Act XCV of 2005

on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products

The purpose of this Act is to set forth the fundamental regulations pertaining to medicinal products, the supply of medicinal products and the rights of users of medicinal products, in harmony with Community legislation and international regulations and recommendations.

Responsibility for laying down provisions for the supply of medicinal products shall lie with the State. As part of this duty, the State shall determine the set of requirements necessary to ensure that persons in need of safe and effective medicinal products, whose quality is in conformity with statutory requirements, shall be able to obtain them on a regular basis.

As part of the State's responsibilities for the preservation and restoration of human health, and guided by its responsibility for such,

in light of the fact that the essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health, and that the measures adopted within the framework of public policies concerning the distribution and use of medicinal products are aimed to ensure any person in need shall have access to sufficient medicinal products for treatment,

recognizing, however, that, characteristic of the market of medicinal products for human use, the users of medicinal products or the patients have little influence at this time on selecting the medicinal product that is right for them, and

in addition to the above, taking into consideration that this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community,

Parliament has adopted the following Act:

Section 1.

For the purposes of this Act:

1) 'medicinal product' shall mean any substance or combination of substances presented for treating or preventing disease in human beings or any substance or combination of substances which may be used in or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

2) 'magistral formula' shall mean any medicinal product prepared by a pharmacist in a pharmacy in accordance with the instructions set out in the Hungarian or European Pharmacopoeia (hereinafter referred to as "Pharmacopoeia") or in the Catalogue of Standard Prescriptions (Fo-No) (hereinafter referred to as "Catalogue of Prescriptions") in accordance with a doctor's prescription or upon his own initiative in accordance with the prescriptions of the Pharmacopoeia and which is intended to be supplied directly to the patients served by the pharmacy in question;

3) 'homeopathic medicinal product' shall mean any medicinal product prepared from substances called homeopathic stocks made according to the homeopathic manufacturing procedure described by the Pharmacopoeia in accordance with a homeopathic manufacturing procedure described by the Pharmacopoeia; a homeopathic medicinal product may contain a number of principles;

4) 'narcotic drug' shall mean the substances listed in Annex I and II of the Schedule to Law-Decree No. 4 of 1965 promulgating the Single Convention on Narcotic Drugs done at New York on 30 March 1961;

4/a) 'medicinal product classified as a narcotic drug' shall mean any medicinal product that contains any active substance that is classified as narcotic and listed in Annex I and II of the Schedule to Law-Decree No. 4 of 1965 promulgating the Single Convention on Narcotic Drugs done at New York on 30 March 1961;

5) 'psychotropic substance' shall mean the substances listed in Annexes I-IV of Law-Decree No. 25 of 1979 promulgating the Convention on Psychotropic Substances done at Vienna on 21 February 1971, as well as the substances listed in Appendix A) and B) of the Schedule to the Act on Medicinal Products for Human Use;

5/a) 'medicinal product classified as a psychotropic substance' shall mean any medicinal product that contains any active substance that is classified as a psychotropic substance and listed in Annexes II-IV of Law-Decree No. 25 of 1979 promulgating the Convention on Psychotropic Substances done at Vienna on 21 February 1971, as well as the substances listed in Appendix B) of the Schedule to the Act on Medicinal Products for Human Use;

6) 'investigational medicinal product' shall mean a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products that already have a marketing authorization but are used or assembled (formulated or packaged) in clinical trials in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form of the medicinal product in question;

7) 'clinical trial' shall mean any investigation in human subjects conducted at a single site or according to a single protocol but at more than one site:

a) intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or,

b) to identify any adverse reactions to one or more investigational medicinal product(s) and/or,

c) to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy, and the risk-benefit balance,

not including non-interventional trials;

8) 'non-interventional trial' shall mean a study:

a) where the medicinal product(s) with a marketing authorization is (are) prescribed not for the trial;

b) where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization;

c) where the assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study;

d) where no additional diagnostic or monitoring procedures are applied to the patients; and

e) where only epidemiological methods are used for the analysis of collected data;

9) 'marketing authorization holder' shall mean a natural or legal person or unincorporated organization, to whom the competent authority has granted authorization for the marketing of a specific medicinal product;

10) 'representative of the marketing authorization holder' shall mean a natural or legal person or unincorporated organization designated by the marketing authorization holder to represent him in the territory of the Republic of Hungary in the cases specified by the marketing authorization holder;

11) 'manufacture of medicinal products' shall mean the authorized production of medicinal products in a controlled industrial environment;

12) 'production batch' shall mean a specific quantity of starting materials, packaging materials or products produced during a continuous manufacturing process or a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such;

13) 'name of the medicinal product' shall mean the name given to a medicinal product as indicated in the marketing authorization, which may be either an invented name (which shall not be liable to be confused with the common name used), or a common or scientific name, together with a trade mark or the name of the marketing authorization holder;

14) 'international non-proprietary name' shall mean the common name recommended by the World Health Organization, or, if one does not exist, the usual common name used;

15) 'classification of a medicinal product' shall mean the category of a medicinal product that is indicated in the marketing authorization, or in connection with magistral formulas in the Pharmacopoeia or the Catalogue of Prescriptions, declaring it a prescription or non-prescription medicinal product;

16) 'non-prescription medicinal product' shall mean all medicinal products qualified as such by the licensing authority in the marketing authorization, or in the case of magistral formulas, which are qualified as such in the Pharmacopoeia or the Catalogue of Prescriptions;

17) 'summary of product characteristics' shall mean a guide contained in the marketing authorization and addressed to doctors and pharmacists, containing the particulars, dosage and administration and characteristics of the medicinal product in question;

18) 'package leaflet' shall mean a leaflet containing information for the user (patient) in a comprehensible manner according to this Act, which accompanies the medicinal product;

19) 'immediate packaging' shall mean the container or other form of packaging immediately in contact with the medicinal product;

20) 'outer packaging' shall mean the packaging into which is placed the immediate packaging;

21. ‘Pharmacopoeia’ shall mean the official publication, published and amended by the government body for pharmaceuticals for mandatory use by the manufacturers and distributors of medicinal products and for doctors and pharmacists, containing the general rules for the manufacture of medicinal products, the quality of medicinal products and pharmaceutical ingredients, the control of medicinal products and the classification of medicinal products, and the quality norms and composition of certain medicinal products;

22. ‘Standard Catalogue of Prescriptions (Fo-No)’ shall mean the official publication, published and amended by the government body for pharmaceuticals for mandatory use by the manufacturers and distributors of medicinal products and for doctors and pharmacists, containing regulations for the preparation of magistral formulas, and the quality norms and composition of certain medicinal products;

23) 'patient care interests deserving special consideration' shall refer to the situation when a medicinal product which does not have a valid marketing authorization in the Republic of Hungary offers the potential of successful treatment, and no medicinal product marketed in the Republic of Hungary at the time has the capacity of providing such treatment;

24) 'European Medicines Agency' shall mean the European Medicines Agency established under Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

25) 'risks related to use of the medicinal product' shall mean any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health, and any potential risks presented by the medicinal

product for the environment;

26) 'risk-benefit balance' shall mean an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined in Point 25;

27)-28)

29. ‘advanced therapy (novel) medicinal product’ shall mean any of the medicinal products shown in Article 2 (1) *a)* of Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No. 726/2004.

Scope

Section 2.

(1) The provisions of this Act shall apply to the manufacture, production, placing on the market, distribution and use of medicinal products for human use, and to the clinical trial and use of investigational medicinal products.

(2) Where there is any doubt in connection with a product - taking into consideration of what is contained in Subsection (1) - to which the definition set out in Point 1 of Section 1 applies, and that may be subject to the definition of another product contained in another piece of legislation as well, the provisions of this Act shall prevail.

(3) This Act shall not apply to whole blood, plasma or blood cells of human origin, except for plasma which is prepared by a method involving an industrial process, nor to medical supplies, food preparations, dietary supplements, cosmetics, and other products intended for human use, as well as disinfectants not used in or on the human body, and medical laboratory diagnostic agents.

Clinical Trial

Section 3.

(1) Concerning the authorization and conduct of clinical trials the provisions of the Health Care Act pertaining to medical research in human subjects shall apply subject to the exceptions set out in this Act.

