstuffs, feedingstuff supplements, premixes;
- 2) hygiene articles;
- 3) biocides;
- 4) devices used in veterinary medicine within the meaning of Article 2 (2) of the Act on devices used in veterinary medicine of 20 April 2004 (Journal of Laws No. 93, item 893);
- 5) printed forms used in veterinary medicine;
- 6) devices used for identification of domestic animals within the meaning of Article 4 (22) of the Act on Feedingstuffs of 22 July 2006 (Journal of Laws No. 144, item 1045).

8. The following shall not be considered wholesale trade:

- 1) (repealed);
- 2) accepting and dispensing, including importing and exporting, medicinal products and medical devices intended for humanitarian aid except for narcotic agents and psychotropic substances and products containing precursors of group I-R, if the recipient consents to accept them – provided that such products meet the requirements defined in separate regulations.
- 3) acceptance, storage and issue by sanitary and epidemiological stations of vaccines purchased under the Protective Vaccination Programme

9. The minister competent for health matters shall establish, by way of a Regulation, the requirements which should be met by medicinal products used in humanitarian aid and the detailed procedures for accepting and dispensing medicinal products intended for humanitarian aid.

Article 73. ⁽³⁰²⁾ (repealed).

Chapter 6

Pharmaceutical Wholesale Stores

Article 74. 1. Taking up business activity of operating a pharmaceutical wholesale store shall require obtaining an authorisation of the Main Pharmaceutical Inspector.

2. The authorisation shall be granted, refused to be granted, subjected to variations and cancelled by way of a decision issued by the Main Pharmaceutical Inspector, subject to paragraph 3 and 4.

3. ⁽³⁰³⁾ The authorisation for operation of a pharmaceutical wholesale store selling veterinary medicinal products shall be granted, refused to be granted, subjected to variations and cancelled by way of a decision issued by the Chief Veterinary Officer. The provisions of Article 75, 76, 77 (1) and Article 78 (1) shall apply per analogy.

4. The Chief Veterinary Officer shall notify the Main Pharmaceutical Inspector on issuing the decision in matters referred to in paragraph 3.

5. Carrying out wholesale trade in narcotic agents, psychotropic substances and precursors of group I-R shall require an additional authorisation defined in separate regulations.

6. A fee shall be charged for granting an authorisation for operating a pharmaceutical wholesale store and pharmaceutical wholesale store selling veterinary medicinal products.

6a. ⁽³⁰⁴⁾ A fee of half of the amount referred to in paragraph 6 shall be charged for a variation to the authorisation or its renewal if the authorisation has been issued for a limited time.

6b. ⁽³⁰⁵⁾ The fees referred to in paragraphs 6 and 6a shall constitute the revenue of the State budget.

7. ⁽³⁰⁶⁾ The minister competent for health matters, or the minister competent for agricultural matters with respect to veterinary medicinal products, shall establish, by way of a Regulation, the level of the fee referred to in paragraph 6, taking into account in particular the type of conducted business activity, and this fee cannot exceed more than seven times the minimum wages determined on the basis of the minimum wage regulations.

Article 75. 1. The application for granting the authorisation for operating a pharmaceutical wholesale store, hereinafter referred to as "the application", should contain:

- 1) name of the entrepreneur applying for the authorisation;
- 2) registered office and address of the entrepreneur;
- 3) specification of types of medicinal products to be traded when the range of products is to be limited;

- 4) specification of the place and premises intended for operating a pharmaceutical wholesale store;
- 5) specification of additional reloading chambers referred to in Article 76, located outside the place where pharmaceutical wholesale store is to be operated, if any;
- 6) date of taking up the intended activity;
- 7) date of developing the application and signature of the person submitting the application.

2. The following should be enclosed to the application:

- 1) excerpt from the register in accordance with separate regulations;
- 2) ⁽³⁰⁷⁾ legal title to the wholesale store premises or reloading chambers;
- 3) ⁽³⁰⁸⁾ layout and technical description of the wholesale store premises, subject to subparagraph 5 of paragraph 1, developed by a person authorised for their development;
- 4) authenticated copies of documents certifying the competencies of the qualified person responsible for operating the wholesale store and declaration of such person that he or she will take up such duties;
- 5) description of the procedures making it possible to effectively suspend the trade in a medicinal product or recall a medicinal product from the market and from hospital pharmacies;
- 6) ⁽³⁰⁹⁾ opinion of the Voivodeship Pharmaceutical Inspector on suitability of the premises intended for the wholesale store and in the case of a wholesale store selling veterinary medicinal products, an opinion of the Voivodeship Veterinary Officer;
- 7) ⁽³¹⁰⁾ opinion of the State Sanitary Inspection on the premises in accordance with separate regulations.

3. If the entrepreneur intends to operate a wholesale store in two or locations, a separate application must be submitted for each business location.

4. The application referred to in paragraph 1 must be submitted by the entrepreneur to the Main Pharmaceutical Inspector, and in the case of a pharmaceutical wholesale store selling veterinary medicinal products – to the Chief Veterinary Officer.

Article 76. 1. The authorisation for operating a pharmaceutical wholesale store should contain:

- 1) name and registered office of the entrepreneur;
- 2) name of the pharmaceutical wholesale, if any;
- 3) authorisation number;
- 4) location of operation of the pharmaceutical wholesale store;
- 5) specification of additional reloading chambers, if any;
- 6) period of validity of the authorisation, if limited;
- 7) basic conditions of operating the pharmaceutical wholesale store and duties incumbent upon the entrepreneur in connection with operation of a pharmaceutical wholesale store;
- 8) specification of the types of medicinal products to trade in which the wholesale store is authorised, if the range of products is limited.

2. An authorisation for operating a wholesale store shall be granted for an unlimited time, unless the applicant applied for an authorisation for a limited time.

3. A reloading chamber is an element of the transport system of the wholesale store and may be located outside the wholesale store site. To the medicinal products contained in the reloading chambers, the respective transport documentation has to be enclosed, including the documentation of time of delivery of such products to the chamber.

4. The rooms of the reloading chamber shall have to comply with the technical conditions for pharmaceutical wholesale store premises, which shall be confirmed in a decision of the Voivodeship Pharmaceutical Inspector in whose area the reloading chamber is located.

5. Reloading chambers located outside the location of pharmaceutical wholesale operation may be used by the entrepreneur having the authorisation for operating a

pharmaceutical wholesale store for temporary storage of medicinal product for not longer than 36 hours, exclusively in closed transport packages or in collective packages of the manufacturer, in the conditions established for the medicinal products concerned.

6. ⁽³¹¹⁾ (repealed).

Article 76a. ⁽³¹²⁾ 1. Putting into operation a reloading chamber shall require a variation to the authorisation for operating a pharmaceutical wholesale store.

2. The request for variation to the authorisation referred to in paragraph 1 shall include the data contained in Article 75 (1) (1), (2), (5) and (7).

3. The following shall be enclosed to the application:

- 1) legal title to reloading chamber rooms;
- 2) layout and technical description of reloading chamber rooms, developed by a person authorised for their development;
- 3) the decision referred to in Article 76 (4).

Article 77. 1. The entrepreneur taking up business of operating a pharmaceutical wholesale store should:

- 1) have at such entrepreneur's disposal the facilities making it possible to correctly carry out wholesale trade;
- 2) employ a qualified person – wholesale store manager – responsible for managing the wholesale store, complying with the requirements defined in Article 84;
- 3) perform the duties defined in Article 78.

2. The provision of subparagraph 2 of paragraph 1 shall not be applicable if business activity is taken up by a master sciences in pharmacy meeting the requirements referred to in Article 84, who performs the manager function personally.

Article 78. 1. The duties of the entrepreneur carrying out the business of operating a pharmaceutical wholesale store include:

- 1) ⁽³¹³⁾ purchase of medicinal products exclusively from an entrepreneur carrying out manufacturing business or conducting wholesale trade;
- 2) possession of only medicinal products obtained from persons authorised to supply such products;
- 3) delivering of medicinal products exclusively to authorised persons;
- 4) complying with the Good Distribution Practice;
- 5) ensuring constant supplies of the appropriate range of products;
- 6) ⁽³¹⁴⁾ submitting to the minister competent for health matters, and in the case of veterinary medicinal products to the minister competent for agricultural matters, quarterly reports on the volume of sales of medicinal products, along with the structure of such sales;
- 7) ⁽³¹⁵⁾ storage documents referred to in subparagraph 6, for 5 years counting from the end of the specific calendar year.

2. The minister competent for health matters shall establish, by way of a Regulation, the list of entities authorised to purchase medicinal products in pharmaceutical wholesale stores, and the minister competent for agricultural matters shall establish, by way of a Regulation, the list entities authorised to purchase veterinary medicinal products in pharmaceutical wholesale stores selling veterinary medicinal products, taking into account in particular the scope of the business operated by individual entities.

3. The minister competent for health matters shall establish, by way of a Regulation, the method and scope of submitting the data referred to in subparagraph 6 of paragraph 1, protecting the trade secret and taking into account in particular the structure of trade in medicinal products forwarded to outpatient treatment centres and healthcare establishments and the method of product identification.

4. ⁽³¹⁶⁾ Minister competent for agricultural matters shall establish, by way of a Regulation, the scope of data referred to in subparagraph 6 of paragraph 1 and the method of their forwarding, ensuring that the trade secret will be kept and taking into account in

particular the structure of trade in veterinary medicinal products forwarded to animal treatment centres and the method of product identification.

Article 79. The minister competent for health matters, in consultation with the minister competent for agricultural matters with respect to pharmaceutical wholesale store selling veterinary medicinal products, shall establish, by way of a Regulation, the Good Distribution Practice procedures, taking into account in particular:

- 1) the rules of medicinal product storage upon the conditions defined in the marketing authorisation;
- 2) maintenance of appropriate technical and sanitary condition of the premises;
- 3) the rules and procedure for accepting and dispensing of medicinal products;
- 4) transport and loading conditions;
- 5) the procedures of correct wholesale store operation, including the activities performed by the employee who accepts and dispenses the goods, and the rules and procedure for drawing up the acceptance certificate;
- 6) the method of appointing a substitute person for the qualified person responsible for wholesale store operation within the scope of duties referred to in Article 85.

Article 80. 1. The Main Pharmaceutical Inspector shall refuse to grant the authorisation for operating a pharmaceutical wholesale store:

- 1) when the applicant does not meet the conditions for operating a wholesale store laid down in Article 77-79;
- 2) when the applicant's authorisation for operating a pharmacy or pharmaceutical wholesale store was cancelled not earlier than three years before application submittal;
- 3) when the applicant operates or submitted an application for issuing an authorisation for operating a pharmacy.

2. The Chief Veterinary Officer shall issue the decisions referred to in paragraph 1 in the case of wholesale stores selling veterinary medicinal products.

Article 81. 1. ⁽³¹⁷⁾ The Main Pharmaceutical Inspector, or the Chief Veterinary Officer in the case of wholesale stores selling veterinary medicinal products, shall cancel the authorisation for operating a pharmaceutical wholesale store if the entrepreneur carries out trade in medicinal products not authorised to be placed on the market.

2. The Main Pharmaceutical Inspector, or the Chief Veterinary Officer in the case of wholesale stores selling veterinary medicinal products, may cancel the authorisation, in particular when:

- 1) despite prior notification, the entrepreneur makes impossible or difficult for the Pharmaceutical Inspection to carry out its official activities;
- 2) the entrepreneur stores medicinal products inconsistently with the marketing authorisation terms;
- 3) the entrepreneur did not put the wholesale store into operation within 4 months of the date when the authorisation was obtained or does not carry out the business covered by the authorisation for a period of at least six months.

3. The authorisation for operating a pharmaceutical wholesale store shall expire:

- 1) in the case of death of the person for whom the authorisation was granted;
- 2) if the company is deleted from the register kept in accordance with separate regulations.

4. Cancellation or finding expiration shall take place by way of a decision of the authority which has issued the authorisation for operating a wholesale store.

5. ⁽³¹⁸⁾ If the Main Pharmaceutical Inspector considers that the circumstances referred to in paragraph 2 or 3 occur with respect to an entrepreneur holding an authorisation for wholesale trade issued by the competent authority of another European Union Member State or European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area, the Main Pharmaceutical Inspector shall notify forthwith on this

fact and on the decisions made the European Commission and the competent authority of another European Union Member State or European Free Trade Association (EFTA) Member State – party to the Agreement on the European Economic Area.

Article 82. ⁽³¹⁹⁾ The Main Pharmaceutical Inspector shall notify the following on cancellation of the authorisation for operating a pharmaceutical wholesale store:

- 1) the competent customs authorities;
- 2) the competent authorities of European Union Member States and European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area.

2. The Main Pharmaceutical Inspector shall notify competent customs authorities on expiry of the authorisation for operating a pharmaceutical wholesale store.

3. The Chief Veterinary Officer shall notify competent customs authorities on cancellation or expiry of an authorisation for operating a pharmaceutical wholesale store selling veterinary medicinal products.

Article 83. 1. The Main Pharmaceutical Inspector, or the Chief Veterinary Officer in the case of wholesale stores selling veterinary medicinal products, shall keep a register of authorisations for operating a pharmaceutical wholesale store.

2. The register referred to in paragraph 1 should contain the data referred to in Article 76 (1) (1) – (6) and (8).

3. Granting, making variations to, cancellation or expiry of an authorisation shall require appropriate amendments to the register referred to in paragraph 1.

Article 84. 1. A pharmacist with two years' experience in working in a pharmaceutical wholesale store or in a pharmacy can be the qualified person referred to in Article 77 (1) (2), subject to paragraphs 2 – 4.

2. ⁽³²⁰⁾ Moreover, also a veterinarian holding the professional licence and with two years of experience in veterinarian's profession can be a qualified person in a wholesale store selling veterinary medicinal products, provided that this is such person's only place of work as a veterinarian and that such person is not an owner or co-owner of the animal treatment centre or does not operate a centre of rehabilitation for animals within the meaning of the provisions of the Act on Nature Protection of 16 April 2004 (Journal of Laws No. 92, item 880 and z 2005 No. 113, item 954 and No. 130, item 1087).

3. Also a person holding the secondary school leaving examination certificate and appropriately trained in occupational safety and health can be a qualified person responsible for operating a pharmaceutical wholesale store which trades exclusively in medical gases,.

4. It shall be prohibited for a single person to be a qualified person responsible for operating a pharmaceutical wholesale store and to perform at the same time the pharmacy manager function.

5. It shall be possible to be a qualified person responsible for operating a pharmaceutical wholesale store only in one pharmaceutical wholesale store.

