MEDICINES ACT 395/1987

Unofficial translation; Amendments up to 1340/2010 included

Chapter 1 — General provisions

Objectives

Section 1 (80/2003)

The objective of this Act is to maintain and promote the safety of medicinal products and their safe and proper use. A further objective of the Act is to ensure the appropriate manufacture and availability of medicinal products in Finland.

Scope of application

Section 2

(1) This Act applies to medicinal products, their manufacture, import, distribution, sale and other release for consumption, and to medicinal product manufacturers, medicinal product wholesalers and pharmacies practising the aforementioned activities, to laboratories performing preclinical safety testing of medicinal products, and to the preparation and distribution of medicinal products by hospitals and health centres. (1112/2010)

(2) This Act also contains provisions on marketing authorisations and registration of medicinal products and on other supervision relating to operations referred to above in subsection 1. (853/2005)

(3) The provisions of this Act do not apply to products that are used solely for treating parasitic, fungal or bacterial diseases of aquarium fish, or to vitamin products for cage birds, terrarium animals or small rodents kept exclusively as pets. Section 55(1) does not apply to the homeopathic products referred to in section 22a of the Act. (853/2005)

(4) The provisions of this Act concerning the granting of marketing authorisations, changes to medicinal products, fees related to marketing authorisations, revocation of marketing authorisations and prohibition of the release of a medicinal product for consumption do not apply to medicinal products whose marketing authorisation and related supervision are subject to a decision of the European Medicines Agency or the Commission of the European Communities or the Council of the European Union (*an institution of the European Union*) as laid down in European Community Law. If urgently required to protect human or animal health or the environment, the Finnish Medicines Agency may temporarily prohibit release for consumption of a medicinal product until an institution of the European Union resolves the matter. Provisions concerning fees related to the placing on the market and supervision of medicinal products referred to in this subsection may be issued by Ministry of Social Affairs and Health decree. The amount of such fees is determined by provisions issued in the Act on the Charge Criteria of the State (150/1992). The Finnish Medicines Agency may issue further regulations on the placing on the market and supervision of medicinal products referred to in this subsection insofar as the matter is not provided by European Community Law and the jurisdictional competence has not been reserved for institutions of the European Union. (773/2009)

Definitions

Section 3 (853/2005)

(1) *Medicinal product* means a product or substance intended for internal or external use to cure, alleviate or prevent a disease or its symptoms in humans or animals.

(2) Medicinal products are also considered to include substances or combinations of substances used internally or externally than can be used to restore, correct or modify the vital functions of humans or animals through pharmacological, immunological or metabolic influence or to determine the state of health or the reason for a disease.

(3) In ambiguous cases where the product may, taking all its properties into account, correspond to the definition of a medicinal product or another product elsewhere in legislation or in the legislation of the European Union, what has been laid down on medicinal products applies.

Section 4

(1) A medicinal product means a medicinal product:

1) that is prepared or imported in accordance with this Act; and

2) that is intended for use as a medicinal product; and

3) that is sold or otherwise released for consumption in a sales package. (1046/1993)

(2) Blood plasma from a human is also considered to be a medicinal product if an industrial process is used in its production. (853/2005)

Section 5

A active substance is a substance with an effect on humans or animals that is defined in detail chemically or by other scientific means and is used in the manufacture of a medicinal product or as a medicinal product in its own right.

Section 5a (853/2005)

Traditional herbal medicinal product means a medicinal product intended for humans which contains one or more plant-derived substances, one or more herbal medicinal products or their combinations as active substances and which meets the registration requirements laid down in section 22(1). A traditional herbal medicinal product may also contain vitamins or minerals if they enhance the impact of the plant-derived substances.

Section 5b (853/2005)

(1) *Homeopathic product* means a medicinal product prepared from homeopathic stocks in accordance with the homeopathic method described in the European Pharmacopoeia or,

if it is not available, in pharmacopoeias used officially in EU Member States. A homeopathic product may be prepared from more than one homeopathic stock.

(2) Provisions concerning homeopathic products also apply to other products prepared using homeopathic methods as referred to in subsection 1.

Section 5c (853/2005)

(1) *Reference medicinal product* means a medicinal product which has been granted a marketing authorisation referred to in section 21 or for which a state belonging to the European Economic Area has granted a marketing authorisation in accordance with article 5 of Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, hereafter the Veterinary Medicinal Products Directive, or article 8 of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, hereafter Human Medicinal Products Directive, or for which the European Union has granted a marketing authorisation. (1112/2010)

(2) *Generic medicinal product* means a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form, and whose bioequivalence with a reference medicinal product has been demonstrated by appropriate bioavailability tests. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy. Applicants for marketing authorisations must provide the additional information necessary for proving the safety or efficacy of the various salts, esters or derivatives of the active substance. Various immediate-release oral pharmaceutical forms are considered to be one and the same pharmaceutical form. Bioavailability studies need not be carried out if the applicant demonstrates that the generic medicinal product meets the criteria defined in the relevant detailed guidelines issued by the European Union Commission.

Section 5d (853/2005)

Medicinal gas means gas or gas mixture whose use is based on its pharmacological effect, which is intended for dosage to patients for treatment, diagnostic or preventive purposes and which has been produced and inspected in accordance with good manufacturing practice.

Section 6 (773/2009)

If necessary, the Finnish Medicines Agency will decide whether a substance or product is considered a medicinal product, a traditional herbal medicinal product or a homeopathic product.

Other Acts

Section 7 (773/2009)

(1) Any medicinal products referred to in this Act that are also narcotic drugs under the Narcotics Act (373/2008) are additionally subject to the provisions of the Narcotics Act.

(2) In addition to what is provided on medicinal products in this Act, the provisions of the Alcohol Act (1143/1994) or provisions issued pursuant to it on substances or products containing alcohol also apply to medicinal products containing alcohol.

(3) The Act on Obligatory Reserve Supplies of Medicinal Products (979/2008) lays down provisions on obligatory reserve supplies of medicinal products.

(5) Whenever a medicinal product referred to in this Act is to be regarded as hazardous waste as referred to in the Waste Act (1072/1993), the product will be subject to the hazardous waste provisions of the Waste Act or provisions issued pursuant to it.

Chapter 2 — Manufacture of medicinal products

Industrial manufacture

Section 8

(1) Medicinal products may only be manufactured industrially by medicinal product manufacturers that have acceptable production facilities and equipment and a licence from the Finnish Medicines Agency. The licence may incorporate conditions. (773/2009)

(2) Further provisions on information to be given in licence applications and on the application procedure will be issued by Government decree. The period of time during which licence application decisions must be made will also be laid down by Government decree. (700/2002)

See sections 1 and 2a of the Medicines Decree (693/1987) on application for and granting of licences.

Section 9

(1) Medicinal product manufacturers must have an accountable director who is primarily responsible for ensuring that medicinal products manufactured by the medicinal product manufacturer meet the requirements set for them by the provisions of this Act and provisions issued pursuant to it and are of flawless quality, and that the provisions of this Act and provisions issued pursuant to it on the manufacture of medicinal products and on quality control are complied with in the industrial manufacture of medicinal products.

(2) Accountable directors of medicinal product manufacturers must be certified Masters of Pharmacy or have some other appropriate higher first degree. Accountable directors are also required to have a sufficient period of experience in manufacturing or quality control of medicinal products in the service of a medicinal product manufacturer. An accountable director must not simultaneously act as accountable director in another company that has been licensed to manufacture medicinal products, Neither must an accountable director act as accountable director in a medicinal product wholesaler or as a licensed pharmacist, manager of a hospital pharmacy or dispensary, head of a military pharmacy or manager of a pharmacy or subsidiary pharmacy. If necessary, further provisions on the qualifications of accountable directors may be issued by Government decree. (700/2002)

(3) If an accountable director does not, in addition to the qualifications stated in subsection 2, meet the qualifications laid down in article 53 of the Directive of the European Parliament and of the Council on the Community Code Relating to Veterinary Medicinal Products (2001/82/EC) and in article 49 of the Directive of the European Parliament and of the Council on the Community Code Relating to Medicinal Products for Human Use (2001/83/EC), the licence holder must employ at least one person with the qualifications laid down in the above directives. The Finnish Medicines Agency will issue further provisions on the duties of such a person. (773/2009)

(4) As regards units and laboratories carrying out duties in the sphere of quality control of medicinal products, derogations from the qualifications of accountable directors and persons meeting the qualifications laid down in subsections 2 and 3 may be laid down by Government decree. (296/2004)

Section 10 (1112/2012)

(1) If required for technical, economic or production-related reasons, a medicinal product manufacturer may have a medicinal product manufactured (contract manufacture) or controlled (contract analysis) either in part or in full by another medicinal product manufacturer (contract manufacturer) or institution (contract analyst), respectively.

(2) A contract manufacturer and a contract analyst performing release analysis of medicinal substances or medicinal products must have the licence referred to in section 8 for the industrial manufacture of medicinal products. Contract manufacturers and contract analysts must give the Finnish Medicines Agency at least 60 days' advance notification of the commencement of their operations. A copy of the agreement made between the medicinal product manufacturer and the contract manufacturer or contract analyst must be appended to the notification.

(3) The Finnish Medicines Agency may issue regulations concerning the procedures to be observed in contract manufacture and contract analysis.

Section 11 (700/2002)

(1) Medicinal product manufacturers must comply with good manufacturing practice for medicinal products corresponding to the principles and guidelines relating to provisions issued by the European Union and the Convention on mutual recognition of inspections of manufacture of pharmaceutical products (Finnish Treaty Series 20/1971). Only such active substances as have been manufactured in accordance with the European Union guidelines on good manufacturing practice may be used in the manufacture of medicinal products. The Finnish Medicines Agency may issue further regulations on observing good manufacturing practice and on the extent to which good manufacturing practice also covers the manufacture of auxiliary substances used in the production of medicinal products. (773/2009)

(2) Medicinal product manufacturers must keep records of the sale of medicinal products. Such records must be retained for a minimum of five years. Further provisions on the content and storage of such records may be issued by Government decree.

Preparation other than industrial manufacture

Section 12 (1112/2010)

(1) Medicinal products may be prepared in a pharmacy or in a subsidiary pharmacy belonging to it only for sale in that pharmacy or in a subsidiary pharmacy or service point belonging to it.

(2) Licensed pharmacists may, however, have particular medicinal products prepared by another pharmacy or acquire from another pharmacy particular raw materials imported in accordance with section 17(1)(3) for their own production. Licensed pharmacists are required to notify the Finnish Medicines Agency of this. The Agency may issue regulations concerning the procedures to be observed in the preparation of medicinal products in pharmacies and in contract manufacture as well as further provisions on the notification procedure.

Section 12a (1112/2010)

(1) Automated dose dispensing taking place in a pharmacy and a subsidiary pharmacy belonging to it as well as contract preparation are subject to a licence from the Finnish Medicines Agency. The licence must be granted if the requirements laid down in section 15 are met. The licence may incorporate conditions pertaining to the preparation, release and use of the medicinal product or otherwise required for medicinal product safety.

(2) A pharmacist may contract out automated dose dispensing to another pharmacy to which a licence for automated dose dispensing has been granted.

Section 13 (773/2009)

Pharmacies, the Military Pharmacy, hospital pharmacies and dispensaries must give the Finnish Medicines Agency advance notification of the pharmacy’s own preparations.

Section 14 (700/2002)

Hospital pharmacies or dispensaries are allowed to prepare medicinal products to the extent required by hospital district, hospital or health centre operations or operations referred to in section 62(3). Manufacture of medicinal products must comply with good manufacturing practice for medicinal products corresponding to the principles and guidelines adopted in connection with the provisions issued by the European Communities and the Convention on mutual recognition of inspections of manufacture of pharmaceutical products.

Section 15 (1112/2010)

(1) A precondition for the preparation of medicinal products and for automated dose dispensing in a pharmacy, subsidiary pharmacy, hospital pharmacy or dispensary is that the personnel are sufficiently familiar with the preparation of medicinal products and that there are appropriate production facilities and equipment for such preparation. The

activities must furthermore comply, as applicable, with the good manufacturing practice for medicinal products under section 11.

(2) Further provisions on the preconditions for a licence may be issued by Government decree. The Finnish Medicines Agency may issue regulations on application for licences under section 12a(1).