(2) The authorization of the government body for pharmaceuticals - issued on the basis of the opinion of the competent research ethics committee of the Medical Research Council or relying on the prior express consent of the special authority granted upon the client’s request lodged before the opening of the proceedings - shall be required for the clinical trial of any investigational medicinal product in the territory of the Republic of Hungary.

(3)

(4) The administrative time limit for the authorization of clinical trials shall be sixty days, within which period the assessment for ethics purposes shall be completed within not more than forty-two days. The administrative time limit for clinical trials involving investigational medicinal products for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms shall be ninety days from the date of submission of the application, within which period the assessment for ethics purposes shall be completed within not more than seventy-two days. The administrative time limit for clinical trials involving investigational medicinal products for xenogenic cell therapy shall be twelve months from the date of submission of the application, within which period the assessment for ethics purposes shall be completed within not more than eleven months.

(5) The sponsor of a clinical trial shall obtain sufficient liability insurance coverage for any damages that may occur in connection with the clinical trial from an insurance company that is established or has a branch in any Member State of the European Economic Area (hereinafter referred to as "EEA"), or in any State enjoying equal treatment with EEA Member States by virtue of an agreement with the European Communities or with the EEA (hereinafter referred to as "States which are parties to the EEA-Agreement"). The liability insurance policy shall afford sufficient cover for any and all potential claims for damage in connection with the clinical trial.

(6) Commencement of authorized clinical trials shall be notified to the government body for pharmaceuticals.

(7)

(8) The sponsor of the clinical trial shall enter into an agreement for the conduct of the clinical trial with the medical service provider conducting it, or with the head of the clinical trial. The agreement shall be deemed valid only on the basis of the consent of the government body for pharmaceuticals granted on the basis of the opinion of the competent research ethics committee of the Medical Research Council or relying on the prior express consent of the special authority granted upon the client’s request lodged before the opening of the proceedings.

Provisions for the Manufacture of Medicinal Products

Section 4.

(1) With the exception of magistral formulas produced in pharmacies, medicinal products may only be produced in the territory of the Republic of Hungary in possession the authorization of the government body for pharmaceuticals granted for this specific purpose. The organization holding a license for the manufacture of a medicinal product shall be construed as the manufacturer of that medicinal product.

(2) The government body for pharmaceuticals shall authorize the production of a medicinal product if the

applicant is able to satisfy the personnel and infrastructure requirements set out in specific other legislation to ensure that the quality of the medicinal products manufactured will be in conformity with the requirements laid down in the marketing authorization. An authorization for the manufacture of a medicinal product shall also constitute entitlement for trading the manufacturer's own products on the wholesale market, on condition that the manufacturer is able to comply in its wholesale distribution operations with the personnel and infrastructure requirements set out in specific other legislation for the wholesale distribution of medicinal products.

(3) Another precondition for the authorization referred to in Subsection (1) is for the applicant to have liability insurance coverage for any potential claims for damages in connection the technological processes in the manufacture of medicinal products.

(4) Applications for authorization shall be submitted to the government body for pharmaceuticals on the standard forms containing the information decreed by the competent minister.

(5) The government body for pharmaceuticals shall inspect the production site and shall check to ascertain as to whether the applicant is able to comply with the personnel and infrastructure requirements prescribed in specific other legislation for the manufacture of medicinal products, and has sufficient facilities for documentation and quality assurance.

(6) The government body for pharmaceuticals shall adopt a decision concerning the application within ninety days. The government body for pharmaceuticals shall send a copy of the authorization to the European Medicines Agency.

(7) Any person engaged in the manufacture of medicinal products classified as narcotic and psychotropic substances and medicinal products containing any active substance falling under the scope of the legislation on regulatory procedures relating to drug precursors and laying down provisions concerning the powers and responsibilities of public authorities must have a separate authorization for that particular purpose.

(8) The authorized manufacturer of medicinal products shall make arrangements:

a) in connection with the medicinal products produced:

aa) for quality control or certification of quality, and for a computerized system in connection with the certification of quality;

ab) for setting up a laboratory in compliance with the requirements set out in specific other legislation for reasons of quality assurance;

ac) for the withdrawal from circulation and for their seizure;

b) for keeping the records prescribed in specific other legislation and for retaining at least two complete factory package units from each production batch for the purposes of investigation for the period of the proposed shelf life indicated, plus one year;

c) for notification of the authority issuing the marketing authorization concerning any medicinal product deemed defective, indicating the defect and the serial number;

d) for the withdrawal from the market of any medicinal products it has produced and placed on the market and for notifying the authority issuing the marketing authorization concerning the nature of the defect;

e) for collecting the complete batch of the medicinal products that were withdrawn from the market from the buyers to whom they were delivered;

f) for the destruction of defective products and documentation of the process;

g) for drawing up warehousing procedures.

(9) All products shipped to the buyer from the warehouse shall be accompanied by a quality certificate. The factory packaging of products delivered shall have affixed the manufacturer's corporate logo to permit identification of the products' place of origin subsequently.

(10) Authorized manufacturers of medicinal products shall notify the government body for pharmaceuticals of the suspension of their operations of manufacture of medicinal products for any period over six months, indicating the proposed duration of suspension, at least three months before the scheduled date of suspension.

(11) Authorized manufacturers of medicinal products shall notify the government body for pharmaceuticals without delay concerning any changes in their particulars listed under Subsection (2). The government body for pharmaceuticals shall adopt a decision concerning the amendment of the authorization under Subsection (1) according to the changes notified within thirty days. The administrative time limit for proceedings opened upon such notification may be extended on one occasion by maximum sixty days.

(12) At the request of a manufacturer of medicinal products, the government body for pharmaceuticals shall issue an official certificate based on the report drawn up on the inspection of production. The official certificate shall contain:

a) the manufacturer's particulars (name, address);

b) if the inspection pertains to the production of a specific medicinal product or pharmaceutical form, the identification data of these;

c) the date and time of the inspection;

d) the date of the certificate; and

e) the findings of the inspection.

(13)

Section 4/A.

The authorization of the government body for pharmaceuticals for the manufacture of medicinal products (hereinafter referred to as “authorization for the manufacture of medicinal products”) is required for the importation

of medicinal products from outside the European Economic Area (hereinafter referred to as “EEA”), or from any State enjoying equal treatment with EEA Member States by virtue of an agreement with the European Communities or with the European Union (hereinafter referred to as “third country”), or for the manufacture of such products for export only.

Authorization for the Marketing of Medicinal Products

Section 5.

(1) Marketing authorization is the official resolution issued by the authority of competence and jurisdiction permitting a medicinal product to be administered to humans for therapeutic purposes. Unless this Act contains provisions to the contrary, a medicinal product - not including magistral formulas - may be placed on the market only if authorized by the government body for pharmaceuticals or by the European Commission in accordance with Regulation (EC) No. 726/2004 of the European Parliament and of the Council, Regulation (EC) No. 1901/2006 of the European Parliament and of the Council or Regulation (EC) No. 1394/2007 of the European Parliament and of the Council.

(2) The government body for pharmaceuticals shall grant a marketing authorization for a medicinal product if:

a) the qualitative and quantitative particulars of the constituents are known and declared, including the manufacturing process; and

b) its therapeutic efficacy has been clinically substantiated, except for homeopathic medicinal products for which the simplified registration procedure is authorized; and

c) the risk-benefit balance is favourable.

(3) In proceedings for the granting of marketing authorizations the government body for pharmaceuticals shall accept the findings of investigations conducted in States other than those which are parties to the EEA-Agreement if:

a) it is prescribed by law or international agreement; or

b) it is satisfied that the method of execution and control of tests conducted in any State that is not a party to the EEA-Agreement is in compliance with requirements set out in the Republic of Hungary.

(4) The government body for pharmaceuticals shall refuse to grant a marketing authorization if the information that is to be conveyed in a comprehensible manner according to this Act on the immediate or outer packaging (hereinafter referred to as "label") or if the package leaflet is not in compliance with the requirements set out in this Act and in specific other legislation pertaining to labelling and to the package leaflet, or it is not consistent with the summary of product characteristics.