Article 85. The duties of a qualified person responsible for managing a pharmaceutical wholesale store shall include complying with the rules of Good Distribution Practice, and especially dispensing medicinal products to authorised entities, and additionally:

- 1) ⁽³²¹⁾ providing to Pharmaceutical Inspection authorities, and in the case of the veterinary medicinal product also to the competent Voivodeship Veterinary Officer, the information on suspecting or finding that the medicinal product concerned does not comply with the quality requirements established for it;
- 2) suspending the trade in and recalling from the market and withdrawing from use medicinal products, having received the respective decision of the competent authority;
- 3) (repealed);

- 4) ensuring appropriate training for the personnel within the scope of duties incumbent upon such personnel.

Chapter 7

Pharmacies

Article 86. 1. A pharmacy shall be a public healthcare institution in which authorised persons provide in particular pharmaceutical services referred to in paragraph 2.

2. The name of pharmacy shall be reserved exclusively for the place of provision of pharmaceutical services including:

- 1) dispensing medicinal products and medical devices defined in separate regulations;
- 2) preparation of magistral formulas within not less than 48 hours of submittal of the prescription by the patient, and in the case of a prescription for a magistral formula containing narcotic agents or marked “dispense immediately” – within 4 hours;
- 3) preparation of officinal formulas;
- 4) granting information on medicinal products and medical devices.

3. In the case of hospital pharmacies, a pharmaceutical service shall be also:

- 1) preparation of drugs for parenteral nutrition;
- 2) preparation of drugs for enteral nutrition;
- 3) preparation of drugs in daily doses, including cytotoxic drugs;
- 4) manufacturing infusion fluids;
- 5) arranging hospital supplies in medicinal products and medical devices;
- 6) preparation of solutions for haemodialysis and peritoneal dialysis;
- 7) participation in monitoring of adverse reactions to drugs;
- 8) participation in clinical trials conducted in a hospital;
- 9) participation in pharmacotherapy rationalisation;
- 10) participation in the management of medicinal products and medical devices in a hospital.

4. In hospital pharmacies, apart from pharmaceutical service provision:

- 1) records of samples for clinical trials and donated medicinal products and medical devices shall be kept;
- 2) procedures for dispensing medicinal products or medical devices by the hospital pharmacy to hospital wards and to patients shall be established.

5. Medicinal products or magistral formulas intended for humans which will be used in animals may be dispensed in generally accessible pharmacies on the basis of a veterinarian’s prescription.

6. (repealed).

7. (repealed).

8. The products defined in Article 72 (5), having legally required attestations and authorisations, may be sold at dedicated counters in generally accessible pharmacies, provided that their storage and sale will not interfere with the core operation of the pharmacy.

9. The minister competent for health matters may establish, by way of a Regulation, other types of activities than those defined in paragraphs 2 – 4 and 8, related to healthcare, permissible to be conducted in a pharmacy.

Article 87. 1. Pharmacies shall be classified in the following categories:

- 1) generally accessible pharmacies;
- 2) hospital pharmacies, supplying hospital wards or other establishments not identified by their name, designed for persons whose health status requires 24-hour or whole-day health services provided in such establishment or in an organisational unit of the establishment;
- 3) onsite pharmacies, supplying, in healthcare establishments set up by the Minister of National Defence and the Minister of Justice, doctor surgeries, laboratories, infirmaries, and therapeutic wards, and other establishments not identified by their

name, designed for persons whose health status requires 24-hour or whole-day health services provided in such establishment or in an organisational unit of the establishment.

2. The purposes of operation of generally accessible pharmacies shall include:

- 1) supplying the public in medicinal products, officinal formulas, magistral formulas, medical devices and other articles referred to in Article 86 (8);
- 2) performing the activities defined in Article 86 (1) and (2).

3. The Voivodeship Pharmaceutical Inspector may exempt the entities referred to in subparagraph 2 of paragraph 1 from the duty of operating a hospital pharmacy, taking into account:

- 1) the type of services provided;
- 2) the number of beds and their occupation.

4. The function of a hospital pharmacy in entities referred to in paragraph 3 shall be performed by the hospital pharmacy department responsible for performance of the tasks defined in Article 86 (2) (1) and (4), Article 86 (3) (5), (7), (9) and (10) and Article 86 (4).

Article 88. 1. In a generally accessible pharmacy, a pharmacist referred to in Article 2b (1) (1), (2) and (5) – (7) of the Act on Chambers of Pharmacists of 19 April 1991 (Journal of Laws of 2003 No. 9, item 108), responsible for pharmacy operation, hereinafter referred to as "the pharmacy manager" shall be appointed; a single person may be a manager of only one pharmacy.

2. ⁽³²²⁾ A pharmacy manager may be a pharmacist referred to in paragraph 1, who is not older than 65 years and has worked in a pharmacy for at least 5 years or has worked in a pharmacy for at least 3 years, in the case when such person has specialised in retail pharmacy.

2a. ⁽³²³⁾ (repealed).

3. Provided that the respective consent is obtained from the Voivodeship Pharmaceutical Inspector, issued upon request of the person concerned, after prior consultation with the District Pharmacists' Chamber, the period discussed in paragraph 2 may be prolonged to 70 years of age to a person who turned 65 years of age.

4. The pharmacy manager shall appoint for the time of his or her absence resulting from illness or leave, a pharmacist referred to in paragraph 1, who will replace him or her as provided for in Article 95 (4) (5).

5. The pharmacy manager's duties include:

- 1) organisation of work in the pharmacy which includes , acceptance, dispensing, storage and identification of medicinal products and medical devices, correct preparation of magistral formulas and officinal formulas, and granting information about drugs;
- 2) supervision of on-the-job training for students and pharmaceutical technicians;
- 3) reporting information on an adverse reaction to a medicinal product or medical device to the Office President;
- 4) notifying to Pharmaceutical Inspection bodies suspected or confirmed non-compliance of a specific medicinal product with the quality requirements established for such product;
- 5) ⁽³²⁴⁾ purchase of medicinal products exclusively from entities holding the authorisation for operating a pharmaceutical wholesale store and for their dispensing in accordance with Article 96;
- 6) keeping the records of the persons referred to in Article 90, employed in the pharmacy;
- 7) transferring to the District Chambers of Pharmacists the data necessary for keeping the register of pharmacists envisaged by the Act on Chambers of Pharmacists;
- 8) suspending the trade in or recalling from the market and withdrawing from use medicinal products after the respective decision of the competent authority is received.

6. The minister competent for health matters shall establish, by way of a Regulation, the form of the records of the persons referred to in paragraph 5, including for example the following data:

- 1) forenames and surnames of the Master of Sciences in Pharmacy or pharmaceutical technician;
- 2) the date and place of birth of the Master of Sciences in Pharmacy or pharmaceutical technician;
- 3) the number and date of the diploma (certificate) of university (school) graduation by the Master of Sciences in Pharmacy or pharmaceutical technician and the name of the university or school that issued the diploma (certificate);
- 4) the number and date of issue of the attestation of the right to exercise the profession of a pharmacist;
- 5) the number and date of issue of the certificate attesting that the pharmacist completed one-year on-the-job training;
- 6) the number and date of issue of the certificate attesting that the Master of Sciences in Pharmacy has a specialisation degree;
- 7) date and signature of the pharmacy manager.

Article 89. 1. Within the framework of postgraduate education, the pharmacist shall obtain the specialist title confirming the possession of the specific professional qualifications upon completion of specialisation training, hereinafter referred to as "the specialisation", defined in the specialisation curriculum, and upon passing the State examination.

2. Specialisation may be taken up, subject to paragraph 3, by a person who meets all the following conditions:

- 1) holds the professional licence for exercising the pharmacist's profession;
- 2) has been exercising his or her profession for at least one year;
- 3) has been qualified for specialisation training in the qualification procedure.

3. The pharmacist shall pay for the qualification procedure referred to in subparagraph 3 of paragraph 2 and for the examination procedures and continuous training courses.

4. The level of the fee referred to in paragraph 3 shall be determined by the manager of the training unit specified in Article 89a (1).

5. The minister competent for health matters shall consider the specialist title obtained abroad equivalent to the specialist title in the Republic of Poland if all the following conditions are met:

- 1) the pharmacist holds the professional licence for the territory of the Republic of Poland;
- 2) the specialisation curriculum as relate to the required theoretical knowledge and practical skills, the method of confirming the knowledge obtained and the skills are essentially consistent with the curriculum of the specialisation concerned in the Republic of Poland;
- 3) the procedure and rules for taking the examination or another form of confirming the knowledge and skills obtained shall meet the conditions of the examination taken by the pharmacist in the Republic of Poland.

6. The pharmacist who does not meet the requirements defined in subparagraph 2 of paragraph 5 may be required to undergo supplementary training.

7. The minister competent for health matters shall establish, by way of a Regulation:

- 1) the list of pharmaceutical specialisations, with particular consideration the requirements for the staff;
- 2) the framework specialisation curricula and the time of undergoing the specialisation training, with particular consideration of the scope and forms of gaining theoretical knowledge and the list of practical skills;
- 3) the procedure and rules for conducting the qualification procedure referred to in subparagraph 3 of paragraph 2, with particular consideration of the form of request for specialisation initiation and criteria of assessing the qualification procedure;

- 4) the method of undergoing the specialisation training, with particular consideration of the procedure for documenting its course;
- 5) the procedure and rules for taking the State examination referred to in paragraph 1, with particular consideration of the requirements for the written and oral examinations;
- 6) the procedure for recognising the equivalence of the specialist title obtained abroad, with particular consideration of the scope of training undergone abroad and the procedure for and the scope of undergoing supplementary training referred to in paragraph 6;
- 7) the form of the diploma granted after the examination referred to in paragraph 1 is passed;
- 8) the method of determining the fees referred to in paragraph 3, taking into account in particular the expenses related to the qualification procedure.

Article 89a. 1. Specialisation training within the framework of postgraduate education shall be conducted by faculties or other organisational units of universities which offer studies in pharmacy, hereinafter referred to as "training units", upon obtaining the accreditation granted by the minister competent for health matters.

2. The basis for accreditation granting and its obtaining by the training unit applying for accreditation shall be meeting by such unit the specific standards of specialisation training for pharmacists.

3. Accreditation shall be granted upon request of the training unit applying for accreditation. The document confirming accreditation obtaining shall be the accreditation certificate.

4. Accreditation shall be granted, refused to be granted or cancelled by way of an administrative decision. The provisions of the Code of Administrative Procedure shall apply to matters unregulated in this Act.

5. The request referred to in paragraph 3 shall be submitted at the latest 4 months before the planned date of commencement of specialisation training conduct by the training unit.

6. The request referred to in paragraph 3 should contain:

- 1) name of the training unit applying for accreditation;
- 2) declaration on meeting the conditions indispensable for complete implementation of the detailed specialisation curriculum, including the information on the number and qualifications of the teaching staff, the teaching base and the organisational conditions appropriate for the specific specialisation type.

7. The detailed specialisation curriculum shall be enclosed to the request.

8. The minister competent for health matters shall establish, by way of a Regulation, the standards of specialisation training for pharmacists, taking into account in particular the data on the number and qualifications of the staff, the teaching base and the organisational conditions of training.

Article 89b. 1. Accreditation shall be granted for not less than 3 years and not more than 10 years.

2. The minister competent for health matters shall establish, by way of a Regulation, the form of accreditation certificate, taking into account in particular the data covered by such certificate, such as the name, address and registered office of the training unit and the specialisation type.

Article 89c. The minister competent for health matters may cancel the certificate if the training unit does not implement the detailed specialisation curriculum or does not comply with the standards of specialisation training for pharmacists, as referred to in Article 89a (8).

Article 89d. 1. The minister competent for health matters shall carry out supervision of specialisation conducting.

2. Within the framework of supervision referred to in paragraph 1, the minister competent for health matters shall have the right to:

- 1) inspect the training unit;
- 2) demand presentation of the documentation and explanations concerning the conducted specialisation training;
- 3) issue orders to remedy the deficiencies found.

Article 89e. 1. The pharmacist (employed with a pharmacy or a wholesale store) must improve his or her professional qualifications by participation in continuous training, to update the knowledge held and constant supplementary training in the progress of pharmaceutical sciences.

2. Continuous training shall be conducted in accredited training units defined in Article 89a (1).

3. Having consulted the Supreme Pharmaceutical Council and the Polish Pharmaceutical Society, the minister competent for health matters shall establish, by way of a Regulation, the framework curriculum of continuous training, with particular consideration of the scope and forms of obtaining theoretical knowledge, methods of undergoing training with consideration of the type of documentation of their course, continuous education standards, and also the fees for the training.

Article 90. Exclusively pharmacists and pharmaceutical technicians can be employed for performing professional activities in a pharmacy, to the extent of their professional competencies.

Article 91. 1. A pharmaceutical technician with two years' experience in full-time work in a pharmacy may perform in a pharmacy professional activities consisting in preparation, manufacturing, dispensing of medicinal products and medical devices, except for the medicinal products that contain:

- 1) very potent substances included in the Official List of Medicinal Products Authorised for Marketing in the Territory of the Republic of Poland,
- 2) narcotic substances,
- 3) psychotropic substances of groups I-P and II-P

– defined in separate regulations.

2. A pharmaceutical technician referred to in paragraph 1 may also carry out auxiliary activities at making and preparation of the medicinal products referred to in Article 86 (3) (1) – 4) and (6).

3. The minister competent for health matters shall establish, by way of a Regulation, the curriculum of program of on-the-job training in a pharmacy and the procedure and rules for undergoing such training by a pharmaceutical technician, taking into account in particular the scope of knowledge indispensable for the performance of activities defined in paragraphs 1 and 2, the duties of the training tutor, the scope of activities that may be performed by the trainee on his or her own, the form and method of keeping the pharmacy training register.

Article 92. The pharmacist referred to in Article 88 (1) should be present in a pharmacy during its opening hours.

Article 93. 1. In a hospital or onsite pharmacy, the pharmacy manager shall be established.

2. The provisions of Article 88 (2) – (5) shall apply per analogy to the manager of a hospital or onsite pharmacy.

Article 94. 1. The opening hours of generally accessible pharmacies should be adjusted to the needs of the public and should ensure availability of services also at night, on Sundays and during other holidays.

2. The opening hours of generally accessible pharmacies within a specific area shall be defined by the Poviats management after consultation with the borough leaders (mayors, town presidents) of Gminas of the Poviats and with the pharmaceutical self-government.

3. Having consulted the Supreme Pharmaceutical Council, the minister competent for health matters shall establish, by way of a Regulation:

- 1) the maximum level of additional payments charged by the pharmacy for night dispatch, taking into account the necessity to dispense the drug;
- 2) the group of medicinal products for night dispensing for which no additional fee is charged, taking into consideration the necessity to provide life- or health-saving assistance.

Article 94a. ⁽³²⁵⁾ 1. It shall be prohibited to conduct advertising of the operations of pharmacies or pharmacy outlets addressed to the general public, which would directly relate to medicinal products or of medical devices entered in the lists of reimbursed drugs, or medicinal products or of medical devices with a name is identical with the name of medicinal products or medical devices entered in these lists.