Section 15a (773/2009)

(1) Medicinal products may be manufactured for clinical trials under a licence granted by the Finnish Medicines Agency. Such licences may incorporate conditions relating to the manufacture, surrender and use of a medicinal product or otherwise required for medicinal product safety.

(2) In addition to what is provided in subsection 1 above, medicinal products used in clinical trials can be manufactured by licence holders referred to in section 8 and those manufacturing or preparing medicinal products as referred to in sections 12, 14 and 84 in accordance with what is provided and laid down in this Act and in provisions and decisions issued under it. Such manufacturers of medicinal products must notify the Finnish Medicines Agency of the manufacture of a medicinal product to be used for clinical trials before the manufacture begins.

(3) The manufacture of medicinal products for clinical trials must comply with, as appropriate, what is laid down on the manufacture and preparation of medicinal products in or under this Act.

(4) The Finnish Medicines Agency may issue further regulations and guidelines on the manufacture and preparation of medicinal products for clinical trials, on application for licences referred to in subsection 1 and on notification referred to in subsection 2.

Section 15b (296/2004)

(1) Units manufacturing medicinal products for clinical trials must employ at least one person meeting the qualifications laid down in article 13(2) of the Directive of the European Parliament and of the Council 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 (2001/20/EC). The Finnish Medicines Agency will issue further provisions on the duties of this person. If the unit’s manufacture of medicinal products is extensive, the unit must have an accountable director whose duties and qualifications are determined under section 9.

(2) Units manufacturing medicinal products for clinical trials may have medicinal products contract-manufactured for clinical trials under the conditions laid down in section 10.

(3) Units manufacturing medicinal products for clinical trials must comply with the good manufacturing practice for medicinal products referred to in section 11.

Section 15c (773/2009)

(1) The non-industrial manufacture of the advanced therapy medicinal products referred to in 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 is subject to licence granted by the Finnish Medicines Agency. The licence may be granted for the manufacture of a medicinal product by prescription from a physician for the individual treatment in a hospital of a particular patient. The licence may incorporate conditions pertaining to the preparation, release, traceability and use of the medicinal product or required for medicinal product safety. The licence may be granted for a fixed or indefinite term.

(2) The manufacture of advanced therapy medicinal products must comply, as appropriate, with what is laid down on the manufacture and preparation of medicinal products in or under this Act.

(3) The Finnish Medicines Agency may issue further regulations and guidelines on application for the licence under subsection 1 and the contents of such application, the quality requirements applicable to the non-industrial manufacture of advanced therapy medicinal products, and the traceability of the products and pharmacovigilance.

Section 16 (773/2009)

The Finnish Medicines Agency will issue further regulations and guidelines concerning the advance notification referred to in section 13 and concerning the good manufacturing practice for medicinal products that is based on provisions issued by the European Communities and the Convention on mutual recognition of inspections of manufacture of pharmaceutical products, in accordance with sections 12 and 14. The Finnish Medicines Agency may also issue further regulations and guidelines concerning the sales package labelling of the medicinal products manufactured.

Chapter 3 — Import of medicinal products

Section 17 (853/2005)

(1) Medicinal products may be imported:

1) by any party permitted to manufacture medicinal products industrially at a medicinal product manufacturer’s facility;

2) by any party that has a licence under section 32 to practise medicinal product wholesaling;

3) by licensed pharmacists, the University of Helsinki licensed pharmacy, the University of Kuopio licensed pharmacy and the Military Pharmacy for pharmacy operations and for operations referred to in section 12(2);

4) by hospital pharmacies in individual cases for operations of the relevant hospital district, hospital or health centre and for operations referred to in section 62(3);

5) by universities, institutions of higher education and scientific research institutions for their own research purposes; and

6) for clinical trials of medicinal products, by parties with the right to manufacture medicinal products for clinical trials.

(2) Hospital pharmacies, universities, institutions of higher education and scientific research institutions must notify the Finnish Medicines Agency of any imports. (773/2009)

(3) If a medicinal product with a marketing authorisation or a registered medicinal product or a medicinal product intended for clinical trials of medicinal products is imported from a state outside the European Economic Area, the importer must have the licence referred to in section 8 for the industrial manufacture of medicinal products.

(4) Businesses other than those referred to in subsection 1(1-3) may import medicinal substances for their own production purposes. The businesses must notify the Finnish Medicines Agency of such imports. (773/2009)

Section 18 (700/2002)

Provisions concerning records of imported medicinal products and concerning notifications of imports referred to in section 17(2) will be issued by Government decree.

Section 19 (22/2006)

(1) Private individuals may import into Finland medicinal products for their own personal medication procured from suppliers with retail distribution rights for such products. The import of medicinal substances is not permitted. The procurement of prescription medicinal products must be based on prescriptions issued by a person entitled to prescribe medication. In addition, persons entering Finland may bring with them medicinal products for treatment of a pet arriving in the country at the same time up to a maximum amount equivalent to one month’s needs at a time.

(2) Persons in permanent residence outside Finland and entitled to practise the profession of a physician or a veterinary surgeon may, when entering the country, bring with them and use medicinal products that have a marketing authorisation in the country in which they primarily practise their profession if the entry into the country and need for medicinal products are based on medication needs of a person or group of persons or an animal or group of animals arriving in Finland temporarily for a major international sports competition or a comparable other event. The right to import does not, however, apply to doping substances referred to in chapter 44, section 16 of the Criminal Code (39/1889). Imported medicinal products may only be used for the treatment of persons or animals by the physician or veterinary surgeon who has imported them and under whose treatment responsibility the persons or animals are.

(3) If licensed physicians, dentists or veterinary surgeons in permanent residence in Finland have exported medicinal products from Finland in preparation for providing medicinal treatment for persons or animals in permanent residence in Finland but temporarily abroad, they may bring such unused medicinal products back to Finland.

(4) Further provisions may be issued by Government decree on detailed conditions concerning imports referred to in subsections 1–3 and restrictions concerning the country or method of procurement of the medicinal product, the nature of the competition or other event referred to in subsection 2 and the maximum amount to be imported. Provisions may also be issued by Government decree to deny or restrict the right under subsection 2 to import medicinal products containing substances classified as narcotics. An obligation may also be laid down requiring advance notification concerning imports relating to subsection 2 above to the authorities or to the organizer of the event that is the reason for

the temporary residence, on grounds laid down by Government decree. Provisions may also be issued by Government decree to restrict imports of substances used for veterinary medication, if they may endanger the safety or quality of animal-derived food or if they may endanger resistance to animal diseases in Finland.

Chapter 4 — Marketing authorisation and registration (853/2005)

Scope of application

Section 20 (853/2005)

The provisions of this chapter apply to medicinal products and medicinal gases that are manufactured industrially or are imported.

Section 20a (773/2009)

A medicinal product may be sold to the general public or otherwise released for consumption only if the Finnish Medicines Agency has granted an authorisation for the product or registered it under this Act or if it has a marketing authorisation granted by an institution of the European Union.

Marketing authorisation

Section 21 (853/2005)

(1) The Finnish Medicines Agency grants marketing authorisation for medicinal products other those appearing in the Annex to Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency when:

1) the product has been established to be appropriate as a medicinal product;

2) the product cannot be considered to be hazardous to the patient’s health, the user or public health and a veterinary medicinal product, considering its indication, cannot be considered to be hazardous to the consumer, the environment or the target animal, taking into account the beneficial effects of the product relative to the risks associated with its quality, safety and efficacy (*risk/benefit ratio*);

3) the products meets the manufacture and quality requirements under the pharmacopoeia or otherwise imposed on it;

4) the effects of the medicinal substance and the medicinal product have been duly established through preclinical and clinical trials; and

5) product composition and other data have been duly reported.

(773/2009)

(2) The marketing authorisation of a medicinal product may incorporate conditions when these are necessary to ensure the correct and safe use of the medicinal product.

(3) For particular reasons related to the safety or efficacy of the medicinal product, the marketing authorisation may be conditional such that the holder of the marketing authorisation must undertake measures ordered in the marketing authorisation. The Finnish Medicines Agency publishes the reasons for the grant of a conditional marketing authorisation and specifies the measures required. The holder of the marketing authorisation must submit to the Finnish Medicines Agency each year a report on the fulfilment of the conditions of the marketing authorisation. (773/2009)

(4) A marketing authorisation is not required for a radioactive medicinal product prepared at the moment of use by using radionuclide generators, product combinations or radioactive precursors which have marketing authorisation.

Section 21a (853/2005)

(1) In derogation to what is laid down in section 21(1)(4) and without restricting the application of legislation concerning the protection of industrial and commercial rights, applicants do not need to submit findings of preclinical and clinical trials or safety and residue testing on veterinary medicinal products if the applicants can show that authorisation is being sought for a generic medicinal product that is equivalent to a reference medicinal product that has or has had a marketing authorisation under section 21 or a marketing authorisation granted by a European Economic Area member state or by the European Community for a minimum of eight years. If, in the case of a biological medicinal product, the raw ingredients or manufacturing processes specifically differ from the reference product, the applicants must append to their applications the findings of preclinical and clinical trials separately prescribed by the Finnish Medicines Agency. Where necessary, the Agency must give further instructions on how the conformity of raw ingredients and manufacturing methods is to be shown.

(2) The findings of appropriate preclinical and clinical trials and appropriate safety and residue tests on veterinary medicinal products must, however, be submitted if the product does not fully comply with the definition of a generic medicinal product given in section 5c or if it has not been possible to demonstrate bioequivalence through bioavailability testing or if the product’s therapeutic indication or administration route differ from those of the reference medicinal product.

(3) The marketing authorisation of a generic medicinal product will enter into force at the earliest when ten years have passed from the granting of the original marketing authorisation of the reference medicinal product. If the holder of a marketing authorisation for a reference medicinal product is, during the eight years following the granting of the authorisation, granted an authorisation for one or more new therapeutic indications which have, in the scientific evaluation carried out before granting the authorisation, been found to bring significant clinical benefits in comparison with existing treatments, the marketing authorisation will enter into force at the earliest when 11 years have elapsed from the granting of the original marketing authorisation for the reference medicinal product.

(4) If a veterinary medicinal product containing a new active substance is meant for one or more food-producing animals, the ten-year period referred to in subsection 3 will be extended by one year each time the authorisation is extended to cover a new food-producing animal species. The extension must nevertheless not exceed three years. It is a

condition for the extension that the marketing authorisation is granted within five years of the granting of the marketing authorisation for the reference medicinal product. A further condition for the extension is that the holder of the marketing authorisation has submitted an application for the establishment of maximum residues for the species concerned in accordance with Council Regulation 2377/90/EEC laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, hereafter referred to as the *Residue Regulation*. The ten-year extension referred to in this subsection does not apply to veterinary medicinal products whose reference medicinal products have been granted marketing authorisation on 30 April 2004 or before.

(5) Marketing authorisations for generic medicinal products for fish, bees or other species specified in accordance with the procedure referred to in article 89(2)of Veterinary Medicinal Products Directive will, however, enter into force at the earliest 13 years after the granting of the marketing authorisation for the reference medicinal product.

Section 21b (853/2005)

When a marketing authorisation is sought for a medicinal product which has the same quality and quantity of active substances and the same pharmaceutical form as a product that has been granted a marketing authorisation previously and the holder of the marketing authorisation has consented to the use of the pharmaceutical, preclinical and clinical findings recorded in the documents of the product's marketing authorisation application and, in the case of a veterinary medicinal product, also the findings of safety and residue testing, findings of this nature need not be appended to the application.

Section 21c (853/2005)

(1) In derogation to what is laid down in section 21(1)(4) and without restricting the application of legislation protecting industrial and commercial rights, applicants for marketing authorisations need not submit findings of preclinical and clinical trials on the medicinal product or, in the case of veterinary medicinal products, the findings of safety and residue testing, if the applicants show that the active substances of the product have an established pharmaceutical history of at least ten years in a European Economic Area state and their efficacy has been recognised and safety level approved. The efficacy and safety level must in such a case be shown through appropriate scientific literature as specified by the Finnish Medicines Agency. (773/2009)

(2) If a medicinal product contains many active agents contained in medicinal products that have already been granted a marketing authorisation and these active substances have not been used previously in combination for treatment purposes, findings on the combination from clinical and preclinical trials and, where necessary, also findings from safety and residue testing for veterinary medicinal products must be submitted on the combination. No findings need be submitted for the single active substances or the publication references referred to in subsection 1. Time limits under section 21a(1) and 21a(3–5) apply to the generic medicinal products of new combinations containing several medicinal substances.