(5) The marketing authorization, in addition to the medicinal product's identification data, shall contain:

a) the number of the marketing authorization, the name of the marketing authorization holder and the manufacturer's address;

b) the summary of product characteristics;

c) the label information;

d) the package leaflet;

e) the classification of the medicinal product;

f) the expected shelf life of the medicinal product and storage instructions.

(6) The administrative time limit for marketing authorization procedures is two hundred and ten days from the day following the date of submission of the application. Marketing authorization may be granted only if the applicant is established in any State that is a party to the EEA-Agreement. The marketing authorization holder shall be responsible for marketing the medicinal product. The designation of a representative shall not relieve the marketing authorization holder of his legal responsibility concerning the product.

(7) The marketing authorizations issued under Subsections (1)-(6) shall remain in effect for five years. The authorization may be renewed upon request, if submitted at least six months before the expiry of the prescribed period of validity and subject to reassessment of the risk-benefit balance. The marketing authorization of a medicinal product shall remain in effect for an unlimited period of time, except where the government body for pharmaceuticals has decided to renew it for five years only, relying on data conveyed under the requirement of notification of adverse events as laid down in specific other legislation.

(8)

(9) The marketing authorization holder shall notify any change in the person of the manufacturer of the medicinal product or in the person of the marketing authorization holder to the government body for pharmaceuticals within thirty days following the effective date of the change in question.

(10) Applications for any amendments concerning the products for which the government body for pharmaceuticals has granted authorization by means other than the procedures specified in a binding legislation of the European Union shall be assessed in accordance with the procedure laid down by Commission Regulation (EC) No. 1234/2008.

Section 6.

(1) The government body for pharmaceuticals, under patient care interests deserving special consideration, may - ex officio - authorize the marketing of a medicinal product that has been authorized for marketing in any State that is a party to the EEA-Agreement.

(2) In connection with the authorization of a medicinal product for marketing in accordance with Subsection (1), prior to granting the authorization the government body for pharmaceuticals:

a) shall notify the marketing authorization holder in the State that is a party to the EEA-Agreement where the medicinal product in question has been authorized, concerning its intention to grant a marketing authorization for the product by virtue of this Act; and

b) shall request the competent authority of that State to supply a copy of the assessment report prepared in accordance with specific other legislation for the medicinal product in question and a copy of the marketing authorization of the medicinal product.

Provisional and Special Marketing

Section 7.

(1) At the manufacturer's request and if justified by patient care interests deserving special consideration, the government body for pharmaceuticals may grant a provisional marketing authorization, before all trials are completed in full, for a product that is deemed to be of appropriate quality based on the assessment already completed and where the risk-benefit balance is considered to be favourable for therapeutic value, for a maximum period of one year. The government body for pharmaceuticals shall lay down in the provisional marketing authorization the reporting requirements for the marketing authorization holder pertaining, in particular, to the safety of the product. The conditions set out by the government body for pharmaceuticals shall be reported at the times prescribed in the authorization to the government body for pharmaceuticals.

(2) The government body for pharmaceuticals may temporarily authorize the distribution of an unauthorized medicinal product for the period referred to in Subsection (1) in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm and hence may present a substantial risk to public health.

(3) Upon request and in justified cases deserving special consideration, the government body for pharmaceuticals may grant a special marketing authorization for the distribution of an unauthorized medicinal product that meets the criteria set out in Paragraph a) of Subsection (2) of Section 5, however, the requirements set out in Paragraphs b) and c) are merely suspected and cannot be confirmed since the number of patients involved in the clinical trial of the product is insufficient due to the rarity of the disease. The government body for pharmaceuticals shall lay down in the special marketing authorization the reporting requirements for the marketing authorization holder pertaining, in particular, to the safety of the product. The conditions set out by the government body for pharmaceuticals shall be reported at the times prescribed in the authorization to the government body for pharmaceuticals.

(4) The government body for pharmaceuticals shall assess compliance with the requirements set out in Subsections (1)-(3) at least once a year. At the manufacturer's request the government body for pharmaceuticals may extend the time limit specified in the provisional marketing authorization to maximum one year.

Labelling and Package Leaflet

Section 8.

Unless otherwise prescribed in this Act, the outer packaging of medicinal products, if any, and the immediate packaging shall have affixed the information prescribed in specific other legislation.

Section 9.

A package leaflet must be inserted in the packaging of all medicinal products if the information prescribed in specific other legislation is not indicated on the outer or the immediate packaging.

Section 10.

(1) One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, shall be submitted to the government body for pharmaceuticals enclosed with the request for marketing authorization.

(2) Applications for the authorization of changes pertaining to labeling and the package leaflet, which do not effect the summary of product characteristics, shall be submitted to the government body for pharmaceuticals. If the government body for pharmaceuticals fails to render its decision within ninety days following the date of receipt of the application for modification, the authorization shall be considered granted.

(3) The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly legible in the Hungarian language and shall contain the information prescribed in specific other legislation. Apart from Hungarian the leaflet may be printed in several languages, provided that the same information is given in all the languages used.

(4) The government body for pharmaceuticals may exempt labels and package leaflets for specific medicinal products from the obligation that all particulars shall appear and that the labelling and the leaflet must be in the Hungarian language, when the product is not intended to be delivered directly to the patient for self-administration.

(5)

Wholesale Distribution of Medicinal Products

Section 11.

(1) Wholesale distribution of medicinal products shall comprise all activities relating to the supply of medicinal products to retailers, including the storage and transportation of medicinal products, exporting to and importing from States which are parties to the EEA-Agreement, and exporting to States outside of this area, in consequence of which medicinal products are conveyed from the manufacturer or producer to persons authorized to supply medicinal products to the public. Unless this Act contains provisions to the contrary, all activities relating to the wholesale distribution of medicinal products must be authorized by the government body for pharmaceuticals.

(2) The government body for pharmaceuticals shall grant the above-specified authorization, if the applicant is able to satisfy the personnel and infrastructure requirements set out in specific other legislation.

(3) Authorized wholesale distributors of medicinal products - subject to the exceptions set out in specific other legislation - shall not be authorized to supply medicinal products directly to the public, and shall be authorized to supply medicinal products only to persons with authorization or entitlement to engage in activities for the wholesale distribution of medicinal products or for providing medical services.

(4) The authority shall adopt a decision concerning applications for authorization and for the amendment of existing authorizations within ninety days following the date of receipt of the application. Wholesale distribution authorizations shall remain valid until revoked.

(5)

Supply of Medicinal Products

Section 12.

(1) Supply of medicinal products shall comprise all the activities by which medicinal products are made available directly to the users, including the manufacture, production, storage and distribution of medicinal products.

(2) Unless otherwise provided for by law, medicinal products may be procured on the behalf of and dispensed to patients by pharmacies.

(3) Unless otherwise prescribed by law, pharmacies may procure medicinal products only from economic operators authorized to engage in activities relating to the wholesale distribution of medicinal products.

(4) Where a pharmacy is unable to supply a particular medicinal product from stock immediately, the patient concerned shall be informed of the estimated date of availability.

Section 13.

Section 14.

Special Provisions on Medicinal Products Classified as Narcotics or Psychotropic Substances

Section 15.

(1) Any operations concerning the manufacture, placing on the market, wholesale distribution of medicinal products classified as narcotic and psychotropic substances, for the importation into and exportation of such medicinal products from the territory of the Republic of Hungary, and their purchase for scientific purposes shall also be subject to authorization by the authority specified in specific other legislation. The decisions of the authority designated in specific other legislation, adopted in accordance with this provision may not be appealed.

(2) The regulations pertaining to the manufacture, storage and wholesale distribution of medicinal products classified as narcotic and psychotropic substances, as well as the registration and data disclosure obligations of the persons authorized to engage in these activities, furthermore, the regulations for the prescription of these products, their sale in pharmacies - including storage, records, and their dispensation from pharmacies -, and for the use of these products in medical institutions and the records on such usage is laid down in specific other legislation.

(3) The authorization proceedings relating to narcotic and psychotropic substances, and the issue and amendment of authorizations shall be subject to an administrative service fee payable in accordance with the provisions of specific other legislation.