2. The Voivodeship Pharmaceutical Inspector shall supervise the compliance with the provisions of this Act as related to the advertising activity of pharmacies and of pharmacy outlets.

3. If violation of the provision of paragraph 1 is found, the Voivodeship Pharmaceutical Inspector shall order, by way of a decision, cessation of such advertising.

4. The decisions referred to in paragraph 3, shall be immediately enforceable.

Article 95. 1. Generally accessible pharmacies must have on stock medicinal products and medical devices in quantity and in selection indispensable to cover the healthcare needs of the local population, with particular consideration of reimbursed drugs for which a price limit has been established on the basis of separate regulations, subject to paragraph 2.

2. Upon request of the pharmacy manager, the Voivodeship Pharmaceutical Inspector may exempt the pharmacy from the duty to trade in narcotic agents of group I-N and in psychotropic substances of group II-P.

3. If the required medicinal product, including a magistral formula, is unavailable in a generally accessible pharmacy, the pharmacist referred to in Article 88 (1) should ensure its purpose within the time limit agreed with the patient.

4. The minister competent for health matters shall establish, by way of a Regulation, the basic conditions for operating a pharmacy, taking into account in particular the:

- 1) conditions of storage of medicinal products and of medical devices;
- 2) conditions of preparing magistral and officinal formulas, including the aseptic conditions;
- 3) ⁽³²⁶⁾ conditions of preparing homeopathic medicinal products;
- 4) keeping the documentation in particular on the purchased, sold, prepared, retained, and recalled from the market medicinal products and medical devices;
- 5) detailed rules of appointing substitutes for pharmacy managers for a defined period of time and notification of such appointments to the Voivodeship Pharmaceutical Inspector and the District Chamber of Pharmacists;
- 6) procedure and rules for carrying out inspections of medicinal products and medical devices accepted in the pharmacy;
- 7) procedure for exempting from the obligation of trading in narcotic agents in the I-N group and psychotropic substances in the II-P group;
- 8) conditions and procedure for submitting by the pharmacy manager the specific information on trade in and stock of defined medicinal products and medical devices.

Article 96. 1. Medicinal products and medical devices shall be dispensed from generally accessible pharmacies by a pharmacist or a pharmaceutical technician within the framework of such person's professional competencies:

- 1) on the basis of a prescription;

- 2) without prescription;
- 3) on the basis of a requisition document issued by authorised organisational units or by natural persons authorised pursuant to separate regulations.

2. In the case of sudden health- or life-threatening emergency, the pharmacist referred to in Article 88 (1) may dispense without prescription the medicinal product which can be only dispensed on prescription in the smallest therapeutic package, except for narcotic agents, psychotropic substances and precursors of group I-R.

3. The pharmacist referred to in Article 88 (1) shall record the fact of dispensing the medicinal product referred to in paragraph 2 in the developed pharmaceutical prescription; the pharmaceutical prescription should contain the name of the dispensed medicinal product, the dose, the cause of dispensing the medicinal product, the identification data and the address of the person to whom the medicinal product was dispensed, the date of dispensing, signature and stamp of the pharmacist referred to in Article 88 (1). The pharmaceutical prescription shall replace a prescription with 100% payment by the patient and shall be subject to recording.

4. Pharmacist and pharmaceutical technician may refuse to dispense the medicinal product if such dispensing may pose a hazard to the patient's life or health.

5. Medicinal products and medical devices dispensed from a pharmacy shall not be returnable, subject to paragraph 6.

6. The provision of paragraph 5 shall not apply to the medicinal product or medical device returned to the pharmacy due to a quality defect or inappropriate dispensing.

7. The minister competent for health matters, or the Minister of National Defence and the Minister of Justice with respect to hospital or onsite pharmacies supervised by the Minister of National Defence and the Minister of Justice, respectively, shall establish, by way of a Regulation, the process of dispensing medicinal products and medical devices from a pharmacy, taking into consideration in particular the following:

- 1) the duties of the persons filling a prescription or requisition document, making a magistral formula or an official formula;
- 2) the cases where dispensing a medicinal product or medical device may be refused;
- 3) the data that should be contained in the requisition document for the purchase of medicinal products or medical devices;
- 4) the procedure and rules for keeping the records referred to in paragraph 3.

Article 97. 1. A generally accessible pharmacy may be situated in a separate building or in a building serving other purposes, provided that it is separated from other rooms in the building and from other businesses.

2. The premises of a generally accessible pharmacy include the core area and the auxiliary area. The dispatch chamber included in the core area has to be accessible by disabled persons.

3. The core area of a generally accessible pharmacy cannot have a surface area less than 80 m². The core area in generally accessible pharmacies located in villages with up to 1500 inhabitants and in rural areas shall be permissible to have a surface area not less than 60 m².

4. ⁽³²⁷⁾ In the case of homeopathic product making, the core area of the pharmacy has to be appropriately increased, depending on the range of such products.

5. Having consulted the Supreme Pharmaceutical Council, the minister competent for health matters shall establish, by way of a Regulation, the list of rooms included in the core and auxiliary areas of a pharmacy, taking into account in particular the size of individual rooms, having in mind that the performance of tasks of the pharmacy has to be ensured.

Article 98. 1. The premises of a hospital pharmacy – their size, type, number of rooms, taking into account paragraphs 5 and 6, should arise from the type of activities carried out by the pharmacy, taking into consideration the therapeutic profile and the number of health services provided in the hospital in which the pharmacy was established.

2. The core area of a hospital pharmacy cannot have a surface area less than 80 m².

3. In the case of making magistral formulas, preparing parenteral nutrition drugs, enteral nutrition drugs, individual therapeutic doses, and doses of cytostatic drugs, the core area should be increased correspondingly to the services provided.

4. In the case when an infusion fluid manufacturing area exists, the core area should be enlarged by the space indispensable for creation of an infusion fluid manufacturing area and for creation of a quality control laboratory where physicochemical, microbiological, and biological tests can be performed. With consent of the Voivodeship Pharmaceutical Inspector, biological tests may be conducted in another institution.

5. The minister competent for health matters shall establish, by way of a Regulation, the detailed requirements that have to be fulfilled by pharmacy premises, in particular specifying the organisation and equipment of such premises.

6. The Minister of National Defence and the Minister of Justice, in consultation with the minister competent for health matters, shall establish, by way of Regulations, the detailed requirements that have to be fulfilled by the premises of the onsite pharmacy referred to in Article 87 (1) (3), in particular specifying the organisation and equipment of such premises.

Article 99. 1. A generally accessible pharmacy may be operated only on the basis of the obtained authorisation for operating a pharmacy.

2. The Voivodeship Pharmaceutical Inspector shall be responsible for granting, refusing to grant, amending, cancellation or finding the expiry of an authorisation for operating a pharmacy.

3. The authorisation referred to in paragraph 1 shall not be granted when the applicant:

- 1) carries out or has applied for an authorisation to carry out wholesale trade in medicinal products or
- 2) ⁽³²⁸⁾ operates in the Voivodeship more than 1% of generally accessible pharmacies or entities directly or indirectly controlled by such applicant, in particular subsidiaries within the meaning of the competition and consumer protection regulations, operate jointly more than 1% of pharmacies in the Voivodeship;
- 3) ⁽³²⁹⁾ is a member of a capital group within the meaning of the Competition and Consumer Protection Act, the members of which operate more than 1% of generally accessible pharmacies in the Voivodeship.

4. A natural person, a legal person and a company without legal personality shall have the right to obtain an authorisation for operating a pharmacy.

4a. A pharmacy operator must employ a person responsible for operating the pharmacy referred to in Article 88 (2), warranting that the pharmacy shall be duly operated.

4b. If the applicant for authorisation for operating a pharmacy is a physician or a *dentist* ⁽³³⁰⁾, the authorisation shall be issued if the applicant presents the declaration that he or she shall not exercise the physician's profession.

5. (repealed).

6. The provision of paragraph 4a) shall not be applicable to a pharmacist having the competencies referred to in Article 88 (2).

Article 100. 1. The applicants for an authorisation for operating a generally accessible pharmacy, referred to in Article 99 (4), shall submit an application containing the following:

- 1) name, registered office and address, and in the case of a natural person forename, surname and address;
- 2) ⁽³³¹⁾ NIP and PESEL number or – if not assigned – passport, ID card or another identification document number, in the case when the applicant is a natural person;
- 3) pharmacy address;
- 4) pharmacy name, if any;
- 5) date of taking up the activity;
- 6) date of development of the application and the applicant's signature.

2. The following should be enclosed to the application:

- 1) legal title to the premises of the generally accessible pharmacy;

- 2) excerpt from the register in accordance with separate regulations;
- 3) layout and technical description of the premises intended for the pharmacy, developed by an authorised person;
- 4) opinion of the Sanitary Inspection ⁽³³²⁾ on the pharmacy premises drawn up in accordance with separate regulations;
- 5) forename and surname of the pharmacist responsible for management of the pharmacy and the documents attesting that the requirements laid down in Article 88 (2) are met;
- 6) ⁽³³³⁾ declaration specifying all entities directly or indirectly controlled by the applicant, in particular subsidiaries within the meaning of the Competition and Consumer Protection Act. The applicant states the name of the entity, its registered office and address, and in the case of a natural person such person's forename, surname and address;
- 7) ⁽³³⁴⁾ declaration specifying all members of the applicant's capital group within the meaning of the Competition and Consumer Protection Act. The applicant states the name of the entity, its registered office and address, and in the case of a natural person such person's forename, surname and address.

3. The applicant shall submit the application referred to in paragraph 1 to the Voivodeship Pharmaceutical Inspector.

4. The minister competent for health matters shall establish, by way of a Regulation, the data required in the technical description of the premises, taking into account in particular the situation of the premises, their availability, the conditions of deliveries of goods, the core and auxiliary surface areas.

Article 101. The Voivodeship Pharmaceutical Inspector shall refuse to grant an authorisation for operating a generally accessible pharmacy when:

- 1) the applicant does not meet the conditions defined in Article 88, Article 97, Article 99 (4), (4a) and (4b) and Article 100 (2) and (4);
- 2) ⁽³³⁵⁾ the applicant's authorisation for operating a pharmacy was cancelled not earlier than three years before application submittal,
- 3) the applicant operates or has applied for an authorisation to operate a wholesale store;
- 4) the applicant does not warrant correct operation of the pharmacy.

Article 102. The authorisation for operating a pharmacy should contain the following:

- 1) name and registered office address of the party to which the authorisation was issued, a in the case of a natural person such person's forename, surname and address;
- 2) Gmina in which the pharmacy is to be established;
- 3) pharmacy operation address;
- 4) pharmacy name, if any;
- 5) number of authorisation for operating a pharmacy;
- 6) date of expiry of the authorisation for operating a pharmacy, if designated;
- 7) basic conditions of operation of the pharmacy.

Article 103. 1. ⁽³³⁶⁾ The Voivodeship Pharmaceutical Inspector shall cancel the authorisation for operating a generally accessible pharmacy if the pharmacy trades in medicinal products which have not been authorised for marketing.

2. The Voivodeship Pharmaceutical Inspector may cancel the authorisation if:

- 1) the deficiencies specified in the decision of the Pharmaceutical Inspector issued on the basis of this Act were not remedied within the designated time;
- 2) despite prior notification, performance of official activities by the Pharmaceutical Inspection or the National Health Fund was made impossible or difficult;
- 3) the pharmacy does not satisfy, in a persistent manner, the population's demand for medicinal product dispensing;

- 4) the pharmacy was not put into operation within 4 months of the date when the authorisation was granted or the pharmacy does not carry out the business covered by the authorisation for a period of at least 6 months;
- 5) ⁽³³⁷⁾ the decision of the Voivodeship Pharmaceutical Inspector referred to in Article 94a (3) or the decision of the Main Pharmaceutical Inspector referred to in Article 62 (2) was not enforced.

Article 104. 1. Authorisation for operating a pharmacy shall expire in the cases of:

- 1) death of the person for whom the authorisation was granted, if the authorisation was granted for an entity being a natural person;
- 2) discontinuation of the operations;
- 3) winding up the legal person, unless separate regulations provide otherwise.

1a. ⁽³³⁸⁾ An authorisation for operating a pharmacy shall not expire in the case of death of a natural person if at least one of such person's legal successors meets the requirements referred to in Article 99 (3) – (4b) and Article 101 (2) – (4).

1b. ⁽³³⁹⁾ The legal successor referred to in paragraph 1a, operating the pharmacy, must apply to the Pharmaceutical Inspector for variations to the authorisation with respect to specification of the authorisation holder within 6 months of the date of death of the natural person referred to in (1a).

2. The authorisation shall be found expired by way of a decision of the authority which has issued such authorisation.

3. (repealed).

4. (repealed).

Article 105. ⁽³⁴⁰⁾ 1. A fee at a level of five times the minimum wages determined on the basis of the minimum wage regulations shall be charged for granting an authorisation for operating a pharmacy.

2. A fee of half of the amount referred to in paragraph 1 shall be charged for a variation to the authorisation or its renewal if the authorisation has been issued for a limited time.

3. The fees referred to in paragraphs 1 and 2 which shall constitute the revenue of the State budget.

Article 106. 1. A hospital pharmacy may be put into operation after the consent of the competent Voivodeship Pharmaceutical Inspector is obtained, provided that the requirements defined in Article 98 are met and a pharmacy manager meeting the requirements laid down in Article 88 (2) is employed.

2. The consent referred to in paragraph 1 shall be granted upon request of the director of the healthcare establishment in which the hospital pharmacy is to be put into operation.

3. A hospital pharmacy may supply drugs to other healthcare establishments designed for persons whose health condition requires 24-hour health services in an appropriate permanent facility, where no pharmacies exist, on the basis of an agreement between the respectively authorised entities, provided that this will not have a negative impact on the core operations of the pharmacy.

4. A hospital pharmacy manager shall be required to forthwith notify the Voivodeship Pharmaceutical Inspector on entry into the agreement referred to in paragraph 3, with another healthcare establishment, as well as on intended winding up of the hospital pharmacy, stating the grounds for such winding up.

Article 107. 1. The Voivodeship Pharmaceutical Inspector shall keep a register of authorisations for operating generally accessible pharmacies and pharmacy outlets, and a register of granted consents for operating hospital or onsite pharmacies.

2. Such register should contain:

- 1) for generally accessible pharmacies and pharmacy outlets – the particulars defined in Article 102 (1) – (6) and the forename and surname of the pharmacy manager;
- 2) for hospital or onsite pharmacies:
 - a) healthcare establishment,
 - b) pharmacy address,
 - c) scope of operation of the pharmacy and forename and surname of its manager.
3. Making variations to, cancellation or expiry of the authorisation or making variations to, cancellation or expiry of the consent shall require appropriate amendments to the register.