(3) If a generally approved medicinal substance is approved for a new therapeutic indication on the basis of significant preclinical or clinical trials, a new indication may be applied for on the basis of such trials at the earliest when one year has elapsed since the amendment to the marketing authorisation. The restriction only concerns the first new therapeutic indication.

(4) If new testing on maximum residues has been carried out on a veterinary medicinal product meant for a food-producing animal in accordance with the Residue Regulation and new clinical trials have been carried out on another food-producing animal species in order to obtain a marketing authorisation, and these trials have been taken into account in the granting of a marketing authorisation under subsection 1, another applicant for a marketing authorisation may not refer to such trials until at least three years have elapsed since the granting of the first marketing authorisation based on them.

Special authorisation procedures

Section 21d (773/2009)

If a medicinal product that has been granted a marketing authorisation in Finland is imported by a party other than the holder of the marketing authorisation or a representative authorised by the holder of the marketing authorisation to import the medicinal product, the medicinal product must have a parallel import marketing authorisation. The Finnish Medicines Agency grants such a parallel import marketing authorisation if the there is no therapeutic difference between the parallel import product and the product that has been granted a marketing authorisation previously. A parallel import marketing authorisation can be granted only to medicinal products imported from a European Economic Area state.

Section 21e (773/2009)

In derogation to what is laid down in section 21(1) and 21(2), the Finnish Medicines Agency may grant a temporary authorisation for the use of a medicinal product, if special grounds exist on the basis of suspected or detected spreading of harmful causes of disease, toxins, chemical substances or hazardous nuclear radiation and there is no other appropriate treatment or medication available.

Section 21f (773/2009)

For special reasons relating to treatment or public health, the Finnish Medicines Agency may, the provisions of section 21 notwithstanding, grant a temporary authorisation for a fixed period (*special authorisation*) for releasing a medicinal product for consumption. Further provisions concerning the special authorisation procedure and the conditions for granting special authorisation may be issued by Government decree.

Section 21g (773/2009)

What is laid down in this Act on marketing authorisations notwithstanding, the Finnish Food Safety Authority may, in the case of a serious animal disease epidemic, grant an import authorisation or an authorisation for use for an immunological veterinary medicinal product which does not have marketing authorisation if a suitable product is not otherwise available or if the epidemic situation otherwise so requires. The Finnish Medicines Agency must be notified of the authorisation without delay.

Section 21h (311/2009)

The use of an immunological veterinary medicinal product may be prohibited by decree issued by the Ministry of Agriculture and Forestry if the administration of the product to animals hampers the detection, control or eradication of animal diseases in Finland or causes difficulties to proving that live animals or foodstuffs or products derived therefrom do not contain disease agents or that the disease which the product is intended to prevent does not occur in Finland.

Registration

Section 22 (773/2009)

(1) Traditional herbal medicinal products intended to be released for human consumption must be registered. The Finnish Medicines Agency registers a traditional herbal medicinal product if:

1) the product is suitable for use in terms of composition and indication without diagnosis, prescription or supervision of treatment by a physician;

2) the product is intended for oral or external use or use by inhalation;

3) sufficient information exists on the traditional use, safety, pharmacological effects and efficacy of the product;

4) before the date of filing the application, the product or an equivalent product that contains the same active substances, has the same or a similar indication, strength and dosage and the same or a similar administration route as the product that is the object of the application has been used as a medicinal product continuously for at least 30 years, 15 of them in an EEA state; and

5) the product does not meet the conditions for marketing authorisation under sections 21 or 21c or for registration under section 22a.

(2) If registration is sought for a product which has been used in European Economic Area states for less than 15 years but which otherwise meets the conditions for registration laid down in subsection 1, the Finnish Medicines Agency must submit the matter to the European Medicines Agency EMEA Committee on Herbal Medicinal Products. It is possible to derogate from the said condition of 15 years of use if the Committee draws up a Community herbal monograph for the product. The herbal monograph must be taken into account when the final decision is made unless there are special reasons of medicinal product safety indicating otherwise.

(3) The Finnish Medicines Agency may incorporate conditions into the registration to ensure correct and safe use of traditional herbal medicinal products and conditions concerning the place of sale.

Section 22a (773/2009)

(1) Homeopathic products to be released for consumption to which the marketing authorisation procedure of section 21 does not apply must be registered. The Finnish Medicines Agency registers such products if:

1) a product is intended to be administered orally or externally; products intended for veterinary use may also have some other administration route described in the pharmacopoeia;

2) no special medicinal indication is given in the product's labelling or other related information;

3) the product does not contain more than one ten thousandth of the mother tincture or more than one hundredth of the smallest dose of medicinal substance requiring prescription and used in ordinary medicinal treatment; and

4) the product does not meet the conditions for marketing authorisation under section 21.

(2) The Finnish Medicines Agency may incorporate conditions into the registration to ensure correct and safe use of the product and conditions concerning the place of sale.

(3) Homeopathic products prepared in a pharmacy are not registered but an advance notification concerning them must be made to the Finnish Medicines Agency.

Miscellaneous provisions

Section 23 (773/2009)

(1) When processing matters relating to granting marketing authorisations and registrations and changes to medicinal products, the Finnish Medicines Agency must take into account any applications pending in a competent pharmacovigilance authority in another European Economic Area state and decisions made by competent authorities, and comply with decisions relating to the granting of marketing authorisations, changes to medicinal products and revocation of granted authorisations or prohibition of release for consumption of a medicinal product as provided in European Community Law.

(2) If, because of serious risk to public health or, in the case of a veterinary medicinal product, potential risk to human health, animals or the environment, the Finnish Medicines Agency cannot approve an evaluation statement, summary of product characteristics, package insert or labelling approved or proposed by another European Economic Area state, the Agency must provide a detailed explanation with justifications for its view to the Member State concerned and to the party applying for a marketing authorisation or registration or for their amendment. The Finnish Medicines Agency must take into account the guidelines issued by the European Commission for assessment of serious risk to public health or potential risk to human health, animals or the environment.

(3) If an application pending in a competent pharmacovigilance authority in one or more European Economic Area states in addition to Finland has been submitted to a European Union institution for decision by an authority other than the Finnish Medicines Agency, the Finnish Medicines Agency may nevertheless grant the medicinal product a marketing authorisation on the applicant's request. When the European Union institution concerned has resolved the matter, the Finnish Medicines Agency must, on its own initiative, take action to amend the marketing authorisation granted by it to comply with the decision of the European Union institution.

(4) A marketing authorisation or other authorisation for releasing a medicinal product for consumption will not be granted to a veterinary medicinal product containing substances

with hormonal, thyrostatic or beta-antagonistic effects as referred to in Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-antagonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC, unless the indication of the medicinal product has been approved in the said Directive.

Section 23a (773/2009)

(1) If a medicinal product that has been granted a marketing authorisation or has been registered is to be changed or when technological and scientific development calls for changes to a product, the holder of the marketing authorisation or registration must submit an application to this effect the Finnish Medicines Agency. The Agency must approve the changes if they meet the requirements laid down for amending authorisations or registrations. All subsequent strengths, pharmaceutical forms, administration routes and package types and all changes and extensions will be part of the original marketing authorisation or registration unless a separate marketing authorisation of registration has been applied for them. In the case of changes that do not essentially affect the evaluation of the conditions for granting marketing authorisations or registrations, a notification to the Finnish Medicines Agency is sufficient.

(2) If a medicinal product's marketing authorisation or registration is valid for a fixed period, the amended authorisation or registration is valid in accordance with the original fixed period.

(3) The Finnish Medicines Agency will issue further provisions on changes and applications and notifications concerning changes referred to in subsections 1 and 2 and on the procedures to be applied to them.

Section 23b (853/2005)

If a condition incorporated into a marketing authorisation under which a medicinal product intended for humans may be supplied only on the basis of a prescription (*prescription condition*) has been lifted on the basis of extensive preclinical or clinical trials carried out by the holder of the marketing authorisation, holders of marketing authorisations for other medicinal products containing the same active substance may not apply for the lifting of the prescription condition on the basis of such trials before one year has elapsed since the amendment of the condition concerning the marketing authorisation of the reference medicinal product.

Section 24 (773/2009)

(1) Marketing authorisations referred to in sections 21 and 21a–21d above and registrations referred to in sections 22 and 22a remain valid for five years from the granting of the first marketing authorisation or registration. Authorisations and registrations may be renewed. Renewed marketing authorisations and registrations remain valid indefinitely unless the Finnish Medicines Agency decides, for reasons of medicinal product safety, that the renewed authorisation or registration will also be valid for a period of five years. Authorisations and registrations renewed after the second five-year period will remain valid indefinitely.

(2) Applications for the renewal of marketing authorisations or registrations must be submitted to the Finnish Medicines Agency in writing at least six months before the expiration of the validity of the authorisation or registration.

Section 25 (853/2005)

(1) Marketing authorisations referred to in sections 21 and 21a–21d above and temporary authorisations referred to in section 21e and registrations may be granted to natural or legal persons resident in a European Economic Area state.

(2) Special authorisations may be granted to pharmacies, subsidiary pharmacies, the Military Pharmacy, hospital pharmacies, medicinal product wholesalers, medicinal product manufacturers, the National Institute for Health and Welfare, the Finnish Food Safety Authority and the Finnish Red Cross. (773/2009)

(3) Authorisations and registrations and their amendment or renewal must be applied for by submitting a written, signed application to the Finnish Medicines Agency. Also notifications referred to in section 23a(1) must be submitted to the Finnish Medicines Agency in writing and they must be signed. The Finnish Medicines Agency will issue further provisions on the application and notification procedure referred to in this chapter and related explanations, and about the labelling and inclusion of package inserts in the packaging of medicinal products. (773/2009)

(4) Provisions concerning the time period within which decisions must be given on authorisation, registration, amendment or renewal applications are issued by Government decree.

Section 25a (773/2009)

The Finnish Medicines Agency must draw up evaluation statements for medicinal products for which marketing authorisation has been applied. These statements must be updated whenever significant new information is obtained on the quality, safety or efficacy of a medicinal product. The evaluation statement and its justifications, excluding information that comes under business and professional secrecy, must be publicly accessible. The Finnish Medicines Agency must publish decisions on granting marketing authorisations for medicinal products and their summary of product characteristics.

Section 26 (853/2005)

Holders of marketing authorisations and holders of registrations referred to in section 22 must ensure that medicinal products that have been granted a marketing authorisation and registered traditional herbal medicinal products are constantly available to medicinal product wholesalers and pharmacies to meet the needs of patients and other users.

Notification duty

Section 27 (773/2009)

(1) Holders of marketing authorisations, parallel import marketing authorisations and registrations must notify the Finnish Medicines Agency about placing a medicinal product on the market, discontinuation of keeping a medicinal product on the market and temporary interruptions to keeping a medicinal product on the market. Notifications concerning placement on the market must be made at the latest within one week of the beginning of sales. Notifications concerning discontinuation of or interruption to keeping a medicinal product on the market must be made at least two months in advance unless special reasons indicate otherwise.

(2) If a party other than the holder of a marketing authorisation or its representative intends to import into Finland a medicinal product for which a European Union institution has granted a marketing authorisation, the importer must notify the Finnish Medicines Agency and the holder of the marketing authorisation of such import. The notification must be made at least one month before the planned commencement of the import.

Fees

Section 28 (773/2009)

The authorisations referred to in sections 21 and 21a–21g above, registrations referred to in sections 22 and 22a above and amendments to marketing authorisations and registrations referred to in section 23a above are chargeable. The fees may be ordered payable in advance. Furthermore, full fees or partial annual fees may be charged for measures relating to authorisations and registrations. Further provisions on fees are issued by Ministry of Social Affairs and Health decree, taking into account what is laid down or provided in the Act on the Charge Criteria of the State or under it. The Finnish Medicines Agency may issue further regulations and guidelines on the payment of the fees.