(4) Activities involving narcotic drugs and psychotropic substances, defined in specific other legislation, may only be pursued in possession of the authorization granted under specific other legislation. The above-specified authorization may be granted to an economic operator that fits the definition under the Civil Code, provided that the executive officer of such economic operator, and all members of its executive body have no prior criminal record and they are not restrained by court order from exercising the profession required for holding an executive office in an economic operator or business association, or from practicing the profession required for the pursuit of healthcare activities.

(5) The person nominated to be appointed as narcotics duty officer or as deputy narcotics duty officer under specific other legislation shall have no prior criminal record and shall not be restrained by court order from practicing the profession required for the pursuit of healthcare activities.

(6) Enclosed with the application submitted in accordance with specific other legislation for authorization, the executive officer of the applicant economic operator and members of its executive body, and the person nominated to be appointed as narcotics duty officer shall produce official documentary evidence to verify that he has no prior criminal record, and that he is not restrained by court order from practicing the profession referred to in Subsection (4) or (5), or shall request the body operating the penal register to disclose information to the authority delegated under specific other legislation based on an official request lodged for the purpose of assessment of the application for authorization.

(7) As regards the data request lodged by the authority delegated under specific other legislation to the body operating the penal register shall be limited to the information necessary to determine as to whether the person applying for authorization has no prior criminal record, and that he is not restrained by court order from practicing the profession referred to in Subsection (4) or (5).

(8) Enclosed with the application submitted for authorization by a person of citizenship other than Hungarian, the applicant shall produce the translation of official documentary evidence made out according to the laws of his home state - pertaining to official certificates - to the authority delegated under specific other legislation to verify that he has no prior criminal record, and that he is not restrained by court order from practicing the profession referred to in Subsection (4) or (5).

Section 15/A.

(1) The authority delegated under specific other legislation shall check in the course of a regulatory inspection as to whether the person holding authorization has no prior criminal record and that he is not restrained by court order from practicing the profession referred to in Subsection (4) or (5) of Section 15.

(2) With a view to being able to verify the circumstances referred to in Subsection (1), the authority delegated under specific other legislation shall be authorized to process the personal data:

a) of the person applying for authorization,

b) of the person holding an authorization,

contained in the official certificate made out by the body operating the penal register for this purpose.

(3) The authority delegated under specific other legislation shall be authorized to process the personal data obtained under Subsection (2):

a) until the final and binding conclusion of the procedure for authorization, or

b) for the duration of the regulatory inspection if the authorization is granted, or until the final and binding conclusion of the procedure for the withdrawal of the authorization.

Public Service Obligation Placed on Marketing Authorization Holders, Authorized wholesale distributors of medicinal products and Operators of Pharmacies Relating to the Supply of Medicinal Products

Section 16.

(1) In the event where a marketing authorization holder intends to discontinue the marketing of a specific medicinal product in the Republic of Hungary, the wholesalers of medicinal products engaged under contract, the government body for pharmaceuticals and the health insurance administration agency must be notified accordingly not less than three months before the scheduled termination of marketing, or upon delivery of the last production batch to a medicinal product wholesaler.

(2) Where a marketing authorization holder is unable to supply a specific medicinal product in the Republic of Hungary for at least three months, the marketing authorization holder shall forthwith notify the wholesalers of medicinal products engaged under contract, the government body for pharmaceuticals and the health insurance administration agency accordingly, and shall communicate the expected duration of suspension of the product as well.

(3) Authorized wholesale distributors of medicinal products shall be required to procure and supply the medicinal products to which their authorization for wholesale distribution pertains.

(4) The supply obligation of operators of pharmacies is governed in specific other legislation on the implementation and operation of pharmacies.

(5)

Supervision and Regulatory Control of Medicinal Products and the Supply of Medicinal Products

Section 17.

(1) Holders of marketing authorization and pharmacists engaged in the wholesale distribution of medicinal products or in the supply of medicinal products to the public, as well as the doctors administering the medicinal

products shall report any suspected deficiency in the quality of a medicinal product or production batch to the government body for pharmaceuticals without delay upon gaining knowledge about such deficiency.

(2) The party reporting a suspected deficiency in quality shall, at the time of reporting, provide a specimen of the medicinal product in question, in the volume prescribed in specific other legislation for the purpose of quality control.

(3) If the government body for pharmaceuticals finds, in connection with the report referred to in Subsection (1) or on the basis of information received through other channels, that a medicinal product does not comply with the requirements specified in the marketing authorization, it shall order - by means of a resolution - the suspension of distribution of the medicinal product or production batch in question, or to have them removed from the market. The resolution shall *inter alia* be published on the official website of the government body for pharmaceuticals. The procedure for removal from circulation and for suspension of distribution shall be decreed by the minister in charge of the healthcare system.

(4) If a quality control procedure is required, the government body for pharmaceuticals shall provide for the procurement of the medicinal product in question.

(5) The costs for the removal of a medicinal product from circulation, including the cases defined in Subsections (1)-(3), shall be borne by the marketing authorization holder.

Section 18.

(1) The holder of a marketing authorization and the doctor dispensing a medicinal product, as well as the dispensing pharmacist, shall be required to report any adverse reaction discovered or noticed to the government body for pharmaceuticals, if:

a) it is not listed in the summary of product characteristics of the medicinal product in question;

b) it is severe and undesirable; and

c) it prevents further administration of the medicinal product.

(2) The government body for pharmaceuticals shall assess and evaluate the above-specified reports and shall take the measures deemed necessary under Subsections (3) and (4), and shall notify the party filing the report, the marketing authorization holder and all medical service providers regarding its findings and the measures imposed by way of public announcement, and shall make available its relevant resolution to the public. The decision shall also be published in the Hivatalos Értesítő (Official Bulletin) of the Magyar Közlöny (Hungarian Gazette).

(3) The government body for pharmaceuticals shall suspend the marketing of a medicinal product until the requirements set out in the authorization are satisfied within the prescribed deadline, if on the strength of the reports referred to in Subsection (1):

a) the medicinal product proves to be harmful under normal conditions of use; or

b) it is lacking in therapeutic efficacy; or

c) the risk-benefit balance is not favourable under the authorized conditions of use; or

d) its qualitative and quantitative composition is not as declared in the marketing authorization;

e) the controls on the medicinal product and/or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorization has not been fulfilled.

(4) The government body for pharmaceuticals shall revoke the marketing authorization if:

a) in conclusion of the reports referred to in Subsections (1)-(2) it deems that the problems specified in Paragraphs a)-d) of Subsection (3) cannot be remedied within any foreseeable period of time;

b) the marketing authorization holder failed to remedy the discrepancies by the deadline prescribed in the resolution referred to Subsection (3).

(5) Therapeutic efficacy is lacking when it is concluded that the therapeutic results for which the marketing authorization had been issued cannot be obtained from the medicinal product.

(6) A marketing authorization for a medicinal product shall also be suspended or revoked where the particulars supporting the application for the renewal are incorrect or have not been amended, or where the controls prescribed to be conducted during the manufacturing process have not been carried out.

(7) Where a medicinal product for which the government body for pharmaceuticals has already granted a marketing authorization is not actually present on the market in Hungary for three consecutive years, the government body for pharmaceuticals may withdraw the marketing authorization of such medicinal product.

(8) The government body for pharmaceuticals may disregard the provisions contained in Subsections (6) and (7) in justified cases deserving special consideration and for the protection of public health.

Section 19.

The government body for pharmaceuticals shall routinely inspect the laboratories contracted for testing the safe use of medicinal products as well as medical service providers conducting clinical trials for the purpose of checking their compliance with the professional requirements laid down in specific other legislation

Section 20.

(1) The government body for pharmaceuticals shall be vested with authority to supervise the obligations conferred under this Act or other legislation adopted by authorization of this Act relating to the manufacture, distribution,

placing on the market of medicinal products, as well as the public service obligation for the supply of medicinal products, furthermore, to the clinical trial of investigational products and the activities of laboratories contracted for testing medicinal products for reasons of safety, whereas in connection with pharmacies and other medical service providers the same authority shall be conferred upon the government body in charge of the healthcare system. The regulations concerning the promotion of medicinal products and for the enforcement of the provisions relating to business-to-consumer commercial practices shall be laid down in specific other legislation, including the provisions for any infringement of these provisions.