Chapter 8

State Pharmaceutical Inspection ⁽³⁴¹⁾

Article 108. 1. ⁽³⁴²⁾ The State Pharmaceutical Inspection, hereinafter referred to as "the Pharmaceutical Inspection", shall supervise:

- 1) conditions of manufacturing and import of medicinal products and of veterinary medicinal products,
 - 2) quality and trade in medicinal products, except for of veterinary medicinal products,
 - 3) trade in medical devices, except for of medical devices used in veterinary medicine
- to protect social interests with respect to the safety of health and life of humans when using medicinal products and medical devices found in pharmaceutical wholesale stores, pharmacies, hospital pharmacy departments, pharmacy outlets and points of out-of-pharmacy sale.

2. ⁽³⁴³⁾ (repealed).
3. ⁽³⁴⁴⁾ (repealed).
4. The Pharmaceutical Inspection bodies shall issue decisions:
 - 1) ⁽³⁴⁵⁾ to suspend trade in or to recall from the market or to withdraw from use in healthcare establishments medicinal products in the case of suspicion or establishing that the product concerned is not authorised for marketing in Poland;
 - 2) ⁽³⁴⁶⁾ to suspend trade in or to recall from the market or withdraw from use in healthcare establishments medicinal products in the case of suspicion or establishing that the product concerned does not meet the quality requirements established for it;
 - 3) to suspend trade in or to withdraw from generally accessible pharmacies the goods which are subject to prohibition of trade;
 - 4) ⁽³⁴⁷⁾ to grant, make a variation to, cancel or refuse to grant an authorisation:
 - a) for operating a pharmacy,
 - b) for medicinal product manufacturing,
 - c) for wholesale trade in medicinal products,
 - 5) ⁽³⁴⁸⁾ referring to quality tests a medicinal product authorised for marketing in the territory of the Republic of Poland.
 - 6) ⁽³⁴⁹⁾ (repealed);
 - 7) ⁽³⁵⁰⁾ advertising:
 - a) of medicinal products,
 - b) of operations of pharmacies and pharmacy outlets.
5. ⁽³⁵¹⁾ (repealed).

Article 108a. ⁽³⁵²⁾ In the case when the results of the tests conducted under Article 108 (4) (5), Article 115 (5a), Article 123 (1) confirm that the medicinal product does not meet the quality requirements defined for it, the costs of such tests and of the collected sample shall be covered by the person responsible for the irregularities found with respect to the quality requirements for the medicinal product.

Article 109. The tasks of the Pharmaceutical Inspection shall include in particular:

- 1) ⁽³⁵³⁾ inspecting the conditions of manufacturing and import of medicinal products in accordance with the Good Manufacturing Practice requirements referred to in Article 39 (4) and the data defined in Article 10 (2) (1) – (3), (12), (13) and (15);
- 1a) ⁽³⁵⁴⁾ controlling the conditions of transport, reloading and storage of medicinal products and medical devices;
- 2) ⁽³⁵⁵⁾ supervising the quality of marketed medicinal products;
- 3) ⁽³⁵⁶⁾ controlling pharmacies and other institutions carrying out retail and wholesale trade in medicinal products and medical devices referred to in Article 108 (1);
- 4) controlling the quality of magistral and officinal formulas prepared in pharmacies;
- 5) controlling the correct labelling and advertising of medicinal products and correct labelling of medical devices;
- 6) controlling the trade in narcotic agents, psychotropic substances, and precursors of group I-R;
- 7) cooperation with the specialised team of pharmacy consultants;
- 8) giving opinions on suitability of the premises intended to house a pharmacy or a wholesale store, or a point of out-of-pharmacy sale;
- 9) cooperation with the pharmacists' self-government and with other self-governments;
- 10) keeping the register of generally accessible and hospital pharmacies and of pharmacy outlets;
- 11) keeping the Register of Pharmaceutical Wholesale Stores and Pharmaceutical Manufacturing Sites;
- 12) giving opinions on pharmacies where initial on-the-job training can be conducted.

Article 110. 1. The Pharmaceutical Inspection shall be headed by the Main Pharmaceutical Inspector.

2. The Main Pharmaceutical Inspector shall report to the minister competent for health matters.

Article 111. 1. The Main Pharmaceutical Inspector is appointed by the Prime Minister amongst individuals selected through open competitive recruitment, upon proposal of the minister responsible for health matters. The Main Pharmaceutical Inspector is removed by the Prime Minister.

2. The Deputy of the Main Pharmaceutical Inspector is appointed by the minister responsible for health matters, amongst individuals selected through open competitive recruitment, upon proposal of the Main Pharmaceutical Inspector. The minister responsible for health matters removes the Deputy upon proposal of the Main Pharmaceutical Inspector.

3. The position of the Main Pharmaceutical Inspector may be held by an individual who:

- 1) Holds the professional title of Master of Pharmacy;
- 2) Is a Polish national;
- 3) Enjoys full public rights;
- 4) Has not been sentenced with res judicata judgment for any wilful offence or wilful fiscal offence;
- 5) Has managerial skills;
- 6) Has the length of service of at least six years, including at least three years on a managerial job and
- 7) Is knowledgeable about matters over which the Main Pharmaceutical Inspector is competent.

4. A notice of recruitment for the job of the Main Pharmaceutical Inspector is announced displaying an announcement in a place of general accessibility in the office and publication in the office's Public Institutions Bulletin and in the Public Institutions Bulletin of the Prime Minister's Chancellery. The announcement should include:

- 1) Name and address of the office;
- 2) Job identification;
- 3) Legal requirements for the job;

- 4) Scope of responsibilities performed at the job;
 - 5) Specification of documents required;
 - 6) Deadline and place for submission of documents; and
 - 7) Information about recruitment methods and techniques.
5. The deadline referred to in Section 4 (6) cannot be less than ten days from the publication of the announcement the Public Institutions Bulletin of the Prime Minister's Chancellery.
6. The recruitment for job of Main Pharmaceutical Inspector is handled by a team appointed by the minister responsible for health matters, with at least three members whose knowledge and experience would guarantee selection of best candidates. In the course of recruitment, they evaluate each candidate's professional experience, knowledge necessary to fulfil tasks on the job under recruitment, and managerial skills.
7. The team may retain a third party for the purpose of evaluation of knowledge and managerial skills referred to in Section 6 provided that that party has adequate qualifications to make that evaluation.
8. Each team member and the party referred to in Section 7 are required to maintain the confidentiality of information about persons applying for the job as acquired in the course of recruitment.
9. In the course of recruitment, the team selects no more than three candidates and presents them to the minister responsible for health matters.
10. The team prepares a report regarding the recruitment, including:
- 1) Name and address of the office;
 - 2) Identification of the job under recruitment and the number of candidates;
 - 3) Full names and addresses of no more than three best candidates listed by the degree of their satisfaction of requirements as stated in the recruitment announcement;
 - 4) Information about recruitment methods and techniques that were applied;
 - 5) Reasons for the choice made or reasons for failure to select any candidate; and
 - 6) Members of the team.
11. The result of recruitment is promptly announced publication in the office's Public Institutions Bulletin and in the Public Institutions Bulletin of the Prime Minister's Chancellery. The notice about the result of recruitment includes:
- 1) Name and address of the office;
 - 2) Identification of the job under recruitment; and
 - 3) Full names of candidates who were elected and their residence in the meaning of the provisions of the Civil Code, or information about failure to select any candidate.
12. The publication of the announcement of announcement and its results in the Public Institutions Bulletin of the Prime Minister's Chancellery is free of charge.
13. The team handling the recruitment for the job referred to in Section 2 is appointed by the Main Pharmaceutical Inspector.
14. The procedure of recruitment for the job referred to in Section 2 is governed by Sections 3-12, as appropriate.

Article 112. 1. The tasks of the Pharmaceutical Inspection laid down in the Act shall be performed by the following authorities:

- 1) by the Main Pharmaceutical Inspector as the central State administration authority, assisted by the Main Pharmaceutical Inspectorate;
- 2) the Voivod assisted by the Voivodeship Pharmaceutical Inspector as the manager of the Voivodeship Pharmaceutical Inspection included in the combined Voivodeship administration.

2. The Voivodeship Pharmaceutical Inspector shall perform the tasks and competencies of the Pharmaceutical Inspection laid down in this Act and in separate regulations.

3. In matters related to the performance of tasks and competencies of the Pharmaceutical Inspection, the first-instance authority shall be the Voivodeship Pharmaceutical Inspector and the authority of appeal shall be the Main Pharmaceutical Inspector.

4. The organisational structure of the Main Pharmaceutical Inspectorate shall be defined in its Articles assigned by the minister competent for health matters by way of a Regulation.

Article 113. 1. The Voivodship Pharmaceutical Inspector is appointed and removed by the Voivodship Governor, subject to approval of the Main Pharmaceutical Inspector.

2. The candidate for the Voivodeship Pharmaceutical Inspector shall be selected as a result of a competition procedure whose rules and manner shall be established, by way of a Regulation, by the minister competent for health matters in consultation with the minister competent for public administration matters, taking into account in particular the:

- 1) the composition of the competition committee;
- 2) requirements for the candidates;
- 3) competition procedures.

3. The Voivod shall appoint and recall the Deputy Voivodeship Pharmaceutical Inspector, upon request of the Voivodeship Pharmaceutical Inspector.

4. The Main Pharmaceutical Inspector may request the Voivod at any time to recall the Voivodeship Pharmaceutical Inspector, if such recalling is justified by interest of the public service, and in particular when the activity of the Inspector or of the unit subordinate to the Inspector within the area of the specific Inspectorate:

- 1) threatens correct performance of tasks by the Pharmaceutical Inspection,
 - 2) impairs the safety of manufacture of medicinal products or the quality of medicinal products and medical devices,
 - 3) impairs the safety of trade in medicinal products and medical devices;
- such recalling must be accompanied by a detailed rationale in writing.

Article 114. 1. The tasks of the Pharmaceutical Inspection shall be performed by the persons who meet the conditions defined in paragraphs 2 or 3.

2. ⁽³⁶⁰⁾ The Pharmaceutical inspector may be a person who meets the requirements provided for in separate regulations for employees employed with government administration authorities, and:

- 1) is a pharmacist within the meaning of the provision of Article 2b of the Act on Chambers of Pharmacists of 19 April 1991;
- 2) has at least five-year experience in exercising the profession consistent with the line of such person's education.

3. ⁽³⁶¹⁾ A manufacturing inspector of the Main Pharmaceutical Inspectorate may be a person who has completed university-level education in the following scientific disciplines: pharmacy, medicine, veterinary medicine, biotechnology, biology, chemical engineering, chemistry, microbiology or pharmaceutical technology and has at least five years' experience in exercising the profession indispensable for ensuring the duly work in supervision of the quality of medicinal products.

3a. The five years' experience in work referred to in paragraph 3 shall include work in the Pharmaceutical Inspection at supervision of manufacturing, in research and development units, in analytical testing laboratories and in enterprises with the respective authorisations for conducting laboratory testing or manufacturing related with medicinal products, or conducting the respective scientific research.

4-7. ⁽³⁶²⁾ (repealed).

8. When performing the tasks of the Pharmaceutical Inspection, the pharmaceutical inspectors shall be guided by the recommendations by the Main Pharmaceutical Inspector.

Article 115. The Main Pharmaceutical Inspector:

- 1) shall establish the directions of activities of the Pharmaceutical Inspection;

- 2) shall coordinate and control the performance of tasks by Voivodeship Pharmaceutical Inspectors;
- 3) may give to the Voivodeship Pharmaceutical Inspectors orders to take up some specific activities within their professional competency, except for the matters under the power of administrative decisions as the first instance authority, and may also demand the Voivodeship Pharmaceutical Inspectors to provide information in the whole area of activity of the Pharmaceutical Inspection;
- 4) shall perform the function of the second instance authority with respect to the decisions made by the Voivodeship Pharmaceutical Inspectors;
- 5) shall carry out supervision over the manufacturing conditions of medicinal products for human and animal use;
- 5a) ⁽³⁶³⁾ within the framework of State tests of quality of medicinal products, shall supervise the quality of medicinal products available in the market, except for veterinary medicinal products;
- 6) ⁽³⁶⁴⁾ shall cooperate with the competent pharmaceutical inspections of European Union Member States and European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, in accordance with the guidelines contained in the compilation of procedures on inspections and exchange of information referred to in Article 3 (1) of Commission directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ EU L 262 of 14.10.2003, p. 22; OJ EU Polish special edition, Chapter 13, vol. 32, p. 424);
- 7) ⁽³⁶⁵⁾ (repealed);
- 8) shall constitute the first instance authority in the matters set forth in this Act;
- 9) ⁽³⁶⁶⁾ shall issue the decisions referred to in Article 108 (4) (1) – (3), (4) (b) and (c), (5) and (7) (a).

Article 116. 1. The Voivodeship Pharmaceutical Inspector shall manage the Voivodeship Pharmaceutical Inspectorate.

2. The Voivodeship Pharmaceutical Inspectorate shall include, subject to paragraph 3, drug quality control laboratories performing the tasks laid down in Article 65 (8), performing quality control tests of magistral and officinal formulas and of samples collected in the course of quality control.

3. In justified cases, the Main Pharmaceutical Inspector may grant the consent for derogation of the obligation to establish a laboratory; in such event the drug quality control tests shall be performed under a contract of mandate with the entities defined in Article 22 (2) and (3).

4. The entities defined in Article 22 (2) and (3) shall also be contracted to perform such laboratory studies whose performance in the drug quality control laboratories is impossible due to the lack of appropriate equipment.

5. ⁽³⁶⁷⁾ Drug quality control laboratories may provide services of pharmaceutical analysis; the services shall not interfere with the performance of duties imposed statutorily on the Pharmaceutical Inspection.

6-8. ⁽³⁶⁸⁾ (repealed).

Article 117. 1. The inspectors of the Main Pharmaceutical Inspectorate who carry out supervision of manufacturing conditions may perform their function in the area of several Voivodeships and may be positioned in the Voivodeship Pharmaceutical Inspectorates indicated by the Main Pharmaceutical Inspector.

2. In the cases referred to in paragraph 1, the competent Voivodeship Pharmaceutical Inspector shall organise work posts that will enable the inspectors to perform their tasks as well as shall cover the costs of inspectors' maintenance associated with the exercise of administrative activities.

3. The Main Pharmaceutical Inspector shall ensure that manufacturing and wholesale distribution inspections shall be carried out following the harmonised standard inspection procedures.

4. The task referred to in paragraph 2 shall be financed from the public funds earmarked for this purpose in the Voivod's budget.

Article 118. 1. Supervision over the manufacture of and trade in medicinal products and medical devices in healthcare establishments founded by the Minister of National Defence shall be carried out by organisational units subordinate to the said Minister, taking into consideration the principles of the Good Manufacturing Practice and the Good Distribution Practice.