Expiry or revocation of marketing authorisations and registrations

Section 29 (853/2005)

(1) Marketing authorisations and registrations expire if their holder:

1) has not submitted within the time limit the annual report referred to in section 21(3) on a conditional marketing authorisation;

2) has not paid the annual fee referred to in section 28 within the time limit; or

3) has not placed the medicinal product on the market within three years of the granting of the marketing authorisation or registration or if an interruption in keeping the medicinal product on the market has lasted for a continuous period of three years.

(2) In addition, the Finnish Medicines Agency may revoke a marketing authorisation or registration if it has been shown by new research or other means that the conditions for granting a marketing authorisation or registration no longer exist. A marketing authorisation or registration may be revoked temporarily for a period required by necessary research if there is reason to suspect that the conditions for granting a marketing authorisation or registration no longer exist. (773/2009)

(3) For reasons relating to human or animal health or for other special reasons, the Finnish Medicines Agency may decide on application by the holder of a marketing authorisation or registration that the marketing authorisation or registration is not to expire on the basis of the grounds referred to in subsection 1(3). Holders of marketing authorisations and registrations must submit an application to the Finnish Medicines Agency concerning extension of a marketing authorisation for registration at least three months before the expiry of the three-year time limit. The Finnish Medicines Agency must give a decision on the matter within one month of receiving the application. (773/2009)

(4) The m Finnish Medicines Agency must notify the European Medicines Agency and the competent authorities of European Economic Area states of the expiry and revocation of marketing authorisations or of registrations of traditional herbal medicinal products on the basis of subsections 2 and 3. Notifications concerning urgent decisions made in order to protect public health must be made no later than on the following weekday. In such a case also the European Commission must be notified. All decisions concerning revocation of marketing authorisations and registrations must be published. (773/2009)

(5) Unavoidable costs arising from research referred to in subsection 2 above may be ordered to be paid either in full or in part by the holder of the marketing authorisation or registration concerned.

Section 30 (773/2009)

(1) Holders of marketing authorisations for medicinal products, parallel import marketing authorisations and registrations of traditional herbal medicinal products must keep an adverse effects register to ensure medicinal product safety and patient safety. In this register must be entered data on all detected and suspected adverse effects of the medicinal products of which the controller has become aware, the patient's illnesses or dispositions to these, all medical therapies, the indications of the medical therapies and the adverse effects of the medicinal products as well as data necessary to specify the patient, such as name and personal identity code. When the adverse effect appears in an animal, the data necessary to specify the owner of the animal as well as the species of animal must be entered in the register instead of patient data. The controller must report the data entered in the register to the Finnish Medicines Agency. A notification must also be made of prohibitions or restrictions issued by competent authorities in a European Economic Area state that may affect the assessment of the product's risk-benefit ratio.

(2) The Finnish Medicines Agency records the data referred to in subsection 1 in the national register of adverse effects which it maintains to ensure medicinal product safety and patient safety. In addition, the Finnish Medicines Agency may at any time request information on a medicinal product's risk-benefit ratio.

(3) The data held by holders of marketing authorisations for medicinal products, parallel import marketing authorisations and registrations of traditional herbal medicinal products and entered in the register of adverse effects maintained by the Finnish Medicines Agency may only be used for the purposes of monitoring and reporting adverse effects of medicinal products, scientific research and evaluation of the safety and risk/benefit ratio of medicinal products. However, the data may not be disclosed or used for purposes of decision-making concerning a data subject. The Finnish Medicines Agency must disclose to the National Institute for Health and Welfare any data concerning vaccines which comes into its possession. The disclosure of data from the register of adverse effects maintained by the Finnish Medicines Agency may also be accomplished via online

access. Before online access is provided, the party requesting the data must submit information to verify that appropriate data protection measures are undertaken.

(4) The Finnish Medicines Agency may disclose the personal data in its register of adverse effects for purposes of health care operations, the prevention or treatment of disease, or specified scientific research related to these if the privacy of the data subject is protected in the manner required under the Personal Data Act (523/1999). The Data Protection Ombudsman must be reserved an opportunity to heard before the disclosure of data. Provisions necessary to safeguard the privacy of the data subject must be incorporated into the decision on data disclosure.

(5) Holders of marketing authorisations for medicinal products, parallel import marketing authorisations and registrations of traditional herbal medicinal products must retain the data on adverse effects for a period of fifty years from the expiration of the marketing authorisation or registration. After the end of this period, the data must be disposed of within one year unless the Finnish Medicines Agency for particular reason decides that data storage is to be continued for a period of no more than five years at a time. The Finnish Medicines Agency must retain data on adverse effects for a period of fifty years from the entry of the data in the register.

(6) Holders of marketing authorisations, parallel import marketing authorisations and registrations of traditional herbal medicinal products must at all times have available a person responsible for pharmacovigilance, whose domicile must be in a European Economic Area state.

(7) The provisions of the Act on National Personal Data Registers Kept under the Health Care System (556/1989) concerning the national register of adverse effects also apply to the register. The Finnish Medicines Agency issues further provisions on maintaining adverse effects registers, reporting data to the Finnish Medicines Agency and the duties of the person responsible for pharmacovigilance. When necessary, the Finnish Medicines Agency may give persons authorised to prescribe and supply medicinal products orders and instructions concerning the reporting of adverse effects of medicinal products.

Section 30a (773/2009)

Holders of marketing authorisations, parallel import marketing authorisations and registrations must notify the Finnish Medicines Agency without delay of the withdrawal of a product from the market or interruption of distribution taking place on the holder’s own initiative and relating to the efficacy or safety of a medicinal product and of product defects relating to the manufacture of a medicinal product supplied by a medicinal product manufacturer. When necessary, the Finnish Medicines Agency will issue further provisions concerning the notification of product defects.

Chapter 5 — Sale of medicinal products by medicinal product manufacturers and medicinal product wholesalers

Sale by medicinal product manufacturers

Section 31 (1112/2010)

(1) Medicinal product manufacturers may sell or otherwise supply medicinal substances and their own medicinal products only to another medicinal product manufacturer or medicinal product wholesaler, pharmacy, subsidiary pharmacy, the Military Pharmacy, hospital pharmacy or dispensary. Medicinal products not restricted under law or other provisions to being sold solely by pharmacies may, in addition, be sold or otherwise supplied to retailers of such products.

(2) Medicinal product manufacturers may also sell or otherwise supply medicinal substances and their own medicinal products to universities, institutions of higher education and scientific research institutions for research purposes. The medicinal product manufacturer must notify the Finnish Medicines Agency of this.

Medicinal product wholesaling

Section 32 (853/2005)

(1) Wholesaling of medicinal products means all activity with the purpose of:

1) receiving and forwarding orders for medicinal products;

2) acquiring and keeping medicinal products in order to distribute them to pharmacies, operating units of social and health care services and other parties referred to in sections 34, 35 and 88 of this Act; or

3) exporting medicinal products.

(2) The wholesaling of medicinal products does not, however, include the sale of medicinal products to the general public under section 38, or the delivery of medicinal products from one pharmacy to another pharmacy or to an operating unit of social and health care services, the supply of medicinal products from hospital pharmacies or dispensaries under section 62 or the marketing and invoicing by holders of marketing authorisations or their representatives not involving possession, distribution or storage of the products.

(3) The wholesaling of medicinal products may only be carried out under a licence granted by the Finnish Medicines Agency. In order to be granted a licence, applicants must have proper facilities and equipment for storage of medicinal products and for ensuring operations and the personnel required for operations. Conditions concerning the operations may be incorporated into the licence. (773/2009)

(4) Provisions on recognition of wholesale licences granted in a European Economic Area state in accordance with provisions issued by the European Communities and on the time limit within which decisions must be given on applications for a licence are issued by Government decree.

Section 33

(1) Medicinal product wholesalers must have an accountable director responsible for ensuring that the medicinal products sold by the medicinal product wholesaler meet the requirements set for them in this Act or in provisions issued pursuant to it, and that the medicinal product wholesaler complies with regulations and guidelines issued on the storage, handling and labelling of medicinal products. The accountable director is also

responsible for ensuring that the distribution of medicinal products by the medicinal product wholesaler is carried out in a proper manner.

(2) Provisions concerning quality control to which medicinal products imported from countries outside the European Economic Area must be subjected will be issued by Government decree. (700/2002)

(3) A medicinal product wholesaler's accountable director must be a certified Master of Pharmacy. An accountable director cannot simultaneously act as accountable director in another company that has been granted a licence for medicinal product wholesaling. Neither can an accountable director act as accountable director for a medicinal product manufacturer or as licensed pharmacist, manager of a hospital pharmacy or dispensary, head of a military pharmacy or manager of a pharmacy or subsidiary pharmacy. Further provisions on the qualifications of accountable directors may be issued by Government decree. (700/2002)

Section 34

(1) Medicinal product wholesalers may sell or otherwise supply medicinal products to a medicinal product manufacturer, another medicinal product wholesaler, a pharmacy, subsidiary pharmacy, the Military Pharmacy, a hospital pharmacy or dispensary or to a veterinary surgeon for purposes of veterinary medication. In addition, medicinal products the sale of which has not been restricted by law or other provisions to pharmacies may be sold or otherwise supplied to retailers of these products. (853/2005)

(2) Medicinal product wholesalers may also sell or otherwise supply medicinal substances to other businesses for use in production for purposes other than as a medicinal product, and medicinal products for research purposes to universities, institutions of higher education and scientific research institutions referred to in section 17(1)(5). (853/2005)

(3) When supplying medicinal products to buyers referred to in subsections 1 and 2, the delivery of medicinal products must be accompanied with a document containing information on the medicinal product. Regulations on the information to be contained in this document will be issued by the Finnish Medicines Agency. (773/2009).

Miscellaneous provisions

Section 35 (700/2002)

(1) Medicinal product manufacturers and wholesalers may supply medicinal products free of charge to physicians, dentists, veterinary surgeons, licensed pharmacists and managers of hospital pharmacies and dispensaries as samples and starter packs. Correspondingly, medicinal products the sale of which has not been restricted by law or other provisions to pharmacies may be supplied to retailers of these products. (853/2005)

(2) A medicinal product sample means the smallest package size of a medicinal product supplied free of charge by a medicinal product manufacturer or wholesaler as an introduction to the medicinal product. A starter pack is a special free package intended for the patient in order that treatment can be started without delay.

(3) Further provisions on the conditions and restrictions applicable to the supply of samples and starter packs may be issued by Government decree. In addition, the Finnish

Medicines Agency may issue further regulations on the markings and storage of samples and starter packs and the monitoring of the use of these. (773/2009)

Section 35a (773/2009)

(1) Medicinal product wholesalers must have an action plan and guidelines to ensure that distribution of medicinal products can be prevented effectively, that medicinal product packages supplied can be tracked and that they can be withdrawn from the market if necessary, should the Finnish Medicines Agency make a decision referred to in section 101 or if the medicinal product manufacturer or person responsible for placing a medicinal product on the market decides, on his own initiative, to suspend distribution of a medicinal product.

(2) Good medicinal product distribution practice based on the provisions of the European Communities must be complied with in medicinal product wholesaling. The Finnish Medicines Agency may issue further regulations and guidelines concerning good distribution practice to be complied with in medicinal product wholesaling.

Section 36 (700/2002)

Medicinal product wholesalers must keep records of imports, procurement, storage and sale of medicinal products. The records must be stored for a minimum of five years. Further provisions concerning the content and storage of the records may be issued by Government decree.

Section 37

Medicinal product wholesalers must seek to ensure that the quantity of medicinal products they have for sale corresponds to the need for them.

Section 37a (22/2006)

(1) The wholesale price of a medicinal product must be the same for all pharmacies and subsidiary pharmacies. The wholesale price must take into account all discounts, rebates and other benefits granted to pharmacies and subsidiary pharmacies. Parties that maintain price data on medicinal products must be notified of the wholesale price. The said wholesale price restrictions do not apply to the wholesale prices of medicinal products that may also be sold outside pharmacies.