(2) In the control proceedings the government body for pharmaceuticals shall establish the facts, and shall take the measures consistent with the nature and severity of any discrepancies and irregularities, and shall monitor their implementation.

(3) Where the government body for pharmaceuticals finds that the authorized natural or legal person, or unincorporated business association is in non-compliance with the conditions and requirements set out in this Act or any other legislation adopted by authorization of this Act, or is in breach of the obligations conferred upon it, the government body for pharmaceuticals may:

a) order the state of infringement to be terminated; or

b) prohibit continuation of the illegal conduct; or

c) order or initiate the medicinal product or the production batch that is deemed harmful to life, health or physical safety to be removed from the market; or

d) order the person affected to eliminate the discrepancies within the prescribed deadline, or suspend his authorization until the said discrepancies are eliminated; or

e) revoke the authorization of repeat offenders, or in connection with any severe infringement constituting a public health emergency.

(4) The government body for pharmaceuticals and government body in charge of the healthcare system shall have powers to impose penalties upon the person having committed the infringement. In the case of multiple violations the amount of fines imposed may aggregate.

(5) The amount of the fine imposed for any violation of the public service obligation conferred in this Act for the supply of medicinal products shall be determined with regard to all applicable circumstances, in particular, the scope and gravity of the injury caused to patients, and the duration of the illegal conduct. Repeat offenders shall be penalized accordingly. The fine shall be minimum one hundred thousand forints. Unpaid fines shall be enforced in the same manner as taxes.

(6)

(7) The above-specified fines shall be payable to the account of the government body for pharmaceuticals or the government body in charge of the healthcare system. If the illegal conduct or infringement concerns subsidized medicinal products, 50 per cent of the fine shall be payable to the Health Insurance Fund.

(8) Other aspects in connection with the control of persons engaged in the supply of medicinal products to the public are governed in specific other legislation.

Liability for Damages in Connection with Investigational Medicinal Products or the Administration of Medicinal Products

Section 21.

(1) If, during the clinical trial of an investigational medicinal product, or as a consequence thereof, a natural person suffers health damage, the injured person, or in the event of death, his/her close relative [Paragraph b) of Section 685 of Act IV of 1959 on the Civil Code (hereinafter referred to as "Civil Code")], shall be compensated by:

a) the sponsor of the trial carried out in accordance with an investigation program approved by the authority which has authorized the clinical trials;

b) the sponsor of the trial if the death, disability or severe health damage occurred in consequence of the sponsor withholding any information of knowledge from the authority which has authorized the clinical trials;

c) the authority which has authorized the clinical trials, if the death, disability or severe health injury occurs in consequence of the specifications issued by such authority;

d) the institution carrying out the clinical trials in the event of any deviation from the investigation program approved by the authority which has authorized the clinical trials, and the health damage occurs in consequence of such.

(2) In respect of liability for damages incurred in connection with the use of a medicinal product, the provisions of Act X of 1993 on Product Liability (hereinafter referred to as "PLA") shall apply subject to the exceptions set out in Subsection (4).

(3) With regard to damages resulting from the proper application of a medicinal product, as referred to in Subsection (4) of Section 1 of the PLA, the manufacturer shall not be exempted from product liability relying on Paragraph d) of Subsection (1) of Section 7 of the PLA.

(4) Where a medicinal product was used in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation in possession of authorization by the government body for pharmaceuticals granted according to Section 6 or Subsection (2) of Section 7 of this Act, the State shall compensate such injured person, or in the case of death, his/her dependent relative.

(5) For the purposes of this Section 'dependent relative' shall mean a person supported by the injured person by

virtue of obligation set forth in legal regulations or contract.

Sections 22-23.

Patients' Rights in Connection with the Use of Medicinal Products

Section 24.

(1) In respect of patients' rights related to medicinal products the provisions of the Health Care Act pertaining to patients' rights shall be applied with the additions set forth in Subsection (2).

(2) When dispensing any medicinal product that is not subject to medical prescription at the users (patients) request (hereinafter referred to as "self-medication") pharmacists shall be required to provide prudent information concerning:

a) the therapeutic value and any potential side effects of such product;

b) interaction with other medicaments when taking more than one at the same time;

c) the need for medical attention or assistance if deemed appropriate in his judgement based upon the health of the user (patient);

d) any available substitutes and the price of the medicinal product.

General Provisions Relating to the Use of Medicinal Products

Section 25.

(1) Medicinal products may be prescribed in accordance with Section 129 of Act CLIV of 1997 on Health Care - with the exceptions set out in this Act and in the decree implementing it - in accordance with the indications referred to in the summary of product characteristics as approved in the marketing authorization, or in the Catalogue of Standard Prescriptions where applicable. Medicinal products may be prescribed by any doctor or dentist (hereinafter referred to collectively as “doctor”) who is qualified to engage in activities subject to a doctor’s diploma and who has an official stamp for authorization as laid out in specific other legislation, to prescribe medicinal products.

(2) Any medicinal product that has been authorized for marketing in a country other than in the States which are parties to the EEA-Agreement may be used for a medicinal purpose in exceptional cases if justified by patient care interests deserving special consideration, and if it has been authorized by the government body for pharmaceuticals in accordance with the requirements set out in specific other legislation. Any medicinal product that has been authorized for marketing in any of States which are parties to the EEA-Agreement may be used for a medicinal purpose if it has been notified to the government body for pharmaceuticals in accordance with the provisions of specific other legislation.

(3) The detailed regulations on the prescription of medicinal products by doctors are laid down in specific other legislation.

(4) Donations of medicinal products may be exported from the Republic of Hungary, or may be imported into and used in the territory of the Republic of Hungary under the following conditions:

a) with respect to any medicinal product that has been authorized for marketing in a country other than in the States which are parties to the EEA-Agreement, exportation and importation must be authorized by the government body for pharmaceuticals;

b) with respect to any medicinal product that has been authorized for marketing in any of the States which are parties to the EEA-Agreement, exportation and importation must be notified to the government body for pharmaceuticals.

(5) Where any defect in quality is suspected the government body for pharmaceuticals may proceed to ban the use of the medicinal product in Hungary within three days, or shall notify the competent authority of the country to which the medicinal product was exported.

(6) Medicinal product may be prescribed and used otherwise than for the authorized indications contained in the summary of product characteristics (hereinafter referred to as “prescription for an unauthorized indication”), only if:

a) treatment of a patient with another authorized medicinal product is not possible or unsuccessful according to the summary of product characteristics, and based on the experimental evidence defined in specific other legislation, administering the medicinal product for an unauthorized indication offers the potential of successful treatment, or to improve or stabilize the patient’s condition;

b) the medicinal product in question is authorized for distribution in the Republic of Hungary or in another country; and

c) the doctor specializing in the specific therapeutic area has requested individual authorization from the government body for pharmaceuticals for using the medicinal product for an unauthorized indication for the specific patient under the relevant conditions set out in specific other legislation, and the government body for pharmaceuticals has granted such authorization.

(7) If the summary of product characteristics of the marketing authorization of a medicinal product contains contra-indications, it may not be prescribed for an unauthorized indication.

(8) The government body for pharmaceuticals shall adopt a decision for the issue of an authorization under Subsection (6) within twenty-one days following the date of receipt of the application - or immediately, in any event

within not more than three days in urgent case - following consultation with the competent trade organization if necessary.

(9) The regulations for prescriptions of medicinal products for unauthorized indications in cases of emergency are laid down in specific other legislation.

(10) The doctor shall provide a copy of the authorization referred to in Subsection (8) to the patient before starting to apply the medication, and the patient shall verify receipt by his/her signature. The doctor shall attach this certificate of receipt to the patient's medical file.

(11) The government body for pharmaceuticals shall keep records of the medicinal products prescribed under Subsection (6) with a view to monitor the patient's condition and the efficacy of the medicinal product, where these records are to contain the doctor's name and the serial number of his seal, the patient's name, date of birth and TAJ number, the name of the medicinal product, the active substance, strength, pharmaceutical form and packaging, and a description of the indication for which the doctor wishes to prescribe the medicinal product in question, including the proposed dosage and duration of treatment.