2. ⁽³⁶⁹⁾ With respect to veterinary medicinal products, the Chief Veterinary Officer and Voivodeship Veterinary Officers shall supervise the trade in and the quantity of veterinary medicinal products used. The provisions of Article 119 (3), Article 120 (1) (2), Article 120 (2) and (3), Article 121 (1) and (2), Article 121a (1), Article 122, Article 122a and Article 123 (1) shall apply per analogy.

2a. ⁽³⁷⁰⁾ Within the framework of State tests of quality of veterinary medicinal products, the Chief Veterinary Officer shall supervise the quality of veterinary medicinal products available in the market.

3. The minister competent for health matters shall coordinate the performance of responsibilities by the authorities referred to in paragraphs 1 and 2; the minister may in particular request the respective information.

4. ⁽³⁷¹⁾ Minister competent for agricultural matters in consultation with the minister competent for health matters shall establish, by way of a Regulation, the method of carrying out supervision by Voivodeship Veterinary Officers, and in particular:

- 1) method of carrying out and types of controls,
- 2) procedure and rules for collecting samples for and of performing the tests,
- 3) procedure for performing controls of accepted and dispensed medicinal products and the conditions of their transport,
- 4) the form and method of keeping the control book referred to in Article 123, the method of making entries and the procedure of notifying on remedying the deficiencies found

– taking into account the legislation and guidelines of the European Community.

5. In consultation with the minister competent for health matters, the Minister of National Defence shall appoint, by way of a Regulation, the military authorities supervising the manufacture of and trade in medicinal products and medical devices in healthcare establishments founded by the Minister of National Defence and in military units, taking into account the tasks, competencies, and professional requirements indispensable for the such supervision.

6. ⁽³⁷²⁾ In consultation with the minister competent for health matters, the Minister of National Defence shall establish, by way of a Regulation, the forms of cooperation with the Pharmaceutical Inspection of the military authorities supervising the manufacture of and trade in medicinal products, except for veterinary medicinal products, and medical devices in healthcare establishments founded by the Minister of National Defence and in military units, taking into account:

- 1) the method of information exchange as referred to in paragraph 1;
- 2) the scope of cooperation;
- 3) the conditions and method of organisation, participation and conducting joint training.

Article 119. 1. ⁽³⁷³⁾ In connection with the conducted inspection on the basis of Article 46 (1) and (6) and Article 47a (1) and (2), the manufacturing inspector of the Main Pharmaceutical Inspectorate shall have the right to:

- 1) access all rooms where medicinal products are manufactured and controlled, where medicinal product import-related operations are conducted or active substances are manufactured;

- 2) demand written or oral explanations, and also documents to be shown;
- 3) collect samples for testing.
2. ⁽³⁷⁴⁾ In connection with the inspection conducted on the basis of Article 46 (3) and (4), the manufacturing inspector of the Main Pharmaceutical Inspectorate shall have the right to:
 - 1) access at any time all rooms where medicinal products are manufactured and controlled, where medicinal product import-related operations are conducted or active substances are manufactured;
 - 2) demand written or oral explanations, and also documents to be shown;
 - 3) collect samples for testing.
3. The provision of paragraph 1 shall apply per analogy to pharmaceutical inspectors with respect to control of pharmacies, pharmaceutical wholesale stores and other points of out-of-pharmacy sale of medicinal products and medical devices within the scope of activity of such institutions.

Article 119a. 1. The medicinal products which are being authorised for marketing in the Republic of Poland for the first time on the basis of this Act shall be referred by the Pharmaceutical Inspection to quality tests conducted by the entities referred to in Article 22 (3), directly by the MAH, on the basis of the decision issued by the Main Pharmaceutical Inspector.

2. Quality testing of medicinal products specified in paragraph 1 shall be performed once, not later than within the first year of market placement of the medicinal product. The MAH shall notify the Main Pharmaceutical Inspector on such market placement.

3. The MAH shall bear the cost of the quality testing referred to in paragraphs 1 and 2, including the cost of the sample collected for testing.

Article 120. 1. ⁽³⁷⁵⁾ If breach of the requirements for:

- 1) manufacturing conditions or import of medicinal products is found, the Main Pharmaceutical Inspector shall order, by way of a decision, remedying within the designated time the deficiencies found and may issue a decision prohibiting market placement of the medicinal product or recalling the medicinal product from the market;
- 2) trade in medicinal products or medical devices, the competent authority shall order, by way of a decision, remedying within the designated time the deficiencies found.

2. If the breaches referred to in paragraph 1 may cause direct threat to human life or health, the competent authority shall order, by way of a decision, stoppage of the manufacturing site or its part, of the pharmaceutical wholesale store or its part, pharmacy or another point of sale of medicinal products or medical devices or market recall of the medicinal product or of medical device.

3. The provisions of the Code of Administrative Procedure and on enforcement proceedings in administration shall apply to the safety procedure shall apply per analogy.

Article 120a. ⁽³⁷⁶⁾ If the breaches referred to in Article 120 (1) (1) apply to the duties of the manufacturer of the veterinary medicinal product defined Article 42 (1) (6), the Main Pharmaceutical Inspector shall promptly notify the Chief Veterinary Officer thereon.

Article 121. 1. ⁽³⁷⁷⁾ Where there are reasonable grounds to suspect that the medicinal product does not comply with the requirements established for it, the Voivodeship Pharmaceutical Inspector shall issue a decision to suspend the trade in the specific batches of the medicinal product in his or her area. The Voivodeship Pharmaceutical Inspector shall promptly notify the Main Pharmaceutical Inspector on the decision made.

2. ⁽³⁷⁸⁾ The Main Pharmaceutical Inspector shall adopt the decision to suspend the trade in the product throughout the Republic of Poland.

3. ⁽³⁷⁹⁾ Where there are reasonable grounds to suspect that the medical device does not comply with the requirements established for it, the Voivodeship Pharmaceutical

Inspector shall promptly notify the Office President and the Main Pharmaceutical Inspector thereof and secures the medical device preventing its further marketing and use upon the rules laid down for medicinal products.

4. The decisions referred to in paragraph 1 and 2, may be immediately enforceable.

5. The minister competent for health matters shall establish, by way of a Regulation, the detailed rules and procedure for suspending the trade in and market recall of medicinal products and medical devices, taking into account in particular the procedure and the scope of duties of the Pharmaceutical Inspection bodies in relation to the undertaken activities and Good Manufacturing Practice requirements.

Article 121a. ⁽³⁸⁰⁾ 1. Where there are reasonable grounds to suspect that medicinal product use causes serious adverse reactions changing the risk-benefit ratio, the Main Pharmaceutical Inspector shall issue, upon request of the Office President, the decision to temporarily prohibit market placement of such product, suspend the trade in such product or recall such product from the market. The Main Pharmaceutical Inspector shall promptly notify the minister competent for health matters and the Office President on the decision made. Depending on the circumstances, the Main Pharmaceutical Inspector may order destruction of the medicinal product at the cost of the MAH or entrepreneur conducting the trade, or may allow the utilisation or use of such product for another purpose.

2. In the case of being informed of a hazard to public health in relation to a medicinal product authorised for marketing, upon request of the minister competent for health matters or Office President the Main Pharmaceutical Inspector shall issue a decision temporarily prohibiting the market placement of such product, suspending the trade in such product or recalling such product from the market. The Main Pharmaceutical Inspector shall promptly notify the minister competent for health matters and the Office President on the decision made. Depending on the circumstances, the Main Pharmaceutical Inspector may order destruction of the medicinal product at the cost of the MAH or entrepreneur conducting the trade, or may allow the utilisation or use of such product for another purpose.

3. In the case of being informed of a hazard to life or health of humans or animals or environmental hazard in relation to a veterinary medicinal product authorised for marketing, upon request of the minister competent for agricultural matters, the minister competent for health matters or Office President, the Chief Veterinary Officer shall issue a decision temporarily prohibiting the market placement of such product, suspending the trade in such product or recalling such product from the market. The Chief Veterinary Officer shall promptly notify the minister competent for agricultural matters, the minister competent for health matters and the Office President on the decision made. Depending on the circumstances, the Chief Veterinary Officer may order destruction of the veterinary medicinal product at the cost of the MAH or entrepreneur conducting the trade, or may allow the utilisation or use of such product for another purpose.

4. If the decision referred to in paragraphs 2 and 3 was granted in connection with ongoing explanatory proceedings referred to in Article 18a (6) or Article 19 (4), the Office President shall inform on the decision issued the European Commission and competent authorities of European Union Member States and European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, not later than on the next working day. This decision shall be valid until the end of the explanatory proceedings.

Article 122. 1. Should it be found that a medicinal product does not comply with the established quality requirements, the Main Pharmaceutical Inspector shall make decisions prohibiting market placement of the product or recalling the product from the market and may, as the case may be:

- 1) order its destruction at the MAH's or trading entrepreneur's cost;
- 2) allow the use or utilisation of such product for another purpose.

2. The Voivodeship Pharmaceutical Inspector shall have the right referred to in paragraph 1 if the medicinal product does not comply with the established quality requirements and is located exclusively within the area of such Inspector's jurisdiction.

3. If the products referred to in Article 72 (5), located in a wholesale store or a pharmacy, do not comply with the established quality requirements, the Voivodeship Pharmaceutical Inspector shall issue a decision to suspend further trade in those products, notifying thereon the authority competent for market recall of the product pursuant to separate regulations.

4. The Voivodeship Veterinary Officers shall have the rights referred to in paragraph 3 with respect to a product found in a pharmaceutical wholesale store selling veterinary medicinal products.

Article 122a. ⁽³⁸¹⁾ In the case referred to in Article 33 (1), the Main Pharmaceutical Inspector shall issue a decision to recall the medicinal product from the market.

Article 122b. 1. Inspection is carried out by a GMP inspector from the Main Pharmaceutical Inspectorate upon showing his or her official ID and handing in an authorisation to carry out the inspection as granted by the Main Pharmaceutical Inspector.

2. Control is carried out by a pharmaceutical inspector upon showing his or her official ID and handing in an authorisation to carry out the control as granted by the Voivodeship Pharmaceutical Inspector.

3. The authorisation referred to in Sections 1 and 2 includes, without limitation:

- 1) Identification of legal basis;
- 2) Identification of controlling authority;
- 3) Date and place of issue;
- 4) Full name of the inspector authorised to carry out the control or inspection, and number of his or her official ID;
- 5) Entrepreneur to be subjected to control or inspection;
- 6) Identification of the subject matter scope of the control or inspection;
- 7) Date of commencement and expected date of completion of the control or inspection;
- 8) Signature of grantor; and
- 9) Instructions regarding the rights and duties of inspectee.

4. The inspector confirms the commencement of control or inspection by making a relevant entry in the inspection log.

5. While making a scheduled inspection of a medicinal products manufacturing site or the importing site, prior to the commencement of inspection, the GMP inspector from the Main Pharmaceutical Inspectorate advises the inspectee of the inspection plan, including the anticipated period of inspection, the scope of inspection and the list of personnel obligated to provide explanations of importance for pending inspection, for the purpose of proper and efficient carrying out of the inspection.

Article 122c. 1. Control or inspection activities are performed in the presence of the inspectee or a person authorised by it unless the inspectee waives the right to participate in those activities.

2. A statement of waiver of the right to participate in activities undertaken in the course of control or inspection is made in writing. In the event of refusal to make such a statement, the inspector makes a relevant note in the control or inspection report.

3. In the event that the inspectee waives the right to participate in control or inspection activities, such activities are performed in the presence of a witness. No witness has to be present during activities entailing the taking of evidence based on books, records, notes or other documents.

Article 122d. 1. In the course of control or inspection, the inspector has the right to prepare documentation, also in the audio, photographic and film form.

2. Control or inspection may be participated by specialists or experts on the basis of authorisation issued in their name by, as appropriate, the Voivodship Pharmaceutical Inspector or the Main Pharmaceutical Inspector.

Article 122e. 1. Control or inspection proceedings are documented by the inspector in, as appropriate, a control report or inspection report.

2. A control or inspection report contain, without limitation:

- 1) Identification of inspectee;
- 2) Identification of inspectors;
- 3) Identification of specialists and experts if they participated in the control or inspection;
- 4) Identification of the subject matter and scope of control or inspection;
- 5) Identification of the place and time of control or inspection;
- 6) Summary of findings;
- 7) Presentation of evidence; and
- 8) Instructions regarding the right to make objections or explanations.

3. A control report is signed by:

- 1) Inspectee or person authorised by it;
- 2) Inspectors who carried out that control; and
- 3) Individuals whose explanations were stated in the report as material for control activities.

4. An inspection report is signed by the GMP inspector from the Main Pharmaceutical Inspectorate or GMP inspectors from the Main Pharmaceutical Inspectorate who carried out that inspection.

Article 122f. 1. A control report is made in two identical copies, one is delivered to the inspectee.

2. If the inspectee disagrees with the findings stated in the control report, it may, within seven days of its delivery, make written objections or explanations with simultaneous provision of relevant evidence-based conclusions. The inspector has a duty to consider any objections made within seven days of their delivery. If such objections are admitted, the inspector supplements the control report and submits it for re-signature.

3. In the event of refusal to sign any control report, the refusing party provides explanations, in writing, as to the reasons for refusal.

4. Any refusal to sign the control report, reasons for that refusal and explanations provided are mentioned in the control report by the inspector.

Article 122g. 1. An inspection report is made in three identical copies, one is delivered to the inspectee.

2. If the inspectee disagrees with the findings stated in the inspection report, it may, within seven days of its delivery, make written objections or explanations with simultaneous provision of relevant evidence-based conclusions. The inspector has a duty to consider any objections made within seven days of their delivery. If such objections are admitted, the inspector supplements the inspection report and submits it for re-signature.

Article 122h. 1. In the event that any samples are taken for testing during control or inspection, the inspector documents the sampling in a sampling report.

2. Samples for testing are taken in the amount necessary to do a proper laboratory test.

3. A sampling report is made in three copies, one is delivered to the inspectee, another is attached to the sample sent for quality testing and the third one is retained in the inspector's documentation.

Article 122i. 1. The inspectee from whom samples were taken for testing packages them in the manner preventing any changes affecting their quality and sends them to the laboratory test unit nominated by the inspector.

2. The sample sent for testing should be attached with the report referred to in Article 122h (1) and a laboratory test request issued by the inspector.

3. At the same time when a sample is taken for testing, a test sample should be packaged and sealed and left with the inspectee for storage in conditions preventing any alteration of their quality, in a quantity corresponding to the quantity sampled for testing.

4. The provision of Section 3 does not apply to a prescription drug.

5. The sample left for storage pursuant to Section 3 should be stored by the inspectee until the day of receiving the quality tests result decision.

Article 122j. 1. Upon completion of quality tests, the laboratory test unit issues its decision on results of quality tests of samples taken by the inspector in the course of control or inspection.