(2) In derogation to subsection 1 above, a party engaging in automated dose dispensing may be granted a discount on a medicinal product used in automated dose dispensing that appears on the list of mutually comparable medicinal products referred to in section 57c and in the reference price group referred to in chapter 6, section 18 of the Sickness Insurance Act (1224/2004). The discount may be granted if the adopted reference price changes and the price of the medicinal product used when the change takes effect is higher than the new reference price. The discount may remain in effect for no more than thirty days following the change in the reference price. (311/2009)

Chapter 6 — Pharmacies

General

Section 38 (1112/2010)

For the purposes of this Act:

1) *pharmacy* means a pharmaceutical services operating unit, the field of activities of which comprises the retail sale, distribution and preparation of medicinal products as well as the provision of advisory and other services related to medicinal products;

2) *subsidiary pharmacy* means a separate outlet of the pharmacy, the field of activities of which corresponds to that of the pharmacy;

3) *pharmacy service point* means a separate outlet maintained by the licensed pharmacist for the sale of medicinal products;

4) *online pharmacy service* means the sale of medicinal products on the basis of orders placed by customers over the Internet;

5) *pharmacy business* means engaging in pharmacy operations in a pharmacy, subsidiary pharmacy, pharmacy service point or via an online pharmacy service; and

6) *licensed pharmacist* means a person to whom a licence to operate a pharmacy has been awarded.

Section 38a (773/2009)

Medicinal products may be sold to the general public only from the pharmacies, subsidiary pharmacies, pharmacy service points and online pharmacy services referred to in this Act. Traditional herbal medicinal products and homeopathic products referred to in sections 22 and 22a above, respectively, may however also be sold elsewhere unless the Finnish Medicines Agency decides otherwise in connection with the registration. In addition, nicotine products may also be sold elsewhere in the manner provided below in section 54.

Section 39

There must be a sufficient number of pharmacies in Finland to allow the general public, wherever possible, to obtain medicinal products without difficulty.

Right to operate a pharmacy business

Section 40 (1112/2010)

(1) The operation of a pharmacy business requires a licence from the Finnish Medicines Agency (*pharmacy licence*). A pharmacy licence is granted for operating a specific pharmacy business in a municipality or part thereof. A pharmacy business may not be

operated elsewhere than in a pharmacy, subsidiary pharmacy, pharmacy service point and online pharmacy service referred to in this Act.

(2) Conditions pertaining to the opening hours of the pharmacy business or the administration of a subsidiary pharmacy or pharmacy service point may be incorporated into the pharmacy licence in order to safeguard the availability of medicinal products.

Section 41 (1112/2010)

(1) At the request of the Finnish Medicines Agency, it is the duty of municipalities when necessary to evaluate the effectiveness, placement and sufficiency of pharmacy services in the area. A municipality may submit to the Agency a proposal for the establishment of a pharmacy, subsidiary pharmacy or pharmacy service point, for changing their location area, or transferring them.

(2) The Finnish Medicines Agency makes decisions on the establishment of new pharmacies in municipalities or parts of municipalities if the availability of medicinal products so requires. Decisions are made on the initiative of the Finnish Medicines Agency or the municipality concerned. In assessing the availability of medicinal products, the number of inhabitants, existing pharmacy services in the area and the location of other health care services must be taken into account. The Finnish Medicines Agency may also decide to change the pharmacy location area and transfer a pharmacy from one part of a municipality to another if it is necessary in order to safeguard pharmacy services.

(3) The Finnish Medicines Agency may decide to close a pharmacy if the availability of medicinal products no longer calls for a pharmacy in relation to the number of inhabitants, existing pharmacy services in the area and the location of other health care services concerned. Closure decisions may not be enforced before the relevant pharmacy licence has become available unless the licensed pharmacist concerned has announced willingness to submit to the decision.

(4) The Finnish Medicines Agency must consult the municipality concerned before making decisions referred to in this section.

Section 42 (1112/2010)

(1) The University of Helsinki is entitled to maintain one pharmacy in the city of Helsinki, and the University of Eastern Finland one pharmacy in the city of Kuopio. Besides selling medicinal products, the function of these pharmacies is to provide practical training in connection with pharmacy teaching and to conduct research on pharmaceutical services.

(2) The manager of a pharmacy referred to in subsection 1 above must be a certified Master of Pharmacy. The Finnish Medicines Agency must be notified of the name of the manager of the pharmacy.

Section 43 (1112/2010)

(1) The Finnish Medicines Agency must invite applications for any new or vacated pharmacy licence. The conditions for granting the pharmacy licence under section 40(2) above shall also be announced on the same occasion.

(2) A pharmacy licence may be granted to a certified Master of Pharmacy who has not been declared bankrupt or legally incompetent or has not been assigned a person to supervise his or her interests.

(3) If there is more than one applicant, a pharmacy licence is granted to the applicant who can be considered to have the overall best potential for operating a pharmacy business. In assessing the potential, the applicant's work in pharmacies and other pharmaceutical services, including the date on which any previous pharmacy licence entered into force, as well as studies, managerial skills and other activities pertinent to operating a pharmacy business must be taken into account.

Section 44 (1112/2010)

(1) A pharmacy licence is granted to a named individual. The pharmacy business may not be rented or transferred to another person. If a licensed pharmacist obtains a new pharmacy licence, the pharmacy licence previously issued to the pharmacist will simultaneously be annulled.

(2) Unless otherwise provided in this Act, a licensed pharmacist must manage the pharmacy personally. In the case of illness or for some other special reason, the licensed pharmacist may leave management of the pharmacy for a fixed period to a certified Master of Pharmacy or a certified Bachelor of Pharmacy, such periods combined not to exceed three months per year.

(3) A licensed pharmacist who is prevented from managing the pharmacy personally due to illness or for another special reason for more than three months must notify the Finnish Medicines Agency of the name of the certified Master of Pharmacy or certified Bachelor of Pharmacy designated to manage the pharmacy for the duration.

(4) A licensed pharmacist who in the situation referred to in section 46 has to operate a pharmacy business at two pharmacies must designate a manager for one of the pharmacies and notify the Finnish Medicines Agency thereof.

Section 45 (22/2006)

A licensed pharmacist may operate a pharmacy business up to the age of 68.

Responsibilities of licensed pharmacists in specific circumstances

Section 46

In situations referred to in sections 44(1) and 45 or when relinquishing a pharmacy licence, the licensed pharmacist must nevertheless continue to operate the pharmacy business up to the time a new licensed pharmacist takes possession of the pharmacy.

Section 47 (895/1996)

The party obtaining a pharmacy licence or authorisation for a subsidiary pharmacy must purchase the stock of medicinal products of the pharmacy or subsidiary pharmacy from the previous licensed pharmacist at current prices.

Expiry and revocation of a pharmacy licence

Section 48 (773/2009)

A pharmacy licence is considered to have expired if the licensed pharmacist has not begun to operate the pharmacy business within one year of being informed of the decision to grant the pharmacy licence and the Finnish Medicines Agency has not, upon application, granted an extension to the time limit.

Section 49 (1112/2010)

(1) If there is justified cause to suspect that a licensed pharmacist is unable to personally manage the pharmacy or attend to the availability of pharmacy services for reasons of illness or other similar cause, the Finnish Medicines Agency may, in order to investigate the matter, order the pharmacist to attend a medical examination and may acquire other necessary information.

(2) The Finnish Medicines Agency may temporarily prohibit the pharmacist from managing the pharmacy or from participating in any other pharmacy operations when the pharmacist is suspected of being unable to manage the pharmacy or attend to the availability of pharmacy services in the manner referred to in subsection 1. The prohibition may be issued for no more than one year at a time or until the question of the pharmacist's inability has been finally resolved.

Section 50 (1112/2010)

The Finnish Medicines Agency must revoke a pharmacy licence if the licensed pharmacist:

1) is declared bankrupt and does not re-acquire possession of the property within one year of bankruptcy;

2) is declared legally incompetent;

3) loses the right to act as a certified Master of Pharmacy;

4) is unable to practise as a licensed pharmacist in a proper manner due to illness or abuse of intoxicants or narcotic drugs;

5) is permanently incapacitated from personally managing a pharmacy due to illness or another reason;

6) is convicted of a crime and sentenced to at least two years in prison;

7) materially abuses the rights based on the pharmacy licence;

8) is issued a written warning referred to in section 51 and does not remedy his/her conduct;

9) is otherwise manifestly unsuited to engaging in pharmacy operations.

Disciplinary measures

Section 51 (773/2009)

If, in the capacity of pharmacist, a licensed pharmacist has acted contrary to this Act or provisions issued under it or has otherwise acted incorrectly or negligently in his/her duties or has behaved improperly, and the nature of the incorrectness or negligence does not warrant prosecution in court, the Finnish Medicines Agency may give the licensed pharmacist a warning either orally or in writing.

Subsidiary pharmacies

Section 52 (1112/2010)

(1) The Finnish Medicines Agency may establish a subsidiary pharmacy on its own initiative or on the initiative of a municipality or a joint municipal board. The Finnish Medicines Agency may also establish and authorise a subsidiary pharmacy at the application of a licensed pharmacist. Authorisation is subject to the condition that pharmacy services are needed in the area in order to safeguard the availability of medicinal products and the area does not provide an operating basis for an independent pharmacy. The Agency may authorise a licensed pharmacist to keep up to three subsidiary pharmacies.

(2) The location area of the subsidiary pharmacy is decided by the Finnish Medicines Agency. On its own initiative or on the initiative of a municipality, joint municipal board or holder of subsidiary pharmacy authorisation, the Agency may change the location area designated for a subsidiary pharmacy in order to safeguard the availability of medicinal products.

(3) In derogation to the provisions of subsection 1 above, the University of Helsinki may keep up to sixteen subsidiary pharmacies, each subject to authorisation from the Finnish Medicines Agency.

(4) A subsidiary pharmacy must have a manager responsible for operations who is designated by the licensed pharmacist. The manager must be a certified Master of Pharmacy or a certified Bachelor of Pharmacy. The Finnish Medicines Agency must be notified of the name of the manager of the subsidiary pharmacy.

(5) A subsidiary pharmacy may have shorter opening hours and a narrower selection of medicinal products than the pharmacy when permitted by local pharmaceutical services requirements.

(6) If a pharmacy licence becomes available and the licensed pharmacist had been authorised to keep a subsidiary pharmacy, the subsidiary pharmacy may be managed by a pharmacist referred to in section 46 or a manager of a pharmacy business referred to

section 59 until a new licensed pharmacist has taken possession of the pharmacy. After this, the new licensed pharmacist may manage the subsidiary pharmacy until the matter of keeping the subsidiary pharmacy has been resolved with final effect and the licensed pharmacist to whom authorisation has been granted begins to keep the subsidiary pharmacy.

(7) The Finnish Medicines Agency may issue regulations on the procedure to be observed in applying for subsidiary pharmacy authorisation.

Section 52a (1112/2010)

(1) Based on authorisation granted by the Finnish Medicines Agency, a licensed pharmacist may establish a pharmacy service point in a sparsely populated area or village centre which does not provide an operating basis for a subsidiary pharmacy. For a special reason, a pharmacy service point may also be established elsewhere in order to safeguard the availability of medicinal products. A service point may be established in the location area of the pharmacy or the area of an adjoining municipality. A plan on the manner in which the medicinal product advisory service referred to in section 57(2) below is to be provided must be appended to the application for authorisation. The Agency grants the authorisation if the conditions laid down in this section are met.

(2) The licenced pharmacists must attend to the inspection of the pharmacy service point.

(3) The Finnish Medicines Agency may convert a pharmacy service point to a subsidiary pharmacy if the turnover of the service point is equivalent to at least half of the average turnover of all the country's private subsidiary pharmacies and the operating basis for a subsidiary pharmacy is in place in other respects.

(4) The Finnish Medicines Agency may issue provisions on authorisation applications and on the operations, facilities and medicinal product selection of pharmacy service points as well as on the management and inspection of pharmacy service points.

(5) The licensed pharmacies of the University of Helsinki and the University of Eastern Finland may not establish pharmacy service points.

Section 52b (1112/2010)

(1) Licensed pharmacists and the licensed pharmacies of the University of Helsinki and the University of Eastern Finland may provide pharmacy services also via an online pharmacy service. The administrator of an online pharmacy service must maintain a website on the Internet. Advance notification of online pharmacy service administration must be submitted to the Finnish Medicines Agency. A plan of the manner in which the medicinal product advisory service referred to in section 57(2) below is to be provided must be appended to the advance notification. Operations may be commenced unless the Agency within sixty days of arrival of the notification has requested additional information about the circumstances referred to in this section or prohibited the commencement of operations. The Agency must be notified of the commencement and termination of operations and of any material changes therein. The Agency may prohibit the operations or order the online service to be shut down if the conditions laid down in this section are not met.