(12) The detailed regulations concerning the applications mentioned in Paragraph *c)* of Subsection (6), the authorizations referred to in Subsection (8) and the information to be provided to patients under Subsection (10) are laid down in specific other legislation.

Section 25/A.

Section 25/A.

The government body for pharmaceuticals shall authorize the manufacture of any advanced therapy (novel) medicinal product that does not have the marketing authorization under Point 29 of Section 1, which is prepared on a non-routine basis according to specific quality standards, and used in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient [hereinafter referred to as "custom-made advanced therapy (novel) medicinal product prepared in a hospital"].

Fees Charged for Authorization Procedures Relating to Medicinal Products

Section 25/B.

(1) Authorization and modification procedures and other proceedings - shown in Schedule No. 1 - relating to the manufacturing, placing on the market and distribution of medicinal products for human use, the continuation of the marketing authorization, the wholesale distribution of medicinal products, the reclassification of therapeutic substances and preparations which are not classified as medicinal products, parallel imports, clinical trial of investigational medicinal products, the application of principles of good laboratory practice shall be subject - with the exception set out in Subsection (2) - to an administrative service fee (hereinafter referred to as "fee") as specified in Schedule No. 1, payable by the person requesting the opening of the proceedings or by the applicant of the authorization, or an annual renewal fee for the continuation of the marketing authorization as specified in Schedule No. 1.

(2) Proceedings for the authorization of non-commercial clinical trials - described in the relevant government decree - are free of charge.

(3) The fee charged for the procedures listed in Points I, II and III/A-G of Schedule No. 1 shall be paid separately for each clinical trial and each medicinal product.

(4) The fees shown in Schedule No. 1 shall be determined in consideration of the following:

a) where a homeopathic medicine contains - apart from the homeopathic component - other non-homeopathic (allopathic) components as well, the marketing authorization fees relating to allopathic preparations shall be applied;

b) where a medicinal product is placed in the market as a homeopathic product, that is made by such process and claiming to have therapeutic efficacy, it shall be treated as a non-homeopathic medicine for reasons of assessment of the fee.

(5) In the event of any changes in the particulars contained in the authorizations referred to in Subsection (1), or in the particulars of the marketing authorizations of specific medicinal products, each and every request for modification, independent from any other such request shall be subject to procedural fees separately for each pharmaceutical form or strength, regardless of whether the application is submitted individually or together with other requests pertaining to more than one medicinal product. As regards the modification of the authorization of a clinical trial, each and every request - described by law - lodged independently for modification as to content shall be subject to procedural fees separately, regardless of whether the application is submitted individually or together with other requests pertaining to more than one clinical trial.

(6) The fee shall be paid at the time the application is submitted, whereas the annual renewal fee shall be paid by 31 January of the given year to the government body for pharmaceuticals in the manner decreed by the minister in charge of the healthcare system.

(7) With the exceptions set out in other legislation, the proceeds from the fees shall comprise revenue for the government body for pharmaceuticals, and the special authorities participating in the proceedings as required by law, where the records and accounting of such fees shall fall within the scope of the legislation governing the reporting and bookkeeping obligation of agencies funded by the central budget. The special authorities shall be entitled to a

part of the revenues from fees in the percentage decreed by the minister in charge of the healthcare system.

(8) As regards the procedures for which the fees are charged, and the persons liable for the payment of such fees, Subsections (2)-(3) of Section 28 of Act XCIII of 1990 on Duties (hereinafter referred to as "Duties Act") and the first sentence of Subsection (1) of Section 31 of the Duties Act shall apply, respectively, with the exception that any reference made in the Duties Act to duties shall be understood as fees.

Miscellaneous Provisions

Section 26.

(1) Manufacturers and wholesalers of medicinal products and the operators of pharmacies shall provide for proper destruction of medicinal products which are no longer marketable (inadequate quality, expired) in compliance with the provisions set forth in legal regulations governing environmental protection, and shall partake - in compliance with the provisions of specific other legislation - in the collection and disposal of medicinal waste products from the general public. The destruction of medicinal products classified as narcotic or psychotropic substances shall be governed in specific other legislation.

(2) The provisions for the destruction of medicinal products and the procedures to be followed, the special safety regulations to be applied for medicinal products classified as narcotic or psychotropic substances, and the control and enforcement of environmental protection requirements shall be decreed by the minister in charge of the healthcare system.

(3) The government body for pharmaceuticals shall maintain an official register of the medicinal products authorized for placing on the market and distribution in the Republic of Hungary.

(4) The manufacturer's (importer's) prices and retail prices, and the amount of support of medicinal products authorized for distribution in the Republic of Hungary with public financing shall be published according to the provisions laid down in specific other legislation.

(5) The health insurance administration agency and government body for pharmaceuticals shall post all information that has been published in their official journals concerning the placing on the market and prescription of medicinal products and the amount of social security subsidies provided for the various products, on their official websites as well.

(6) The decisions of the government body for pharmaceuticals adopted in accordance with this Act, or relating to the registration and placing on the market of therapeutic substances and preparations not classified as medicinal products may not be appealed; however.

Sections 27

Electronic communication as referred to in Section 28/B of the APA shall be carried out - with the exceptions set out in Subsections (1)-(6) of Section 25 of this Act and in Subsections (2)-(3) of Section 3 of the legislation on the pursuit of the business of wholesale distribution of medicinal products in conjunction with the importation of medicinal products - via the IT systems of the government body for pharmaceuticals and the government body in charge of the healthcare system in connection with the regulatory proceedings of the government body for pharmaceuticals and the government body in charge of the healthcare system concerning medicinal products, investigational products and products registered as therapeutic substances and preparations which are not classified as medicinal products, and concerning laboratories and individual test sites operating in conformity with the principles of good laboratory practice.

Section 28-29.

Section 30.

Section 31.

Closing Provisions

Section 32.

(1) This Act shall enter into force on 30 October 2005.

(2)

(3) Subsection (2) of Section 4 shall apply to the authorization proceedings opened subsequent to this entering into force; manufacturers of medicinal products wishing to engage in the wholesale distribution of their own medicinal products shall satisfy the personnel and infrastructure requirements prescribed in specific other legislation for the wholesale distribution of medicinal products by 1 March 2006, of which the government body for pharmaceuticals shall be notified accordingly. After 1 March 2006 manufacturers of medicinal products may only engage in wholesale distribution if having satisfied the above-mentioned obligation notification.

(4) The Government is hereby authorized to decree:

a) the detailed conditions for the manufacture, placing on the market, retail and wholesale distribution of medicinal products classified as narcotic and psychotropic substances, for the importation into and exportation of such medicinal products from the territory of the Republic of Hungary, furthermore, their purchase and use for scientific purposes, the procedures for issuing the authorization for such activity, the contents of the register - other than personal data - of authorized operators, and the detailed procedural rules for operating the register, furthermore, the sanctions for any infringement of the provisions of the relevant legislation or of the resolutions adopted by the competent authorities;

b) the sphere of application and procurement of medicinal products classified as narcotic or psychotropic within the meaning of international conventions for scientific purposes;

c) the amount of penalty to be imposed for any violation of the public service obligation conferred in this Act for the supply of medicinal products.