2. The laboratory test unit delivers its decision to the inspector who made the request, and to the inspectee.

Article 122k. 1. Ad hoc recommendations, comments and conclusions resulting from the control or inspection performed are written in the inspection log by the inspector.

2. The inspection log should be produced whenever requested by the inspector

3. No record made in the inspection log may be erased or deleted otherwise.

4. The inspecting party may delete or alter any record in such a way so that deleted or altered words are legible.

5. Deletions and alterations should be made before signing the record.

6. Deletions and alterations made should be identified at the end of record by identifying the log page and contents.";

Article 123. ⁽³⁸²⁾ 1. The pharmaceutical inspector or manufacturing inspector of the Main Pharmaceutical Inspectorate shall record any ad-hoc recommendations, comments and conclusions arising from the performed controls or inspections into the control book which must be held by the entrepreneur conducting the business defined in the Act and a hospital pharmacy, hospital pharmacy department and onsite pharmacy.

2. The minister responsible for health matters will lay down, in a regulation, templates for:

1) Authorisation to carry out control or inspection;

2) Sampling report;

3) Decision on results of quality tests of samples taken; and

4) Inspection log,

- With due consideration of the legislation and guidelines of the European Community

Chapter 9

Penal Regulations and Final Regulation

Article 124. Whoever places a medicinal product on the market or stores a medicinal product for the purpose of market placement without a marketing authorisation held, shall be punishable by a fine, restricted freedom or imprisonment for up to 2 years.

Article 124a. 1. Whoever places on the market or uses veterinary medicinal products not entered in the Register of Medicinal Products Authorised for Marketing in the territory of the Republic of Poland, referred to in Article 28, shall be punishable by a fine, restricted freedom or imprisonment for up to 2 years.

2. A person responsible for animals, who allows using in animals veterinary medicinal products not authorised for marketing, shall be punishable by the same penalty.

Article 125. ⁽³⁸³⁾ Whoever takes up business of manufacturing or import of a medicinal product without the required authorisation, shall be punishable by a fine, restricted freedom or imprisonment for up to 2 years.

Article 126. Whoever places on the market medicinal product after its date of expiry shall be punishable by a fine, restricted freedom or imprisonment for up to 2 years.

Article 126a. ⁽³⁸⁴⁾ Whoever conducts a clinical trial or veterinary clinical trial of a medicinal product without the required authorisation or otherwise than in accordance with the provisions of Chapter 2a, shall be punishable by a fine, restricted freedom or imprisonment for up to 2 years.

Article 127. Whoever takes up business of operating a:

- 1) pharmaceutical wholesale store, or
 - 2) generally accessible pharmacy, or
 - 3) pharmacy outlet,
- without the required authorisation shall be punishable by a fine, restricted freedom or imprisonment for up to 2 years.

Article 128. ⁽³⁸⁵⁾ Whoever, in violation of the provisions of Article 58, within the framework of medicinal product advertising, gives or promises pecuniary advantages to persons qualified to prescribe medicinal products or to persons trading in medicinal products, or accepts such advantages, shall be punishable by a fine.

Article 129. ⁽³⁸⁶⁾ 1. Whoever conducts advertising of medicinal products without the respective authorisation shall be punishable by a fine.

2. Whoever:

- 1) conducts advertising of medicinal products not authorised for marketing in the territory of the Republic of Poland or
 - 2) conducts advertising inconsistent with the Summary of Product Characteristics or Veterinary Summary of Product Characteristics, or
 - 3) does not store advertising specimens, or
 - 4) does not keep the records of the obtained samples of medicinal products, or
 - 5) does not implement forthwith the decisions ordering:
 - a) cessation of appearance or conduct of medicinal product advertising incompliant with the regulations in force,
 - b) publication of the issued decision at places where advertising incompliant with the regulations in force appeared and publication of an erratum to erroneous advertising,
 - c) remedying the deficiencies found.
- shall be punishable by the same penalty.

Article 129a. ⁽³⁸⁷⁾ 1. Whoever addresses to the general public the advertising of medicinal products:

- 1) dispensed exclusively on the basis of a prescription, or
 - 2) with the name identical with the name of a medicinal product issued exclusively on the basis of a prescription, or
 - 3) containing narcotic agents or psychotropic substances, or
 - 4) entered in the lists of reimbursed drugs or medicinal products dispensed without prescription, if their name is identical with that entered in these lists, shall be punishable by a fine.
2. Whoever supplies samples of medicinal products to unauthorised persons,

shall be punishable by a fine.

Article 129b. ⁽³⁸⁸⁾ Whoever, when operating a generally accessible pharmacy or pharmacy outlet, conducts advertising of their activities which directly refers to medicinal products or medical devices entered in the lists of reimbursed drugs, or to medicinal products or medical devices with a name is identical with the name of medicinal products or medical devices entered in these lists, shall be punishable by a fine.

Article 130. Whoever attributes properties of a medicinal product to a product placed on the market despite the fact that such product does not meet the requirements defined in this Act, shall be punishable by a fine.

Article 131. 1. Whoever manages a pharmacy without the necessary authority shall be punishable by a fine.

2. A person, who without the respective professional authority dispenses a medicinal product from a pharmacy, shall be punishable by the same penalty.

Article 132. Whoever prevents, or interferes with, performance of duties by a person authorised to perform control within the scope of a pharmaceutical inspection, shall be punishable by a fine or a penalty of imprisonment for up to 2 years or by both these penalties jointly.

Article 132a. Whoever places on the market or uses in veterinary practice unprocessed pharmaceutical raw materials, shall be punishable by a fine or a penalty of imprisonment for up to 3 years or by both these penalties jointly.

Article 132b. Whoever does not hold the document of purchase of the veterinary medicinal product with anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties and of use of such a product in animals whose tissues and products are intended for human consumption, shall be punishable by a fine or a penalty of imprisonment for up to 2 years or by both these penalties jointly.

Article 132c. ⁽³⁸⁹⁾ Whoever, when conducting retail trade in veterinary medicinal products or medicated feedingstuffs, does not keep the documentation of trade in veterinary medicinal products or medicated feedingstuffs, shall be punishable by a fine or a penalty of imprisonment for up to 2 years or by both these penalties jointly.

Article 132d. ⁽³⁹⁰⁾ Whoever:

- 1) does not keep the register referred to in Article 24 (1) (2), or
 - 2) does not submit to the Office President the reports referred to in Article 24 (1) (3), or
 - 3) violates the order defined in Article 24 (3a),
- shall be punishable by a fine or a penalty of imprisonment for up to 2 years or by both these penalties jointly.

Article 133. In the case of conviction for the offence set forth in Article 124, Article 124a, Article 126, Article 132a and Article 132b, the court shall award forfeiture of the object of the offence, even if such object is not owned by the perpetrator, and the court may order destruction of such object.

Article 134. This Act shall enter into effect on the date and upon the rules laid down in the Act – Regulations Introducing the Act – Pharmaceutical Law, the Act on Medical Devices, and the Act on the Office for the Registration of Medicinal Products, Medical Devices and Biocides.

¹⁾ Article 1 (1) (1a) added by Article 1 (1) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

²⁾ Article 2 (2a):

- added by Article 1 (2) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (1) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁾ Article 2 (2b):

- added by Article 1 (2) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (1) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁴⁾ Article 2 (2c) added by Article 1 (2) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

⁵⁾ Article 2 (2d) added by Article 1 (2) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

⁶⁾ Article 2 (3) amended by Article 1 (2) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

⁷⁾ Article 2 (3a) added by Article 1 (2) (c) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

⁸⁾ Article 2 (3b):

- added by Article 1 (2) (c) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (1) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁹⁾ Article 2 (3c):

- added by Article 1 (2) (c) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (1) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁰⁾ Article 2 (3d):

- added by Article 1 (2) (c) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (1) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹¹⁾ Article 2 (6) amended by Article 1 (2) (d) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹²⁾ Article 2 (6a) added by Article 1 (2) (e) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹³⁾ Article 2 (7a) added by Article 1 (2) (f) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹⁴⁾ Article 2 (7b):

- added by Article 1 (2) (f) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 120 of the Act on Public Offering and Conditions of Introducing Financial Instruments into the Organised Trade System and on Public Companies of 29 July 2005 (Journal of Laws 05.184.1539) on 24 October 2005

- amended by Article 1 (1) (c) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

¹⁵⁾ Article 2 (10) amended by Article 1 (1) (d) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

¹⁶⁾ Article 2 (12) amended by Article 1 (1) (e) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

¹⁷⁾ Article 2 (13) amended by Article 1 (1) (f) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

¹⁸⁾ Article 2 (13a) added by Article 1 (1) (g) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

¹⁹⁾ Article 2 (14) amended by Article 1 (1) (h) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

²⁰⁾ Article 2 (16) amended by Article 1 (2) (g) of the Act of 20 April 2004 ([Journal of Laws 04.92.882](#)) amending this Act on the day of European Union accession by the Republic of Poland.

²¹⁾ Article 2 (17) amended by Article 1 (2) (h) of the Act of 20 April 2004 ([Journal of Laws 04.92.882](#)) amending this Act on the day of European Union accession by the Republic of Poland.

²²⁾ Article 2 (17a):

- added by Article 1 (2) (i) of the Act of 20 April 2004 ([Journal of Laws 04.92.882](#)) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (1) (i) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

²³⁾ Article 2 (18) repealed by Article 1 (1) (j) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

²⁴⁾ Article 2 (19) amended by Article 1 (1) (k) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

²⁵⁾ Article 2 (22a):

- added by Article 1 (2) (j) of the Act of 20 April 2004 ([Journal of Laws 04.92.882](#)) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (1) (l) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

²⁶⁾ Article 2 (23) repealed by Article 2 (1) of the Act Amending the Act on Animal Feedingstuffs and Certain Other Acts of 2 April 2004 ([Journal of Laws 04.91.877](#)) on the day of European Union accession by the Republic of Poland.

²⁷⁾ Article 2 (24):

- amended by Article 1 (2) (k) of the Act of 20 April 2004 ([Journal of Laws 04.92.882](#)) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 42 (1) (a) of the Act – Regulations Introducing the Act on Business Activity Freedom of 2 July 2004 ([Journal of Laws 04.173.1808](#)) on 21 August 2004

²⁸⁾ Article 2 (25) amended by Article 1 (1) (m) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

²⁹⁾ Article 2 (27a) added by Article 1 (2) (l) of the Act of 20 April 2004 ([Journal of Laws 04.92.882](#)) amending this Act on the day of European Union accession by the Republic of Poland.

³⁰⁾ Article 2 (29):

- amended by Article 1 (2) (m) of the Act of 20 April 2004 ([Journal of Laws 04.92.882](#)) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (1) (n) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

³¹⁾ Article 2 (30) amended by Article 1 (1) (n) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

³²⁾ Article 2 (31) amended by Article 1 (1) (n) of the Act of 30 March 2007 ([Journal of Laws 07.75.492](#)) amending this Act on 1 May 2007

- ³³⁾ Article 2 (32) amended by Article 1 (1) (n) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ³⁴⁾ Article 2 (33) repealed by Article 1 (1) (o) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ³⁵⁾ Article 2 (35) amended by Article 1 (1) (p) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ³⁶⁾ Article 2 (35a) added by Article 1 (1) (r) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ³⁷⁾ Article 2 (35b) added by Article 1 (1) (r) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ³⁸⁾ Article 2 (35c) added by Article 1 (1) (r) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ³⁹⁾ Article 2 (36) repealed by Article 1 (2) (n) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- ⁴⁰⁾ Article 2 (37a) added by Article 1 (2) (o) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- ⁴¹⁾ Article 2 (37b) added by Article 1 (1) (s) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ⁴²⁾ Article 2 (39) repealed by Article 1 (1) (t) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ⁴³⁾ Article 2 (40a) added by Article 1 (2) (p) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- ⁴⁴⁾ Article 2 (42a) added by Article 1 (1) (u) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ⁴⁵⁾ Article 2 (43):
- amended by Article 1 (2) (r) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
 - amended by Article 42 (1) (b) of the Act – Regulations Introducing the Act on Business Activity Freedom of 2 July 2004 (Journal of Laws 04.173.1808) on 21 August 2004
- ⁴⁶⁾ Article 2 (44) amended by Article 1 (2) (s) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- ⁴⁷⁾ Article 3 (2):
- shall be applicable from on the day of European Union accession by the Republic of Poland, in accordance with Article 2 of the Act of 6 September 2001 – Regulations Introducing the Act – Pharmaceutical Law, the Act on Medical Devices, and the Act on the Office for the Registration of Medicinal Products, Medical Devices and Biocides (Journal of Laws 01.126.1382) which entered into effect on 1 October 2002
 - amended by Article 1 (3) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- ⁴⁸⁾ Article 3 (4) (4) amended by Article 1 (2) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ⁴⁹⁾ Article 3 (4) (6) added by Article 1 (3) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- ⁵⁰⁾ Article 3a added by Article 1 (3) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ⁵¹⁾ Article 4 (3) (2) amended by Article 1 (4) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ⁵²⁾ Article 4 (3a) added by Article 1 (4) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁵³⁾ Article 4 (7) (1) repealed by Article 1 (4) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁵⁴⁾ Article 4 (7) (2) (c) amended by Article 220 (1) of the Act on Healthcare Services Funded from Public Funds of 27 August 2004 (Journal of Laws 04.210.2135) on 1 October 2004

⁵⁵⁾ Article 4 (9):

- added by Article 1 (4) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (4) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁵⁶⁾ Article 4a added by Article 1 (5) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

⁵⁷⁾ Article 4b added by Article 1 (5) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁵⁸⁾ Article 5 amended by Article 1 (6) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

⁵⁹⁾ Article 6 repealed by Article 1 (7) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

⁶⁰⁾ Article 7 (1) amended by Article 1 (8) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

⁶¹⁾ Article 7 (3) amended by Article 1 (6) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁶²⁾ Article 7 (4):

- amended by Article 1 (8) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (6) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁶³⁾ Article 7a added by Article 1 (7) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁶⁴⁾ Article 7b added by Article 1 (7) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁶⁵⁾ Article 8 (1) amended by Article 1 (8) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁶⁶⁾ Article 8 (1a) (2) amended by Article 1 (8) (b) first indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁶⁷⁾ Article 8 (1a) (3) amended by Article 1 (8) (b) first indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁶⁸⁾ Article 8 (1a) (5) added by Article 1 (8) (b) second indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁶⁹⁾ Article 8 (1b) added by Article 1 (8) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁷⁰⁾ Article 8 (1c) added by Article 1 (8) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁷¹⁾ Article 8 (1d) added by Article 1 (8) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁷²⁾ Article 8 (3) amended by Article 1 (9) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

⁷³⁾ Article 8 (4) amended by Article 1 (9) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