(2) Medicinal products subject to prescription may be supplied from online pharmacy services only by electronic prescription as provided in the Act on Electronic Prescriptions (61/2007).

(3) The Finnish Medicines Agency must maintain and keep available for public review on the Internet an up-to-date list of the authorised online pharmacy services. An online pharmacy service website must provide a link to the list maintained by the Agency.

(4) In other respects, the provisions on distance selling of chapter 6 of the Consumer Protection Act (38/1978) apply to online pharmacy services operations. The provisions concerning online pharmacy services are applied also to the sale of medicinal products taking place via other means of distance communication. The Finnish Medicines Agency may issue provisions on the contents and submission of the advance notification and on online service operations, facilities, technical implementation, medicinal product selection, management and inspection.

Section 53 (773/2009)

The Finnish Medicines Agency may decide to convert a pharmacy into a subsidiary pharmacy when the pharmacy's licence becomes available. The Finnish Medicines Agency will grant authorisation to keep such a subsidiary pharmacy to a licensed pharmacist who is sufficiently qualified to run it, taking into account the location and operating basis of the pharmacy that he/she operates.

Section 54 (773/2009)

(1) If the turnover of a subsidiary pharmacy referred to in section 52(1) is so great as to be equivalent to at least half of the average turnover of all the country's private pharmacies, the Finnish Medicines Agency may change the status of the subsidiary pharmacy to that of pharmacy.

(2) If the turnover of a pharmacy is lower than that of its subsidiary pharmacy and the latter is made a pharmacy as referred to in subsection 1, the Finnish Medicines Agency may, without separately declaring the licence available for application, grant the new pharmacy licence to the licensed pharmacist who had previously been authorised to keep the subsidiary pharmacy.

(3) A decision to change the status of a subsidiary pharmacy to that of pharmacy as referred to in subsection 1 above may not be made until five years have elapsed since the establishment of the subsidiary pharmacy.

Sale of nicotine products (22/2006)

Section 54a (22/2006)

(1) In derogation to what is laid down in section 38a, nicotine products may be sold by tobacco-selling retail stores, kiosks and service stations as well as bars and restaurants on the basis of the authorisation granted by the municipality where the sales outlet is located. Nicotine products must not be sold to individuals under 18 years of age. The sales assistant must be able to supervise the purchasing situation. Sale from vending machines is prohibited. (1112/2010)

(2) Municipalities must grant authorisation to sell nicotine products applied for in writing if the applicant has the potential to store and sell nicotine products in accordance with this Act. Applications must include the following information:

1) the applicant's name or the corporation's business name and contact information, business ID and the addresses of the outlets selling nicotine products;

2) a description of the storage of nicotine products and sales supervision arrangements;

3) name and contact information of the person responsible for sale; and

4) number of points of sale in a given sales outlet and description of their location.

(3) Those granted authorisation for sale of nicotine products must notify the municipality of any changes in the information given in the application and of discontinuation of sale. Municipalities must notify the Finnish Medicines Agency about the granting of authorisations and discontinuation of sales. (773/2009)

Section 54b (22/2006)

(1) What is otherwise laid down in this Act on storage, sale, supervision by the Finnish Medicines Agency, and pharmacovigilance applies as appropriate to any storage, retail, marketing, Finnish Medicines Agency supervision and pharmacovigilance concerning nicotine products that takes place outside pharmacies, subsidiary pharmacies and licensed medicine chests. What is laid down in sections 55, 55a, 56(1) and 57 does not, however, apply to sale referred to in this section. (773/2009)

(2) In addition, what is laid down in section 14(4) of the Act on Measures to Restrict Tobacco Smoking (693/1976) must be observed in the supervision of retail sale of nicotine products by other than pharmacies, subsidiary pharmacies and licensed medicine chests.

Section 54c (22/2006)

(1) Municipalities must on their own initiative and on the basis of notifications made inspect storage places and sales outlets for nicotine products and monitor the sale of nicotine products.

(2) If action contrary to provisions issued in or under this Act are detected in inspections or otherwise, the municipality concerned must prohibit such action and set a time limit for its termination.

(3) If such action is not remedied within the deadline or if the action contrary to provisions and mentioned in the prohibition continues or is resumed after the time limit has expired, the municipality concerned may cancel the retail marketing authorisation for nicotine products either temporarily or completely.

Section 54d (22/2006)

(1) Municipalities may charge applicants for retail marketing authorisations for nicotine products. Municipalities may also charge holders of retail marketing authorisations an

annual supervision fee for monitoring measures. Authorisation and supervision fees may not exceed the cost of providing the service. Further provisions on the grounds for retail marketing authorisation and supervision fees are laid down in the scales of charges approved by the municipalities.

(2) Fees under this section may be collected without judgement or a decision in the order laid down in the Act on the Collection of Taxes and Payments by Distraint (367/1961).

Section 54e (699/2010)

(1) Further provisions on the placement of nicotine products in a retail outlet and on the content of applications for retail marketing authorisation for nicotine products may be issued by Government decree.

(2) The Finnish Medicines Agency may order separate instructions for use to be attached to nicotine products sold by retail outlets. Where necessary, the Finnish Medicines Agency issues regulations on the content of such instructions.

Miscellaneous provisions

Section 55

(1) The amount of medicinal products, the equipment and supplies for administering medicinal products, and the dressings kept by a pharmacy must correspond to its usual customer needs. (895/1996)

(2) Licensed pharmacists must for their part ensure that the medicinal products supplied by pharmacies, subsidiary pharmacies, pharmacy service points and online pharmacy services are of flawless quality and that the proper authorisation is held for the sale or release for consumption of the medicinal product. (1112/2010)

Section 55a (700/2002)

Pharmacies may act as competent authorities referred to in article 75 of the Schengen Convention and may thus issue certificates referred to in the article for carrying medicinal products containing narcotics or psychotropic substances when travelling from one Contracting State to another.

Section 56 (1112/2010)

(1) Pharmacies and subsidiary pharmacies must maintain a necessary number of personnel with a pharmaceutical degree. The licensed pharmacist must ensure that the entire personnel of the pharmacy takes part in further training to a sufficient degree. The basic education and work duties of the personnel must be taken into account in the provision of further training.

(2) The facilities of pharmacies, subsidiary pharmacies and pharmacy service points must be appropriate for selling and storing medicinal products. Facilities used for preparation and

examination of medicinal products must be appropriate for this purpose and equipped accordingly.

Section 57 (1112/2010)

(1) When supplying medicinal products from pharmacies and subsidiary pharmacies every effort must be made, through the advice and guidance of pharmaceutical staff, to ensure that the users of the medicinal products are aware of the correct and safe use of the product in order to ensure successful pharmacotherapy. In addition, medicinal product purchasers must be given information about the prices of medicinal products and about other factors affecting their choice of medicinal product.

(2) When supplying medicinal products from pharmacy service points and via online pharmacy services, licensed pharmacists and the licensed pharmacies of the University of Helsinki and the University of Eastern Finland must ensure that the buyer of medicinal products has access to the advice and guidance of pharmaceutical staff on the correct and safe use of medicinal products and to information about the prices of medicinal products and other factors affecting their choice of medicinal product. Medicinal products supplied from pharmacy service points based on prescription may only be supplied by a certified Master of Pharmacy or a certified Bachelor of Pharmacy.

(3) The Finnish Medicines Agency may issue provisions on the procedures to be observed when supplying medicinal products from pharmacies, subsidiary pharmacies, pharmacy service points and online pharmacy services.

Section 57a (435/2010)

Pharmacies and subsidiary pharmacies must keep records of prescriptions by calendar year. The records must include information on the medicinal product supplied and its amount, the user of the medicinal product or the institution for whose use the medicinal product has been prescribed, and the prescribing party. The records must be retained for five years. The records must be drawn up and stored as further provided by the Finnish Medicines Agency.

Section 57b (22/2006)

(1) When supplying a medicinal product on the basis of a prescription by a physician, dentist or other health care professional entitled to write prescriptions, pharmacies must exchange it to the comparable publicly available medicinal product on the list referred to in section 57c whose price is the lowest or the price of which differs from the lowest price:

1) by no more than 1.50 euros when the product costs less than 40 euros; or

2) by no more than 2.00 euros when the product costs 40 euros or more.

(435/2010)

(2) The lowest-cost price among mutually comparable medicinal products is defined as the retail price inclusive of value added tax of the lowest-cost product on the first day of each quarter-year period or, when reference price groups are in effect, of the lowest-cost reimbursable product in the reference price group. (803/2008)

(3) No exchange must be made, however, if the prescriber of the medicinal product has forbidden exchange on medical or treatment grounds by making an entry to that effect in the prescription, or if the purchaser of the medicinal product refuses the exchange. The pharmacy must supply the same product for the entire validity period of the prescription. If amounts of the medicinal product are supplied more than once under the same prescription, the purchaser of the medicinal product is, however, entitled on the later purchase occasions to buy the medicinal product originally prescribed. In addition, purchasers of medicinal products are always entitled, if they wish, to be given the actual lowest-cost comparable medicinal product available at the time of the transaction, unless the prescriber of the medicinal product has forbidden exchange on medical or treatment grounds.

Section 57c (773/2009)

(1) The Finnish Medicines Agency must draw up a list of mutually comparable medicinal products. Comparable medicinal products may be defined as those which contain the same active substances in the same amounts and which are bioequivalent.

(2) The Finnish Medicines Agency must publish the list referred to in subsection 1 no later than 45 days before the beginning of each quarter-year period.

Section 57d (803/2008)

Where necessary, it may be laid down by Ministry of Social Affairs and Health decree that holders of marketing authorisations must notify authorities to be specified by Ministry of Social Affairs and Health decree and other parties maintaining information on the prices of medicinal products on a regular basis, of the prices of comparable medicinal products at least 21 days before the first day of each quarter-year. In addition, provisions may be laid down by ministerial decree concerning the duty of the authorities to publish the a list of comparable medicinal products and their prices.

Section 58 (22/2006)

(1) The retail price of a medicinal product must comply with the medicinal products price list set out by Government decree. The price complying with the medicinal products price list must be based on the nationally applied wholesale price reported by the holder of the marketing authorisation in accordance with section 37a for the medicinal product in question, and on the margin calculated on the basis of the wholesale price, and value added tax. The sales margin for a single medicinal product calculated on the basis of the wholesale price may be lower than the fee percentage determined under section 2 of the Act on Pharmacy Fee (148/1946).

(2) What is laid down in subsection 1 does not apply to medicinal products that may be sold outside pharmacies, subsidiary pharmacies and medicine chests.

(3) The medicinal products price list must be adjusted as necessary. The Finnish Medicines Agency must supply annual data to the Ministry of Social Affairs and Health on the sales margins of pharmacies and on other matters with a bearing on the price list. (773/2009)

Section 58a (1112/2010)

(1) In addition to that provided in section 38a on the operations of a pharmacy, a pharmacy and a subsidiary pharmacy may also engage in other service provision related to the promotion of health and welfare and the prevention of illness. The purpose of these activities may not be to increase the use of medicinal products unnecessarily.

(2) When pharmacies and subsidiary pharmacies sell products other than medicinal products or engage in the other service provision referred to above in subsection 1, the sales or other activities must not hinder the supply of medicinal products or the advisory services related to medicinal products.

Section 59

(1) If a pharmacy licence expires due to the death of the licensed pharmacist or the revocation of the licence, the Finnish Medicines Agency will determine who shall manage the pharmacy business until a new licensed pharmacist has taken charge of the pharmacy. The Finnish Medicines Agency will also appoint a manager for the pharmacy in cases referred to in section 49. The provisions laid down in this Act on licensed pharmacists also apply, as appropriate, to the manager of a pharmacy. (773/2009)

(2) Only certified Masters of Pharmacy may be appointed to manage a pharmacy on their own account in cases referred to in subsection 1. Certified Bachelors of Pharmacy may, however, be appointed to manage a pharmacy for up to two months at a time.