d) the designation of the government body or bodies for pharmaceuticals

(5) The minister in charge of the healthcare system is hereby authorized to decree:

a) the detailed regulations for the issue of marketing authorization for medicinal products, the requirements for authorization, the procedure for the removal of medicinal products from circulation, and for the suspension of distribution rights;

b) the various types of the medicinal products falling within the scope of this Act;

c) the detailed regulations relating to the application of the principles of good laboratory practice, and for the operation and supervision of laboratories contracted for testing medicinal products for reasons of safety;

d) the conditions for conducting clinical trials, the documents required for the authorization of clinical trials, the detailed regulations for the authorization procedure, the proceedings of the research ethics committee, and the professional requirements for the conduct and control of clinical trials;

e) the conditions for the change of classification of therapeutic substances and preparations which are not classified as medicinal products to be classified as such;

f) the detailed regulations for engaging in the wholesale distribution of medicinal products in conjunction with the importation of medicinal products;

g) the regulations for the prescription of medicinal products by doctors and for prescriptions of medicinal products for unauthorized indications in cases of emergency;

h) the rules for the institutional supply of medicinal products;

i) the qualification requirements for persons contracted to participate in the manufacture of medicinal products and in activities for the wholesale distribution of medicinal products;

j) the procedures for prescription of medicinal products classified as narcotic and psychotropic substances, their sale in pharmacies - including storage, records, and their dispensation from pharmacies -, and for the use of these products in medical institutions and the records on such usage;

k) the personnel and infrastructure requirements for the manufacture of medicinal products for human use;

l) the sphere of diagnostic agents which are not used in or on the human body;

m) the mandatory use of the Pharmacopoeia and the Catalogue of Prescriptions for manufacturers and distributors of medicinal products and for doctors and pharmacists;

n) the regulations relating to the labelling and package leaflets of medicinal products;

o) the form and professional requirements for dispensing medicinal products in pharmacies, and the regulations on consultation by pharmacists;

p) the regulations for the destruction of medicinal products and the procedures to be followed, the special safety regulations to be applied for medicinal products classified as narcotic or psychotropic substances, and the control and enforcement of environmental protection requirements.

q) the regulations relating to custom-made advanced therapy medicinal products prepared in hospitals.

r) the formal and content requirements for a doctor’s certificate - prescribed according to international convention - on medicinal products classified as narcotic or a psychotropic substance required for the movement of travelers through customs carrying such medicinal products that are necessary for their medical treatment.

(6) The minister in charge of the healthcare system is hereby authorized to decree, in agreement with the minister in charge of taxation, the types of administrative service fees, including their amounts and other regulations relating to payment terms and conditions, payable:

a) for proceedings relating to the authorization of narcotic and psychotropic substances, and for the issue and amendment of such authorizations;

b)-c)

d) for proceedings relating to certification of the conditions for the manufacture of products registered as therapeutic substances and preparations which are not classified as medicinal products for public health and epidemiological considerations, and for the issue of the certificate;

e) for the examination (certification) of a production batch of immunological products.

(7) Manufacturers and/or distributors of products registered as therapeutic substances and preparations which are not classified as medicinal products pursuant to the decree on the registration and marketing of therapeutic substances and preparations not classified as medicinal products may apply for having their preparations - containing any ingredient of plant origin - reclassified as medicinal or other products until 31 March 2011. Following the entry of this Act into force no proceedings may be launched for the registration and marketing of any new therapeutic preparations which are not classified as medicinal products.

(8) The conditions for the reclassification of the products under Subsection (7) as medicinal products shall be established by specific other legislation.

(9) Products registered as therapeutic substances and preparations which are not classified as medicinal products, which may be considered traditional herbal medicinal products on account of all their specificities and are available in commercial circulation on 31 March 2011, may be marketed with reference to having medicinal properties until their expiry date, or until 1 April 2013 at the latest.

(10) The minister in charge of the healthcare system is hereby authorized to decree, in agreement with the minister in charge of taxation, the regulations relating to the management, registration and distribution of the fees referred to in Section 25/B.

Section 33.

(1) This Act contains regulations that may be approximated with the following legal regulations of the European Communities together with the ministerial decrees adopted for the implementation of this Act by authorization conferred under Subsection (5) of Section 32:

a) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;

b) 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;

c) Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use;

d) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances;

e) 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.

f) Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products.

g) Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorizations for medicinal products.

(2) This Act contains regulations for the implementation of the following legislation of the Communities:

a) Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

b) Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for pediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004;

c) Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No. 726/2004.

d) Commission Regulation (EC) No. 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorizations for medicinal products for human use and veterinary medicinal products.

Schedule No. 1 to Act XCV of 2005

		Amount
I	Non-homeopathic (allopathic) preparations	
I.A.	All allopathic preparations, except allergens	
I.A.1.	New marketing authorization	
I.A.1.1.	National procedure	
I.A.1.1.a.	Original, or original product line extension	1 350 000
I.A.1.1.b.	Generic, or generic product line extension	675 000
I.A.1.1.c.	Other, or other product line extension	675 000
I.A.1.2.	Mutual recognition procedure	
I.A.1.2.a.	Original, or original product line extension	
I.A.1.2.a.1.	RMS	3 150 000
I.A.1.2.a.2.	CMS	2 250 000
I.A.1.2.b.	Generic, or generic product line extension	
I.A.1.2.b.1.	RMS	1 575 000
I.A.1.2.b.2.	CMS	1 175 000
I.A.1.2.c.	Other, or other product line extension	
I.A.1.2.c.1.	RMS	1 575 000
I.A.1.2.c.2.	CMS	1 175 000
I.A.2.	Modification of marketing authorization	

I.A.2.1.		National	
I.A.2.1.a.		Type IA-IB	180 000
I.A.2.1.b.		Type II	270 000
I.A.2.2.		Mutual recognition procedure	
I.A.2.2.a.		Type IA-IB	
I.A.2.2.a.1.		RMS	250 000
I.A.2.2.a.2.		CMS	180 000
I.A.2.2.b.		Type II	
I.A.2.2.b.1.		RMS	350 000
I.A.2.2.b.2.		CMS	270 000
I.A.2.3.		Changes not effecting the summary of product characteristics, pertaining only to the labeling and the package leaflet [Act XCV of 2005, Subsection (2) of Section 10]	20 000
I.A.2.4.		Transfer of marketing authorization (succession)	100 000
I.A.2.5.		In the Hungarian marketing authorization, addition or removal of packaging units that have already been authorized under the mutual recognition procedure	100 000
I.A.2.6.		Switching to the global identification system	100 000
I.A.2.7.		Change in the classification of the product	270 000
I.A.3.	Renewal of marketing authorization		
I.A.3.1.		National	
I.A.3.1.a.		Original	675 000
I.A.3.1.b.		Generic	325 000
I.A.3.1.c.		Other	325 000
I.A.3.2.		Mutual recognition procedure	
I.A.3.2.a.		Original	
I.A.3.2.a.1.		RMS	1 575 000
I.A.3.2.a.2.		CMS	1 125 000
I.A.3.2.b.		Generic	
I.A.3.2.b.1.		RMS	775 000
I.A.3.2.b.2.		CMS	550 000
I.A.3.2.c.		Other	
I.A.3.2.c.1.		RMS	775 000
I.A.3.2.c.2.		CMS	550 000
I.A.4.	Withdrawal of marketing authorization		67 500
I.A.5.	Annual maintenance of marketing authorization		180 000
I.B	Allergens		
I.B.1.	New marketing authorization		
I.B.1.1.		National	
I.B.1.1.a.		Starting materials (mono-component)	45 000
I.B.1.1.b.		Mixed allergens (multi-component)	315 000
I.B.1.1.c.		Other	315 000
I.B.1.2.		Mutual recognition procedure	
I.B.1.2.a.		Starting materials (mono-component)	
I.B.1.2.a.1.		RMS	245 000
I.B.1.2.a.2.		CMS	90 000
I.B.1.2.b.		Mixed allergens (multi-component)	
I.B.1.2.b.1.		RMS	1 215 000
I.B.1.2.b.2.		CMS	565 000
I.B.1.2.c.		Other	
I.B.1.2.c.1.		RMS	1 215 000
I.B.1.2.c.2.		CMS	565 000
I.B.2.	Modification of marketing authorization		
I.B.2.1.		National	
I.B.2.1.a.		Type IA-IB	
I.B.2.1.a.1.		Starting materials (mono-component)	9 000
I.B.2.1.a.2.		Mixed allergens (multi-component)	45 000
I.B.2.1.a.3.		Other	45 000
I.B.2.1.b.		Type II	
I.B.2.1.b.1.		Starting materials (mono-component)	20 000
I.B.2.1.b.2.		Mixed allergens (multi-component)	100 000
I.B.2.1.b.3.		Other	100 000
I.B.2.2.		Mutual recognition procedure	