⁷⁴⁾ Article 8 (5) added by Article 1 (8) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁷⁵⁾ Article 8a added by Article 1 (9) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁷⁶⁾ Article 9 amended by Article 1 (10) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁷⁷⁾ Article 10 (1):

- introduction to the listing amended by Article 1 (10) (a) first indent of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (11) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁷⁸⁾ Article 10 (2) amended by Article 1 (11) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁷⁹⁾ Article 10 (2a) added by Article 1 (11) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁸⁰⁾ Article 10 (2b) added by Article 1 (11) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁸¹⁾ Article 10 (3) amended by Article 1 (11) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁸²⁾ Article 10 (4):

- amended by Article 1 (10) (c) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (11) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁸³⁾ Article 10 (4a) added by Article 1 (11) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁸⁴⁾ Article 10 (5) amended by Article 1 (11) (e) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁸⁵⁾ Article 10 (6):

- amended by Article 1 (10) (d) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (11) (f) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁸⁶⁾ Article 10 (6a) added by Article 1 (10) (e) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

⁸⁷⁾ Article 10 (7) amended by Article 1 (11) (g) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁸⁸⁾ Article 10 (8) added by Article 1 (11) (h) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁸⁹⁾ Article 10 (9) added by Article 1 (11) (h) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁹⁰⁾ Article 11 amended by Article 1 (12) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁹¹⁾ Article 12 sentence initially amended by Article 1 (13) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁹²⁾ Article 13 (1) amended by Article 1 (14) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁹³⁾ Article 13 (3) amended by Article 1 (14) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁹⁴⁾ Article 14 repealed by Article 1 (15) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁹⁵⁾ Article 15 amended by Article 1 (16) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁹⁶⁾ Article 15a added by Article 1 (17) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁹⁷⁾ Article 16 amended by Article 1 (18) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁹⁸⁾ Article 16a added by Article 1 (19) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

⁹⁹⁾ Article 17 (1) amended by Article 1 (20) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁰⁰⁾ Article 17 (1a) amended by Article 1 (20) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁰¹⁾ Article 17 (2) amended by Article 1 (20) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁰²⁾ Article 17 (2a) added by Article 1 (20) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁰³⁾ Article 17 (3):

- amended by Article 1 (13) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (20) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁰⁴⁾ Article 18 (1):

- amended by Article 1 (14) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (21) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁰⁵⁾ Article 18 (1a) added by Article 1 (14) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹⁰⁶⁾ Article 18 (1b) added by Article 1 (14) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹⁰⁷⁾ Article 18 (2):

- shall be applicable from the day of European Union accession by the Republic of Poland, in accordance with Article 2 of the Act of 6 September 2001 – Regulations Introducing the Act – Pharmaceutical Law, the Act on Medical Devices, and the Act on the Office for the Registration of Medicinal Products, Medical Devices and Biocides (Journal of Laws 01.126.1382) which entered into effect on 1 October 2002

- amended by Article 1 (14) (c) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹⁰⁸⁾ Article 18 (3):

- shall be applicable from the day of European Union accession by the Republic of Poland, in accordance with Article 2 of the Act of 6 September 2001 – Regulations Introducing the Act – Pharmaceutical Law, the Act on Medical Devices, and the Act on the Office for the Registration of Medicinal Products, Medical Devices and Biocides (Journal of Laws 01.126.1382) which entered into effect on 1 October 2002

- amended by Article 1 (14) (c) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹⁰⁹⁾ Article 18a added by Article 1 (22) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹¹⁰⁾ Article 19:

- shall be applicable from the day of European Union accession by the Republic of Poland, in accordance with Article 2 of the Act of 6 September 2001 – Regulations Introducing the Act – Pharmaceutical Law, the Act on Medical Devices, and the Act on the Office for the Registration of Medicinal Products, Medical Devices and Biocides (Journal of Laws 01.126.1382) which entered into effect on 1 October 2002

- amended by Article 1 (15) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (23) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹¹¹⁾ Article 19a:

- added by Article 1 (16) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- amended by Article 1 (24) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹¹²⁾ Article 19b:

- added by Article 1 (16) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- amended by Article 1 (24) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹¹³⁾ Article 19c:

- added by Article 1 (16) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- amended by Article 1 (24) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹¹⁴⁾ Article 19d added by Article 1 (25) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹¹⁵⁾ Article 19e added by Article 1 (25) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹¹⁶⁾ Article 20 (1) (6) amended by Article 1 (26) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹¹⁷⁾ Article 20a added by Article 1 (27) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹¹⁸⁾ Article 20b added by Article 1 (27) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹¹⁹⁾ Article 21 (1) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹²⁰⁾ Article 21 (2) (1):

- amended by Article 1 (17) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- amended by Article 1 (28) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹²¹⁾ Article 21 (2) (2) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹²²⁾ Article 21 (2) (6) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹²³⁾ Article 21 (3) (1) amended by Article 1 (28) (b) first indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹²⁴⁾ Article 21 (3) (3a) added by Article 1 (17) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹²⁵⁾ Article 21 (3) (4) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹²⁶⁾ Article 21 (3) (8) amended by Article 1 (28) (b) second indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹²⁷⁾ Article 21 (3) (9) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹²⁸⁾ Article 21 (4):

- amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (28) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹²⁹⁾ Article 21 (5) (2) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹³⁰⁾ Article 21 (5) (3) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹³¹⁾ Article 21 (6) (1):

- amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (28) (d) first indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹³²⁾ Article 21 (6) (2) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹³³⁾ Article 21 (6) (9) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹³⁴⁾ Article 21 (6) (10) (c) added by Article 1 (28) (d) second indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹³⁵⁾ Article 21 (7) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹³⁶⁾ Article 21 (7a):

- added by Article 1 (17) (c) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (28) (e) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹³⁷⁾ Article 21a added by Article 1 (18) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹³⁸⁾ Article 21a (3a) added by Article 1 (29) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹³⁹⁾ Article 21a (3b) added by Article 1 (29) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁴⁰⁾ Article 21a (4) amended by Article 1 (29) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁴¹⁾ Article 21a (8a) added by Article 1 (29) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁴²⁾ Article 21a (9) amended by Article 1 (29) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁴³⁾ Article 21a (9a) added by Article 1 (29) (e) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁴⁴⁾ Article 23 (1) (2) amended by Article 1 (30) (a) first indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁴⁵⁾ Article 23 (1) (4a) added by Article 1 (30) (a) second indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁴⁶⁾ Article 23 (1) (12) added by Article 1 (19) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹⁴⁷⁾ Article 23 (1) (13) added by Article 1 (30) (a) third indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁴⁸⁾ Article 23 (1) (14) added by Article 1 (30) (a) third indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁴⁹⁾ Article 23 (3) amended by Article 1 (30) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁵⁰⁾ Article 23 (3a) added by Article 1 (30) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁵¹⁾ Article 23 (4) added by Article 1 (19) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹⁵²⁾ Article 23a added by Article 1 (31) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁵³⁾ Article 23b added by Article 1 (31) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁵⁴⁾ Article 24 (1) amended by Article 1 (32) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁵⁵⁾ Article 24 (2) amended by Article 1 (32) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁵⁶⁾ Article 24 (3) amended by Article 1 (32) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁵⁷⁾ Article 24 (3a) added by Article 1 (32) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁵⁸⁾ Article 24 (3b) added by Article 1 (32) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁵⁹⁾ Article 24 (3c) added by Article 1 (32) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁶⁰⁾ Article 24a added by Article 1 (33) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁶¹⁾ Article 25:

- amended by Article 1 (21) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (34) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁶²⁾ Article 26 (1a) added by Article 1 (35) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁶³⁾ Article 26 (1b) added by Article 1 (35) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁶⁴⁾ Article 26 (1c) added by Article 1 (35) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁶⁵⁾ Article 26 (1d) added by Article 1 (35) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁶⁶⁾ Article 26 (1e) added by Article 1 (35) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁶⁷⁾ Article 26 (2):

- amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (35) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁶⁸⁾ Article 26 (3) added by Article 1 (35) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁶⁹⁾ Article 29 (1) amended by Article 1 (22) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹⁷⁰⁾ Article 29 (2):

- amended by Article 1 (22) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (36) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁷¹⁾ Article 29 (2a) added by Article 1 (36) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁷²⁾ Article 29 (3a):

- added by Article 1 (22) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (36) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁷³⁾ Article 29 (5):

- amended by Article 1 (22) (c) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (36) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁷⁴⁾ Article 29 (6) added by Article 1 (36) (e) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁷⁵⁾ Article 29 (7) added by Article 1 (36) (e) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁷⁶⁾ Shall be applicable from the day of European Union accession by the Republic of Poland, in accordance with Article 2 of the Act of 6 September 2001 – Regulations Introducing the Act – Pharmaceutical Law, the Act on Medical Devices, and the Act on the Office for the Registration of Medicinal Products, Medical Devices and Biocides (Journal of Laws 01.126.1382) which entered into effect on 1 October 2002

¹⁷⁷⁾ Article 30 (6) added by Article 1 (37) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁷⁸⁾ Article 31 (1a) added by Article 1 (38) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁷⁹⁾ Article 31 (1b) added by Article 1 (38) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁸⁰⁾ Article 32 (1) amended by Article 1 (23) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹⁸¹⁾ Article 33 (1) (3) amended by Article 1 (39) (a) first indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁸²⁾ Article 33 (1) (3a) added by Article 1 (39) (a) second indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁸³⁾ Article 33 (1) (6) added by Article 1 (39) (a) third indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁸⁴⁾ Article 33 (1) (7) added by Article 1 (39) (a) third indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁸⁵⁾ Article 33 (1) (8) added by Article 1 (39) (a) third indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁸⁶⁾ Article 33 (1) (9) added by Article 1 (39) (a) third indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁸⁷⁾ Shall be applicable from the day of European Union accession by the Republic of Poland, in accordance with Article 2 of the Act of 6 September 2001 – Regulations Introducing the Act – Pharmaceutical Law, the Act on Medical Devices, and the Act on the Office for the Registration of Medicinal Products, Medical Devices and Biocides (Journal of Laws 01.126.1382) which entered into effect on 1 October 2002

¹⁸⁸⁾ Article 33 (4) added by Article 1 (39) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁸⁹⁾ Article 33 (5) added by Article 1 (39) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁹⁰⁾ Article 33a added by Article 1 (40) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁹¹⁾ Article 35 amended by Article 1 (24) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹⁹²⁾ Article 36:

- amended by Article 1 (25) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (41) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁹³⁾ Article 36a:

- added by Article 1 (26) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (41) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁹⁴⁾ Article 37 amended by Article 1 (42) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁹⁵⁾ Chapter 2a added by Article 1 (27) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

¹⁹⁶⁾ Article 37k (3) amended by Article 1 (43) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁹⁷⁾ Article 37k (4) added by Article 1 (43) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁹⁸⁾ Article 37l (2) amended by Article 1 (44) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

¹⁹⁹⁾ Article 37o amended by Article 1 (45) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁰⁰⁾ Article 37w (1) amended by Article 1 (46) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁰¹⁾ Article 37w (2) amended by Article 1 (46) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁰²⁾ Article 37w (2a) added by Article 1 (46) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁰³⁾ Article 37w (2b) added by Article 1 (46) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁰⁴⁾ Article 37w (2c) added by Article 1 (46) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁰⁵⁾ Article 37x (1) amended by Article 1 (47) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁰⁶⁾ Article 37x (3) amended by Article 1 (47) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁰⁷⁾ Article 37aa (1) amended by Article 1 (48) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁰⁸⁾ Article 37aa (2) amended by Article 1 (48) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁰⁹⁾ Article 37aa (3) amended by Article 1 (48) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²¹⁰⁾ Article 37aa (5) amended by Article 1 (48) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²¹¹⁾ Article 37aa (6) amended by Article 1 (48) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²¹²⁾ Chapter 2b added by Article 42 (2) of the Act – Regulations Introducing the Act on Business Activity Freedom of 2 July 2004 (Journal of Laws 04.173.1808) on 21 August 2004

²¹³⁾ Title amended by Article 1 (28) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

²¹⁴⁾ Article 38 (1a) added by Article 1 (29) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on 30 April 2004

²¹⁵⁾ Article 38 (2):

- amended by Article 1 (1) (a) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005

- amended by Article 1 (49) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²¹⁶⁾ Article 38 (3) repealed by Article 1 (49) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²¹⁷⁾ Article 38 (3a):

- added by Article 1 (29) (c) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on 30 April 2004

- amended by Article 1 (1) (b) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005

²¹⁸⁾ Article 38 (4):

- introduction to the listing amended by Article 1 (29) (d) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on 30 April 2004

- amended by Article 1 (49) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²¹⁹⁾ Article 38 (5) amended by Article 1 (49) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²²⁰⁾ Article 38 (6) amended by Article 1 (49) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²²¹⁾ Article 38 (7) amended by Article 1 (29) (e) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

²²²⁾ Article 38 (8) repealed by Article 1 (49) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²²³⁾ Article 38 (9) added by Article 1 (49) (e) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²²⁴⁾ Article 39 (1) (1) amended by Article 42 (4) of the Act – Regulations Introducing the Act on Business Activity Freedom of 2 July 2004 (Journal of Laws 04.173.1808) on 21 August 2004

²²⁵⁾ Article 39 (1a) added by Article 1 (2) (a) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005

²²⁶⁾ Article 39 (2) amended by Article 1 (2) (b) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005

²²⁷⁾ Article 39 (4) amended by Article 1 (2) (c) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005

²²⁸⁾ Article 39 (4) (1) amended by Article 1 (50) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²²⁹⁾ Article 40 (1) amended by Article 1 (3) (a) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005

²³⁰⁾ Article 40 (1a) added by Article 1 (3) (b) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005

²³¹⁾ Article 40 (3) amended by Article 1 (3) (c) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005

²³²⁾ Article 41 (4) amended by Article 1 (4) (a) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005

²³³⁾ Article 41 (5) amended by Article 1 (4) (b) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005

²³⁴⁾ Article 42 (1) (1a) added by Article 220 (2) of the Act on Healthcare Services Funded from Public Funds of 27 August 2004 (Journal of Laws 04.210.2135) on 1 October 2004

²³⁵⁾ Article 42 (1) (4) amended by Article 1 (51) (a) first indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