Section 60 (700/2002)

(1) Further provisions on pharmacy licences and applications for licences and on pharmacies, subsidiary pharmacies, pharmacy service points and online services, their operation and facilities, the qualifications of managers of pharmacies and subsidiary pharmacies, the numbers of pharmaceutical staff and the content and amount of further training will be issued by Government decree as necessary. (1112/2010)

(2) In addition, The Finnish Medicines Agency may issue further regulations and guidelines on the facilities and equipment required for medicinal product storage, preparation and control. (773/2009)

Chapter 7 — Pharmaceutical services in hospitals, health centres and social welfare institutions

Hospital pharmacies and dispensaries

Section 61

(1) Hospital districts may set up hospital pharmacies for their operational needs. Hospitals or health centres maintained by municipalities, joint municipal boards or the State may have a hospital pharmacy or dispensary. (700/2002)

(2) A dispensary referred to in subsection 1 above may also be established in a unit containing hospital beds maintained by a service provider referred to in the Private Health Care Act (152/1990) or in an institution referred to in the Act on Special Care for the Mentally Handicapped (519/1977), if so required due to the number of hospital beds. (248/1993)

(3) A licence from the Finnish Medicines Agency is required before a hospital pharmacy or dispensary can be established. (773/2009)

(4) The operating facilities of hospital pharmacies and dispensaries must be suited to medicinal product supply, storage, preparation and control. They must also be appropriately equipped. (700/2002)

(5) Further provisions on applications for licences and on facilities for hospital pharmacies and dispensaries will be issued by Government decree as necessary. (700/2002)

(6) The Finnish Medicines Agency may also issue further provisions on the operations of hospital pharmacies and dispensaries, good manufacturing practice and facilities and equipment required for medicinal product storage, preparation and control, as necessary. (773/2009)

Section 62 (895/1996)

(1) Notwithstanding the provisions of section 61, hospital pharmacies or dispensaries maintained by municipalities or joint municipal boards may supply:

1) medicinal products to public social and health care institutions of the same municipality or joint municipal board or of an adjoining municipality;

2) vaccines referred to in section 25 of the Communicable Diseases Act (583/1986) to private social and health care institutions of the same municipality or joint municipal board or of an adjoining municipality;

3) medicinal products to other than the social and health care institutions and pharmacies referred to in paragraph 1 in order to safeguard necessary medication for individual patients in situations where there are problems in the availability of medicinal products; and

4) medicinal products for use by peacekeeping troops operating outside Finland.

(22/2006)

(2) With the authorisation of the Finnish Medicines Agency, medicinal products may also be supplied by hospital pharmacies and dispensaries to private social and health care institutions with which the municipality or joint municipal board has made an agreement on purchasing social and health care services under section 4(1)(4) of the Act on Planning and Government Grants for Social Welfare and Health Care (733/1992) or which take care of other duties that under law fall within the sphere of local or central government. (1727/2009)

(3) The Finnish Medicines Agency may, for special reasons, grant authorisation for supplying medicinal products in a manner in derogation to subsection 1 and for releasing medicinal

products manufactured in accordance with section 14 and imported in accordance with section 17(1)(4) to another social and health care institution or pharmacy. (773/2009)

(4) When considering authorisation to be granted by the Finnish Medicines Agency as referred to in this section, the availability of medicinal products must not be allowed to deteriorate significantly in the area. Before granting authorisation, the Finnish Medicines Agency must consult the licensed pharmacists in the area whose operations could be affected by the granting of authorisation. Further provisions on the content of applications for authorisation and on granting authorisation may be issued by Government decree. (773/2009)

Section 63 (773/2009)

Hospital pharmacies and dispensaries must keep records of the procurement of medicinal products and of the supply of medicinal products under section 62. Such records must be retained for a minimum of five years. The Finnish Medicines Agency may issue further regulations on drawing up such records, the data to be included and storage of the records.

Section 64

(1) Hospital pharmacies and dispensaries must have a manager. The manager is responsible for arranging the operation of a hospital pharmacy or dispensary and the pharmaceutical services of the operating unit concerned in accordance with provisions issued in and under this Act. (22/2006)

(2) The manager of a hospital pharmacy must be a certified Master of Pharmacy, and the manager of a dispensary must be either a certified Master of Pharmacy or a certified Bachelor of Pharmacy.

Section 65 (700/2002)

(1) Hospital pharmacies and dispensaries may supply free of charge medicinal products required for uninterrupted treatment of patients discharged from hospital or health centre wards or temporarily transferred to outpatient care. Medicinal products required for initiation of treatment for patients who have visited hospital outpatient clinics or health centres may be supplied free of charge until the patient can reasonably be expected to be able to obtain them from a pharmacy, taking into account the local conditions. A patient may further be supplied free of charge with medicinal products required for the implementation of weaning or replacement therapy or maintenance treatment for narcotic drug addicts. Further provisions on the medicinal products to be supplied and the requirements for supply will be issued by Ministry of Social Affairs and Health decree.

(2) In addition, hospital pharmacies and dispensaries may supply free of charge medicinal products used for primary health care education services and birth control advice as referred to in section 13 of the Health Care Act (1326/2010) and for information and preventive activities as referred to in section 26 of the same Act. Similarly, vaccines referred to in section 25 of the Communicable Diseases Act (583/1986) and medicinal products referred to in section 5(4) of the Act on Customer Charges for Social and Health Care (734/1992) may be supplied free of charge. (1340/2010)

(3) The Finnish Medicines Agency may issue further regulations and guidelines on the procedure for supplying medicinal products referred to in this section. (773/2009)

Section 66 (773/2009)

The Finnish Medicines Agency may revoke for a fixed period or in full a licence referred to section 61 if the operations of the hospital pharmacy or dispensary in question are essentially in violation of this Act or of the licence conditions or good manufacturing practice for medicinal products, or if such operations are a serious risk to medicinal product safety or if measures complying with provisions issued under section 78 have not been taken.

Section 66a (895/1996)

Operations organised by municipalities under this Chapter are subject to the provisions of the Act on Planning and Government Grants for Social Welfare and Health Care (733/1992), unless otherwise provided by law.

Military pharmacies and Finnish Prison Service dispensaries (700/2002)

Section 67 (700/2002)

(1) Military pharmacies may be established for the purposes of providing pharmaceutical services in the Finnish Defence Forces. Further provisions on the establishment of military pharmacies will be issued by Government decree.

(2) Dispensaries may be established for the purposes of providing pharmaceutical services in the Finnish Prison Service. Further provisions on the establishment of a dispensary for the Finnish Prison Service will be issued by Government decree. (22/2006)

Chapter 8

Sections 68-75
Repealed by Act 1046/1993.

Chapter 9 — Control and general supervision

General

Section 76 (773/2009)

General planning, control and supervision of pharmaceutical services falls within the purview of the Finnish Medicines Agency, which operates under the Ministry of Social Affairs and Health.

Section 76a (773/2009)

(1) The Finnish Medicines Agency supervises the performance of preclinical safety tests of medicinal products to ensure that these are performed in accordance with good laboratory practice and issues to laboratories performing these approval as testing laboratory.

(2) The Finnish Medicines Agency may incorporate conditions and restrictions into the approval of a laboratory. Further provisions on the approval procedure are issued by Ministry of Social Affairs and Health decree.

(3) An authorised testing laboratory must notify the Finnish Medicines Agency of any material changes in its operations.

(4) The Finnish Medicines Agency may revoke the approval of a testing laboratory if the laboratory does not meet the requirements for approval or does not observe the conditions, restrictions or regulations imposed on its operations.

Inspections

Section 77 (700/2002)

(1) The Finnish Medicines Agency must ensure that medicinal product manufacturers, manufacturers of medicinal substances, units manufacturing medicinal products for clinical trials, units manufacturing advanced therapy medicinal products for the use of individual patients, contract manufacturers and contract analysts, laboratories performing preclinical safety tests, medicinal product wholesalers, pharmacies, subsidiary pharmacies, hospital pharmacies and dispensaries and the Military Pharmacy are inspected at intervals required for proper supervision of medicinal products. In addition, the Finnish Medicines Agency may inspect the pharmacovigilance operations and facilities of pharmacy service points, online pharmacy services, holders of marketing authorisations for medicinal products or registration for traditional herbal medicinal products and the manufacturers of auxiliary substances used in the manufacture of medicinal products. (1112/2010)

(2) Inspectors must be allowed access to all facilities at the place of business. During the inspection, all documents necessary for carrying out the inspection and requested by the inspector must be presented. In addition, the inspector must be provided free of charge with copies of documents necessary to carry out the inspection and requested by him, and with samples of the substances and products on the premises for further examination separately. The inspector also has the right to take photographs during the inspection.

(3) A record must be kept of the inspection. Provisions on matters requiring particular attention in the inspection and further specification of the content of the inspection procedure as well as inspection records, their storage and period of storage will be issued by Government decree.

Section 77a (773/2009)

Holders of marketing authorisations for veterinary medicinal products must, when so requested by the Finnish Medicines Agency, provide advice and instructions so that a laboratory named under the provisions of Council Directive 96/23/EC on measures to monitor certain substances and

residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664TEEC can adopt an analytical method for detection of veterinary medicinal product residuals.

Section 78 (700/2002)

Inspectors may give orders to correct any defects detected. Immediate action must be taken on any orders given in an inspection.

Section 79 (700/2002)

(1) No appeal may be made against orders given in inspections referred to in section 77 above. Anyone dissatisfied with such an order has the right to request rectification of the decision by the Finnish Medicines Agency. Instructions on the submission to the Finnish Medicines Agency must be appended to the order. Measures laid down in the order must be taken regardless of whether a request for rectification is made. (773/2009)

(2) A request for rectification as referred to in subsection 1 above must be made in writing within 30 days of the completion of the inspection and must include:

1) the name of the maker of the rectification request;

2) the order for which rectification is sought;

3) the extent to which rectification of the order is sought and the particular rectification sought; and

4) justification for the rectification request.

(3) The request for rectification must be personally signed by the maker or drafter of the request.

(4) Evidence which the maker of the request wishes to provide in support of it that has not been submitted previously must be appended to the request for rectification.

Section 80 (1112/2010)

The Finnish Medicines Agency may order the manufacture of a medicinal product to cease until further notice if it emerges in an inspection or by other means that there are defects endangering the proper manufacture of medicinal products or if measures to comply with orders issued under section 78 have not been taken.

Section 80a (773/2009)

The Finnish Medicines Agency may revoke for a fixed period or in full a licence granted to a medicinal product wholesaler if such a wholesaler has essentially violated this Act or the licence conditions or if its operations otherwise seriously endanger medicinal product safety, or if measures in accordance with provisions laid down in section 78 have not been taken.

Section 81 (853/2005)

Repealed by Act 853/2005.

Section 81a (700/2002)

The Customs will supervise compliance with the import provisions of this Act.

Pharmacopoeia and medicinal products list

Section 82 (773/2009)

(1) The Finnish Medicines Agency must approve the pharmacopoeia that is to be complied with at any given time.

(2) The Finnish Medicines Agency may, if necessary, issue regulations supplementary to the pharmacopoeia that it has approved.

Section 83 (773/2009)

(1) Every third year or, if necessary, more often, the Finnish Medicines Agency must approve a medicinal products list, to be drawn up with due regard to the provisions of sections 3 and 5.

(2) Naturally occurring plants or parts thereof collected in Finland or abroad that are mentioned in the medicinal products list may be sold as they are by anyone, unless the Finnish Medicines Agency has separately prohibited this.

Chapter 10 — Miscellaneous provisions

Section 84 (311/2009)

The Finnish Food Safety Authority may import, distribute and sell immunological veterinary medicinal products intended for the prevention or detection of severe animal diseases if a product suitable for this purpose is not otherwise available in Finland or if this is necessary to combat animal disease. The provisions of sections 35a and 36 on medicinal product wholesaling must be observed in the activities.

Section 84a (700/2002)

In states belonging to the European Economic Area, persons entitled to practise the profession of veterinary surgeon may, notwithstanding the provisions of sections 17 and 21, carry with them when entering Finland and use for veterinary medical purposes a medicinal product which has a marketing authorisation in the country in which the veterinary surgeon primarily practises and which contains the same amount of the same active substance as another product that has been

granted marketing authorisation in Finland. Further provisions will be issued by Government decree on the requirements for importing veterinary medicinal products, the maximum amounts of medicinal products to be imported, the supply of medicinal products to animal owners or keepers, bookkeeping concerning the use of medicinal products and document storage.