I.B.2.2.a.				Type IA-IB		
I.B.2.2.a.1.					RMS	
I.B.2.2.a.1.1.					Starting materials (mono-component)	9 000
I.B.2.2.a.1.2.					Mixed allergens (multi-component)	45 000
I.B.2.2.a.1.3.					Other	45 000
I.B.2.2.a.2.					CMS	
I.B.2.2.a.2.1.					Starting materials (mono-component)	9 000
I.B.2.2.a.2.2.					Mixed allergens (multi-component)	45 000
I.B.2.2.a.2.3.					Other	45 000
I.B.2.2.b.				Type II		
I.B.2.2.b.1.					RMS	
I.B.2.2.b.1.1.					Starting materials (mono-component)	30 000
I.B.2.2.b.1.2.					Mixed allergens (multi-component)	200 000
I.B.2.2.b.1.3.					Other	200 000
I.B.2.2.b.2.					CMS	
I.B.2.2.b.2.1.					Starting materials (mono-component)	20 000
I.B.2.2.b.2.2.					Mixed allergens (multi-component)	100 000
I.B.2.2.b.2.3.					Other	100 000
I.B.2.3.				Changes not effecting the summary of product characteristics, pertaining only to the labeling and the package leaflet [Act XCV of 2005, Subsection (2) of Section 10]		20 000
I.B.2.4.				Transfer of marketing authorization (succession)		100 000
I.B.2.5.				In the Hungarian marketing authorization, addition or removal of packaging units that have already been authorized under the mutual recognition procedure		100 000
I.B.2.6.				Switching to the global identification system		100 000
I.B.2.7.				Change in the classification of the product		270 000
I.B.3.			Renewal of marketing authorization			
I.B.3.1.				National		
I.B.3.1.a.					Starting materials (mono-component)	45 000
I.B.3.1.b.					Mixed allergens (multi-component)	180 000
I.B.3.1.c.					Other	180 000
I.B.3.2.				Mutual recognition procedure		
I.B.3.2.a.					RMS	
I.B.3.2.a.1.					Starting materials (mono-component)	145 000
I.B.3.2.a.2.					Mixed allergens (multi-component)	765 000
I.B.3.2.a.3.					Other	765 000
I.B.3.2.b.					CMS	
I.B.3.2.b.1.					Starting materials (mono-component)	90 000
I.B.3.2.b.2.					Mixed allergens (multi-component)	615 000
I.B.3.2.b.3.					Other	615 000
I.B.4.			Withdrawal of marketing authorization			9 000
I.B.5.			Annual maintenance of marketing authorization			
I.B.5.1.				Starting materials (mono-component)		9 000
I.B.5.2.				Mixed allergens (multi-component)		45 000
I.B.5.3.				Other		45 000
II	Homeopathic preparations					
II.A.			New authorizations			
II.A.1.				Mono-component medicinal product		
II.A.1.1.					If the active constituent indicated appears in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	67 500
II.A.1.2.					If the active constituent indicated does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of	270 000

		one of the Member States	
II.A.2.		Multi-component medicinal product	
II.A.2.1.		If the active constituent indicated is the combination of active substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	135 000
II.A.2.2.		If the active constituent indicated (also) contains active substances which does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	540 000
II.A.3.		Other	540 000
II.B.	Modification of marketing authorization		
II.B.1.	Type IA-IB		
II.B.1.1.		Mono-component medicinal product	
II.B.1.1.a.		If the active constituent indicated appears in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	9 000
II.B.1.1.b.		If the active constituent indicated does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	9 000
II.B.1.2.		Multi-component medicinal product	
II.B.1.2.a.		If the active constituent indicated is the combination of active substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	90 000
II.B.1.2.b.		If the active constituent indicated (also) contains active substances which does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	90 000
II.B.1.3.		Other	90 000
II.B.2.	Type II		
II.B.2.1.		Mono-component medicinal product	
II.B.2.1.a.		If the active constituent indicated appears in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	18 000
II.B.2.1.b.		If the active constituent indicated does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	18 000
II.B.2.2.		Multi-component medicinal product	
II.B.2.2.a.		If the active constituent indicated is the combination of active substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	180 000
II.B.2.2.b.		If the active constituent indicated (also) contains active substances which does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of	180 000

	one of the Member States	
II.B.2.3.	Other	180 000
II.B.3.	Changes not effecting the summary of product characteristics, pertaining only to the labeling and the package leaflet [Act XCV of 2005, Subsection (2) of Section 10]	20 000
II.B.4.	Transfer of marketing authorization (succession)	100 000
II.B.5.	In the Hungarian marketing authorization, addition or removal of packaging units that have already been authorized under the mutual recognition procedure	100 000
II.B.6.	Switching to the global identification system	100 000
II.B.7.	Change in the classification of the product	270 000
II.C.	Renewal of marketing authorization	
II.C.1.	Mono-component medicinal product	
II.C.1.1.	If the active constituent indicated appears in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	45 000
II.C.1.2.	If the active constituent indicated does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	180 000
II.C.2.	Multi-component medicinal product	
II.C.2.1.	If the active constituent indicated is the combination of active substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	90 000
II.C.2.2.	If the active constituent indicated (also) contains active substances which does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	350 000
II.C.3.	Other	350 000
II.D.	Annual maintenance of marketing authorization	
II.D.1.	Mono-component medicinal product	9 000
II.D.2.	Multi-component medicinal product	45 000
II.E.	Withdrawal of marketing authorization	27 000
III	Other procedures	
III.A.	New parallel import authorization	500 000
III.B.	Modification of parallel import authorization	180 000
III.B.1.	Type IA-IB	180 000
III.B.2.	Type II	270 000
III.C.	Renewal of parallel import authorization for five more years	250 000
III.D.	Maintenance of parallel import authorization	180 000
III.E.	Extension of the shelf life of a production batch	27 000
III.F.	Authorization of deviation from the marketing authorization for certain production batches	27 000
III.G.	Clinical trials on investigational medicinal products, other than the non-commercial trials referred to in Paragraph *q)* of Subsection (1) of Section 2 of Decree No. 35/2005 (VIII. 26.) EüM on the Clinical Trial of Investigational Medicinal Products for Human Use and on the Implementation of Good Clinical Practice	
III.G.1.	Authorization	580,000
III.G.2.	Modification of authorization for clinical trial	110,000
III.H.	Authorization for the manufacture of medicinal products	
III.H.1.	On-site inspection (each facility)	450 000

III.H.2.	New authorization for the manufacture of medicinal products	225 000
III.H.3.	Modification of authorization for the manufacture of medicinal products	90 000
III.I.	Authorization for the wholesale distribution of medicinal products	
III.I.1.	On-site inspection (each facility)	360 000
III.I.2	New authorization for the wholesale distribution of medicinal products	90 000
III.I.3.	Modification of authorization for the wholesale distribution of medicinal products	90 000
III.J.	Inspection of laboratories involved in safety testing of investigational medicinal products in accordance with the principles of good laboratory practice, and issue of the related certificate	382 500
III.K.	Issue of certificate verifying inspection of the manufacturing and distribution of medicinal products that have been authorized for marketing in Hungary on a regular basis, and the conformity of such medicinal products, separately for each product on an ad hoc basis	22 500
III.L.	Hourly charge for expert services and activities, consultation	8 000
III.M.	Reclassification as medicinal products	405 000
III.N.	Authorization for genetic modification operations	
III.N.1.	Authorization for the genetic modification of natural organisms: separately for each genetic modification procedure	70,000
III.N.2.	Implementation of facilities engaged in genetic modification operations: separately for each facility	260,000
III.N.3.	Contained use of genetically modified organisms and products produced therefrom: separately for each genetic modification operation	135,000
III.N.4.	Deliberate release into the environment of genetically modified organisms and products produced therefrom: separately for each genetic modification operation and for each site of release	300,000
III.N.5.	Placing on the market of genetically modified organisms and products produced therefrom: separately for each genetic modification operation	250,000
III.N.6.	Exportation and importation of genetically modified organisms and products produced therefrom: separately for each application	180,000
III.N.7.	Carriage of genetically modified organisms and products produced therefrom: separately for each application	70,000
III.O.	Reclassification of a test site to a first grade clinical pharmacological test site	450,000
III.P.	Therapeutic substances (preparations) other than pharmaceuticals	
III.P.1.	Modification of marketing authorization	90,000
III.P.2.	Renewal of marketing authorization	90,000