- ²³⁶⁾ Article 42 (1) (6) amended by Article 1 (51) (a) second indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²³⁷⁾ Article 42 (1) (7) added by Article 1 (51) (a) third indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²³⁸⁾ Article 42 (3) added by Article 1 (51) lit b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²³⁹⁾ Article 43 (1) amended by Article 1 (5) (a) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005
- ²⁴⁰⁾ Article 43 (3) amended by Article 1 (5) (b) of the Act of 21 April 2005 (Journal of Laws 05.94.787) amending this Act on 14 June 2005
- ²⁴¹⁾ Article 43 (4) amended by Article 1 (52) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁴²⁾ Article 44 repealed by Article 42 (5) of the Act – Regulations Introducing the Act on Business Activity Freedom of 2 July 2004 (Journal of Laws 04.173.1808) on 21 August 2004
- ²⁴³⁾ Article 45 repealed by Article 2 (2) of the Act Amending the Act on Animal Feedingstuffs and Certain Other Acts of 2 April 2004 (Journal of Laws 04.91.877) on the day of European Union accession by the Republic of Poland.
- ²⁴⁴⁾ Article 46 amended by Article 1 (53) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁴⁵⁾ Article 47 (3) (2) amended by Article 1 (54) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁴⁶⁾ Article 47a:
- added by Article 1 (30) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
 - amended by Article 1 (55) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁴⁷⁾ Article 47b:
- added by Article 1 (30) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
 - amended by Article 1 (56) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁴⁸⁾ Article 47c added by Article 1 (57) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁴⁹⁾ Article 48 (1) (2):
- amended by Article 1 (31) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
 - amended by Article 1 (58) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁵⁰⁾ Article 48 (2):
- shall be applicable from the day of European Union accession by the Republic of Poland, in accordance with Article 2 of the Act of 6 September 2001 – Regulations Introducing the Act – Pharmaceutical Law, the Act on Medical Devices, and the Act on the Office for the Registration of Medicinal Products, Medical Devices and Biocides (Journal of Laws 01.126.1382) which entered into effect on 1 October 2002
 - amended by Article 1 (31) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- ²⁵¹⁾ Shall be applicable from the day of European Union accession by the Republic of Poland, in accordance with Article 2 of the Act of 6 September 2001 – Regulations Introducing the Act – Pharmaceutical Law, the Act on Medical Devices, and the Act on the Office for the Registration of Medicinal Products, Medical Devices and Biocides (Journal of Laws 01.126.1382) which entered into effect on 1 October 2002
- ²⁵²⁾ Article 51a added by Article 1 (59) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁵³⁾ Article 52 (1) amended by Article 1 (60) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

- ²⁵⁴⁾ Article 52 (2) amended by Article 1 (60) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁵⁵⁾ Article 52 (3) amended by Article 1 (60) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁵⁶⁾ Article 52 (4) repealed by Article 3 of the Act Amending the Personal Income Act and Certain Other Acts (Journal of Laws 06.217.1588) on 1 January 2007
- ²⁵⁷⁾ Article 53 amended by Article 1 (61) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁵⁸⁾ Article 54 amended by Article 1 (61) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007, although paragraph 1 of this Article, as regards the information on the assigned dispensing category, on the official retail price and on the maximum amount of supplementary payment made by the patient shall enter into effect on 27 October 2007
- ²⁵⁹⁾ Article 55 amended by Article 1 (61) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007, although paragraph 1 of this Article, as regards celebrities, shall enter into effect on 27 October 2007
- ²⁶⁰⁾ Article 56 amended by Article 1 (61) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁶¹⁾ Article 57 (1a) added by Article 1 (62) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁶²⁾ Article 57 (2) amended by Article 1 (62) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁶³⁾ Article 58 (3) amended by Article 1 (63) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁶⁴⁾ Article 59 amended by Article 1 (64) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁶⁵⁾ Article 60 (5) added by Article 1 (65) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁶⁶⁾ Article 61 (3) added by Article 1 (66) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁶⁷⁾ Article 62 (2) amended by Article 1 (33) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- ²⁶⁸⁾ Article 62 (3) amended by Article 1 (33) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.
- ²⁶⁹⁾ Article 65 (4) amended by Article 1 (67) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁷⁰⁾ Article 65 (6) amended by Article 1 (67) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁷¹⁾ Article 65 (7) amended by Article 1 (67) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁷²⁾ Article 65 (8) repealed by Article 1 (67) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁷³⁾ Article 65 (9) amended by Article 1 (67) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁷⁴⁾ Article 65 (10) (2) amended by Article 1 (67) (e) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁷⁵⁾ Article 65 (10) (2a) amended by Article 1 (67) (e) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007
- ²⁷⁶⁾ Article 67 (2) amended by Article 89 (1) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.
- ²⁷⁷⁾ Article 68 (2) amended by Article 1 (68) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁷⁸⁾ Article 68 (2a) added by Article 1 (68) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁷⁹⁾ Article 68 (3) amended by Article 1 (68) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁸⁰⁾ Article 68 (3a) added by Article 1 (68) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁸¹⁾ From the day of European Union accession by the Republic of Poland – the dentist, consistently with Article 3 of the Act Amending the Physician's Profession Act and the Act Amending the Physician's Profession Act and Amending Other Acts of 10 April 2003 (Journal of Laws 03.90.845) which entered into effect on 6 June 2003

²⁸²⁾ Article 68 (4a) added by Article 1 (35) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

²⁸³⁾ Article 68 (6):

- amended by Article 79 of the Act on Drug Prevention of 29 July 2005 (Journal of Laws 05.179.1485) on 4 October 2005

- amended by Article 1 (68) (e) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁸⁴⁾ Article 69 amended by Article 1 (69) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁸⁵⁾ Article 70 (3) amended by Article 1 (37) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

²⁸⁶⁾ Article 70 (5) amended by Article 89 (2) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

²⁸⁷⁾ Article 70 (6) amended by Article 1 (70) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁸⁸⁾ Article 70 (7) amended by Article 1 (70) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁸⁹⁾ Article 71 (1) amended by Article 1 (71) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁹⁰⁾ Article 71 (1a) added by Article 1 (71) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁹¹⁾ Article 71 (3) amended by Article 1 (71) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁹²⁾ Article 71 (4) added by Article 1 (71) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁹³⁾ Article 71 (5) added by Article 1 (71) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁹⁴⁾ Article 72 (1) amended by Article 1 (38) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

²⁹⁵⁾ Article 72 (3) amended by Article 1 (72) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁹⁶⁾ Article 72 (3a) added by Article 1 (72) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁹⁷⁾ Article 72 (4) amended by Article 1 (38) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

²⁹⁸⁾ Article 72 (5) (1a) added by Article 1 (72) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

²⁹⁹⁾ Article 72 (5) (2) amended by Article 1 (38) (c) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³⁰⁰⁾ Article 72 (5) (2a) amended by Article 110 of the Act on Nutrition and Diet Safety of 25 August 2006 (Journal of Laws 06.171.1225) on 28 October 2006

³⁰¹⁾ Article 72 (7) amended by Article 1 (72) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁰²⁾ Article 73 repealed by Article 42 (6) of the Act – Regulations Introducing the Act on Business Activity Freedom of 2 July 2004 (Journal of Laws 04.173.1808) on 21 August 2004

³⁰³⁾ Article 74 (3) amended by Article 1 (73) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁰⁴⁾ Article 74 (6a) added by Article 1 (73) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁰⁵⁾ Article 74 (6b) added by Article 1 (73) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁰⁶⁾ Article 74 (7) amended by Article 1 (73) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁰⁷⁾ Article 75 (2) (2) amended by Article 1 (39) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³⁰⁸⁾ Article 75 (2) (3) amended by Article 1 (39) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³⁰⁹⁾ Article 75 (2) (6) added by Article 1 (39) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³¹⁰⁾ Article 75 (2) (7) added by Article 1 (39) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³¹¹⁾ Article 76 (6) repealed by Article 1 (40) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³¹²⁾ Article 76a added by Article 1 (41) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³¹³⁾ Article 78 (1) (1) amended by Article 89 (3) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³¹⁴⁾ Article 78 (1) (6) amended by Article 1 (74) (a) first indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³¹⁵⁾ Article 78 (1) (7) added by Article 1 (74) (a) second indent of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³¹⁶⁾ Article 78 (4) added by Article 1 (74) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³¹⁷⁾ Article 81 (1) amended by Article 42 (7) of the Act – Regulations Introducing the Act on Business Activity Freedom of 2 July 2004 (Journal of Laws 04.173.1808) on 21 August 2004

³¹⁸⁾ Article 81 (5) added by Article 1 (75) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³¹⁹⁾ Article 82 amended by Article 1 (76) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³²⁰⁾ Article 84 (2) amended by Article 1 (77) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³²¹⁾ Article 85 (1) amended by Article 1 (78) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³²²⁾ Article 88 (2) amended by Article 1 (42) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³²³⁾ Article 88 (2a) repealed by Article 1 (42) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³²⁴⁾ Article 88 (5) (5) amended by Article 89 (4) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³²⁵⁾ Article 94a added by Article 1 (79) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³²⁶⁾ Article 95 (4) (3) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³²⁷⁾ Article 97 (4) amended by Article 1 (55) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³²⁸⁾ Article 99 (3) (2):

- amended by Article 1 (43) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 122 of the Act on Competition and Consumer Protection (Journal of Laws 07.50.331) on 21 April 2007

³²⁹⁾ Article 99 (3) (3) amended by Article 1 (43) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³³⁰⁾ From the day of European Union accession by the Republic of Poland – the dentist, consistently with Article 3 of the Act Amending the Physician's Profession Act and the Act Amending the Physician's Profession Act and Amending Other Acts of 10 April 2003 (Journal of Laws 03.90.845) which entered into effect on 6 June 2003

³³¹⁾ Article 100 (1) (2) amended by Article 1 (44) (a) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³³²⁾ Currently: of the State Sanitary Inspection, in accordance with Article 5 of the Act Amending the Act on the Sanitary Inspection and Amending Other Acts of 1 March 2002 (Journal of Laws 02.37.329) which entered into effect on 27 April 2002

³³³⁾ Article 100 (2) (6) added by Article 1 (44) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³³⁴⁾ Article 100 (2) (7) added by Article 1 (44) (b) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³³⁵⁾ Article 101 (2) amended by Article 1 (45) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³³⁶⁾ Article 103 (1) amended by Article 42 (8) of the Act – Regulations Introducing the Act on Business Activity Freedom of 2 July 2004 (Journal of Laws 04.173.1808) on 21 August 2004

³³⁷⁾ Article 103 (2) (5) added by Article 1 (80) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³³⁸⁾ Article 104 (1a) added by Article 1 (81) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³³⁹⁾ Article 104 (1b) added by Article 1 (81) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁴⁰⁾ Article 105 amended by Article 1 (82) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁴¹⁾ Title amended by Article 1 (46) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³⁴²⁾ Article 108 (1):

- amended by Article 1 (47) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (82) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁴³⁾ Article 108 (2) repealed by Article 1 (83) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁴⁴⁾ Article 108 (3) repealed by Article 1 (83) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁴⁵⁾ Article 108 (4) (1) amended by Article 89 (5) (a) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³⁴⁶⁾ Article 108 (4) (2) amended by Article 89 (5) (a) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³⁴⁷⁾ Article 108 (4) (4) amended by Article 89 (5) (b) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³⁴⁸⁾ Article 108 (4) (5) amended by Article 89 (5) (b) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³⁴⁹⁾ Article 108 (4) (6) repealed by Article 89 (5) (c) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³⁵⁰⁾ Article 108 (4) (7) added by Article 1 (83) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁵¹⁾ Article 108 (5) repealed by Article 1 (83) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁵²⁾ Article 108a added by Article 1 (84) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁵³⁾ Article 109 (1):

- amended by Article 1 (48) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (85) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁵⁴⁾ Article 109 (1a) added by Article 1 (85) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁵⁵⁾ Article 109 (2) amended by Article 89 (6) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³⁵⁶⁾ Article 109 (3) amended by Article 89 (6) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³⁵⁷⁾ Article 111 (1):

- amended by Article 37 (1) of the Act on Competitions for Managers of Central Government Administration Offices, State Agency Presidents and Presidents of Management Board of State Specified Funds of 27 July 2005 (Journal of Laws 05.163.1362) on 1 September 2005

- amended by Article 63 of the Act on the State Staffing Resource and High State Positions of 24 August 2006 (Journal of Laws 06.170.1217) on 27 October 2006

³⁵⁸⁾ Article 111 (2) repealed by Article 37 (2) of the Act on Competitions for Managers of Central Government Administration Offices, State Agency Presidents and Presidents of Management Board of State Specified Funds of 27 July 2005 (Journal of Laws 05.163.1362) on 1 September 2005

³⁵⁹⁾ Article 111 (3) amended by Article 63 of the Act on the State Staffing Resource and High State Positions of 24 August 2006 (Journal of Laws 06.170.1217) on 27 October 2006

³⁶⁰⁾ Article 114 (2) amended by Article 1 (86) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁶¹⁾ Article 114 (3) amended by Article 1 (86) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁶²⁾ Article 114 (4) – (7) repealed by Article 1 (86) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁶³⁾ Article 115 (5a):

- added by Article 1 (49) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (87) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁶⁴⁾ Article 115 (6) amended by Article 1 (87) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁶⁵⁾ Article 115 (7) repealed by Article 1 (87) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁶⁶⁾ Article 115 (9) amended by Article 1 (87) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁶⁷⁾ Article 116 (5) amended by Article 51 (1) of the Act Amending the Act on Public Finance and Amending Other Acts of 25 November 2004 (Journal of Laws 04.273.2703) on 1 January 2005

³⁶⁸⁾ Article 116 (6) – (8) repealed by Article 51 (2) of the Act Amending the Act on Public Finance and Amending Other Acts of 25 November 2004 (Journal of Laws 04.273.2703) on 1 January 2005

³⁶⁹⁾ Article 118 (2):

- amended by Article 1 (50) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

- amended by Article 1 (88) (a) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁷⁰⁾ Article 118 (2a) added by Article 1 (88) (b) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁷¹⁾ Article 118 (4) amended by Article 1 (88) (c) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁷²⁾ Article 118 (6) added by Article 1 (88) (d) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁷³⁾ Article 119 (1) amended by Article 1 (89) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁷⁴⁾ Article 119 (2) amended by Article 1 (89) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁷⁵⁾ Article 120 (1) amended by Article 1 (90) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁷⁶⁾ Article 120a added by Article 1 (91) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁷⁷⁾ Article 121 (1) amended by Article 89 (7) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³⁷⁸⁾ Article 121 (2) amended by Article 89 (7) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³⁷⁹⁾ Article 121 (3) amended by Article 89 (7) of the Act on Medical Devices of 20 April 2004 (Journal of Laws 04.93.896) on the day of European Union accession by the Republic of Poland.

³⁸⁰⁾ Article 121a amended by Article 1 (92) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁸¹⁾ Article 122a added by Article 1 (93) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁸²⁾ Article 123 amended by Article 1 (94) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁸³⁾ Article 125 amended by Article 1 (53) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³⁸⁴⁾ Article 126a added by Article 1 (95) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁸⁵⁾ Article 128 amended by Article 1 (96) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁸⁶⁾ Article 129 amended by Article 1 (97) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁸⁷⁾ Article 129a added by Article 1 (98) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁸⁸⁾ Article 129b added by Article 1 (98) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007

³⁸⁹⁾ Article 132c added by Article 1 (54) of the Act of 20 April 2004 (Journal of Laws 04.92.882) amending this Act on the day of European Union accession by the Republic of Poland.

³⁹⁰⁾ Article 132d added by Article 1 (99) of the Act of 30 March 2007 (Journal of Laws 07.75.492) amending this Act on 1 May 2007