Section 84b (595/2009)

(1) Pharmacies, the licensed pharmacies of the University of Helsinki and the University of Kuopio included, medicinal product wholesalers and medicinal products manufacturers must pay to the Finnish Medicines Agency for inspections relating to the supervision of the sale of medicinal products and medicinal substances two thousandths (2/1000) of the difference between the sales price and purchase price of medicinal products excluding value added tax (*quality control fee*). The pharmacy fee is deducted from the equivalent sales margin of pharmacies before the fee is determined. Medicinal product manufacturers must pay the fee on the sales by which they supply goods directly to pharmacies or others entitled to make purchases absent any brokerage through a medicinal products wholesaler.

(2) The Finnish Medicines Agency adopts the fee referred to in subsection 1 annually and it is entitled to obtain the data required to calculate the fee free of charge. The Finnish Medicines Agency issues further regulations on the collection of the fee.

Certificates (1046/1993)

Section 85 (773/2009)

The Finnish Medicines Agency may issue certificates concerning medicinal products and their manufacture to medicinal product manufacturers, units manufacturing medicinal products for clinical trials, medicinal product wholesalers and to competent authorities of an export country for the purposes of medicinal product exports.

Clinical trials of medicinal products

Section 86 (296/2004)

For the purposes of this Act, a clinical trial of a medicinal product means intervention research conducted in humans to investigate the effects of a medicinal product on humans and the absorption, distribution, biotransformation or excretion of the product in the human body.

Section 87 (773/2009)

(1) When carrying out clinical trials, the provisions of the Act on Medical Research (488/1999) must be complied with. In addition, what is provided in and under this Act on clinical trials must be taken into account.

(2) An authorisation must be obtained from the Finnish Medicines Agency before starting clinical trials of medicinal products for gene treatment, somatic cell treatment or xenogenic cell treatment and medicinal products containing genetically manipulated organisms. The

Finnish Medicines Agency must be notified in advance of other clinical trials of medicinal products.

(3) Trials may begin when the Ethics Committee has given a favourable opinion referred to in section 3 and section 10c of the Act on Medical Research and when the Finnish Medicines Agency has issued the authorisation required in subsection 2 or when it has informed the commissioning party of trials requiring advance notification that there is no impediment to starting the trials or, if the Finnish Medicines Agency has not given such notification, within 60 days of the date on which the Finnish Medicines Agency received the appropriate advance notification.

(4) The Finnish Medicines Agency must give a decision on applications for authorisation to begin clinical trials of medicinal products for gene treatment, somatic cell treatment or medicinal products containing genetically manipulated organisms within 90 days of having received an appropriate application. The Agency may extend the period by 90 days if giving an opinion calls for extensive further documentation. There is no fixed time limit for decisions on xenogenic cell research. Nevertheless, decisions must be given without undue delay.

(5) If the Finnish Medicines Agency cannot approve the implementation of a trial as described in the application for authorisation or in an advance notification, further documentation must be requested from the commissioning party. The request for further documentation must specify and give justifications for all reasons preventing implementation of the trials according to the research plan. On the basis of a request from the Finnish Medicines Agency, the commissioning party may amend the research plan in order to correct the deficiencies pointed out. If the applicant does not amend the advance notification or authorisation application or if the amendments are not as required in the Finnish Medicines Agency request for further documentation, the clinical trials must not begin.

(6) The Finnish Medicines Agency will issue further provisions on applying for authorisations referred to in subsection 2, on the content of such applications and on advance notifications as well as the quality and manufacture of the medicinal products to be used in trials, safe and proper implementation of the trials, declaration of adverse effects and other issues important in view of research safety.

Section 87a (773/2009)

(1) If changes are made in a research plan relating to clinical trials of medicinal products that may affect the safety of the research subjects or that may change the interpretation of scientific documents used to support the trials or if the change is otherwise important, the Finnish Medicines Agency must be notified of the change. The trials must not continue in accordance with an amended plan before the Ethics Committee has given a favourable opinion thereon and the Finnish Medicines Agency has announced that there is no impediment to continuing the trials according to the amended plan or, if such an announcement has not been made, when 35 days have passed from submitting notification of the amendment.

(2) If the Finnish Medicines Agency does not approve an amendment to a research plan, the commissioning party must be informed of amendments necessary for revision of the plan. Trials may continue when these amendments and any amendments required by the Ethics Committee have been made, or alternatively, trials must continue in accordance with the original plan unless the safety of the subjects calls for interruption or discontinuation of the research project.

Section 87b (773/2009)

(1) It is the duty of the Finnish Medicines Agency to supervise clinical trials. Confidentiality provisions notwithstanding, the Finnish Medicines Agency has, when necessary, the right to inspect, in order to ensure the correctness of the data collected in the research project, all necessary facts including the research site, research documents and documents containing patient information on the subjects. In addition to this, what is laid down in sections 77, 77a and 78–80 applies to such inspections.

(2) If the Finnish Medicines Agency has a justified reason to think that the commissioning party, researcher or some other person connected with the study no longer meets the requirements set, the Finnish Medicines Agency must notify the relevant commissioning party, researcher or other person thereof without delay and present an action plan for the relevant party to correct the situation. The Finnish Medicines Agency must notify the Ethics Committee and the competent authorities of the European Union Member States and the Commission of this plan without delay.

Section 87c (773/2009)

(1) The Finnish Medicines Agency may order clinical trials already begun to be temporarily suspended or terminated if the trials are not being carried out in accordance with the research plan or if the requirements in accordance with the research plan are no longer valid or if the trials do not meet the requirements in accordance with the Act on Medical Research or this Act or provisions or regulations issued under them.

(2) Before issuing the order referred to in subsection 1, the Finnish Medicines Agency must hear the commissioning party or the researcher. The commissioning party and the researcher must provide the documentation requested by the Finnish Medicines Agency within seven days. If the reason for issuing the order constitutes an imminent risk to the research subjects, the Finnish Medicines Agency may order the trials to be suspended without delay. A decision on the discontinuation of trials suspended on the basis of imminent risk must not be given before the commissioning party or the researcher has been heard as specified above.

(3) The Finnish Medicines Agency must without delay notify the European Commission, the European Medicines Agency, the competent authorities responsible for supervision of medicinal products in European Economic Area states and the appropriate ethical committees of an order that it has issued. Justification for the order must be appended to the notification.

Section 87d (773/2009)

The Finnish Medicines Agency is responsible for sending data relating to clinical trials to the database maintained by the European Agency for the Evaluation of Medicinal Products. Further provisions on data to be stored may be issued by Government decree.

Section 88 (296/2004)

Medicinal product manufacturers, units manufacturing medicinal products for clinical trials, medicinal product wholesalers and pharmacies may supply the medicinal products necessary for a clinical trial to the physicians or dentists conducting the trial.

Section 88a (773/2009)

(1) The Finnish Medicines Agency must be notified in advance of clinical trials to be carried out with veterinary medicinal products. The Finnish Medicines Agency supervises clinical trials on veterinary medicinal products and, where necessary, has the right to inspect all matters necessary for ensuring the correctness of the information gathered in the trials, including the trial location and the trial documents.

(2) The Finnish Medicines Agency may, where necessary, forbid commencement of trials referred to in subsection 1 if the trials do not meet the conditions of provisions or orders given in or under this Act. The Finnish Medicines Agency may order clinical trials on veterinary medicinal products that have already started to be interrupted temporarily or discontinued, if substantial defects or negligence have been found in the implementation of the trials and these have not been rectified in spite of an admonition by the Finnish Medicines Agency.

(3) Before issuing an order referred to in subsection 2 the Finnish Medicines Agency must consult the commissioning party of the trials or the researcher. The commissioning party of the trials and the researcher must provide the specifications requested by the Finnish Medicines Agency within seven days. If the justification for the order is imminent risk to the animal subject to research the Finnish Medicines Agency may order immediate interruption of the trials. A decision must not be made on the discontinuation of trials interrupted on the basis of imminent risk until the commissioning party of the trials or the researcher have been consulted as specified above.

(4) Further provisions on the time limit for the advance notification referred to in subsection 1 and on the procedures and time limits relating to interruption of trials may be issued by Government decree. The Finnish Medicines Agency may issue further regulations and guidelines on the notification referred to in subsection 1, on the quality and preparation of the medicinal products used in the trials, on safe and proper implementation of the trials, on the reporting of adverse effects and other matters significant in terms of the safety of the trials.

Obligation to disclose information

Section 89 (1112/2010)

(1) On request, medicinal product manufacturers, units manufacturing medicinal products for clinical trials, laboratories performing preclinical safety tests, units or laboratories carrying out contract analyses or contract manufacture for medicinal product manufacturers, medicinal product wholesalers, holders of marketing authorisations or registrations, licensed pharmacists, the University of Helsinki’s licensed pharmacy, the University of Eastern Finland’s licensed pharmacy, hospital pharmacies and dispensaries, units manufacturing advanced therapy medicinal products for use by individual patients and the Military Pharmacy must, confidentiality provisions notwithstanding, provide the Finnish Medicines Agency with such information and documentation on the import, manufacture, inspection, distribution, sales or other release for consumption of medicinal products as is necessary for the Finnish Medicines Agency to carry out the duties laid down for it in this or some other Act.

(2) Units manufacturing medicinal products for clinical trials, researchers referred to in section 2(4) of the Medical Research Act and commissioning parties referred to in section 2(5) of the same Act must, on request, give the Finnish Medicines Agency, confidentiality

provisions notwithstanding, information and documentation relating to clinical trials of medicinal products that are necessary for the Agency in order for it to carry out the duties laid down in this Act and the Medical Research Act.

Section 89a (773/2009)

Confidentiality provisions notwithstanding, the Finnish Medicines Agency must notify to the European Commission, the European Medicines Agency and the competent medicinal product supervision authorities of the European Economic Area states, and record in databases maintained by the European Medicines Agency, all information acquired in connection with the supervision of medicinal products and pharmacovigilance of which European Community Law requires notification to the above parties or recording in databases maintained by the European Medicines Agency.

Duty of non-disclosure

Section 90 (679/1999)

(1) Licensed pharmacists and their assistants must not disclose confidential private or family information to which they have become privy during the course of their duties unless permitted to do so.

(2) The confidentiality obligation laid down in the Act on the Openness of Government Activities (621/1999) notwithstanding, the Finnish Medicines Agency may disclose information acquired in carrying out duties under this Act relating to a business or professional secret of a private entity or a corporation to an institution of the European Union or other supervisory authority in the manner required by European Community Law, or to the Finnish Food Safety Authority, the Ministry of Social Affairs and Health, the Pharmaceuticals Pricing Board, the Social Insurance Institution, the police, Customs or prosecuting authorities whenever necessary for them to carry out their statutory duties. (773/2009)

Marketing medicinal products

Section 91(853/2005)

(1) The marketing of medicinal products must encourage people to use the products appropriately. Information given in marketing must be in accordance with the information in the approved product characteristics description.

(2) The marketing of medicinal products must not induce people to use the products unnecessarily, give a misleading or exaggerated picture of the composition, origin or medicinal importance of a product or be improper in any other similar manner. Only medicinal products referred to in this Act may be advertised or marketed as medicinal products. It is prohibited to market a medicinal product that does not have a valid marketing authorisation or registration in Finland.

(3) In addition to what is provided in subsections 1 and 2, the provisions of the Consumer Protection Act (38/1978) on marketing regulation also apply.

Section 91a (700/2002)

(1) Medicinal products supplied by prescription or containing narcotic drugs or psychotropic substances must not be marketed to the general public. Advertising targeted at the general public must mention at least the name of the medicinal product, and the generic name if the medicinal product contains only one active substance, information necessary for correct and safe use of the medicinal product and specific and easily readable encouragement to read carefully the separate instructions for use of the medicinal product. Reminder advertising of a medicinal product constitutes an exception, however. In reminder advertising, only the name of the medicinal product, its international generic name or trademark and, in addition, the holder of the marketing authorisation or registration, may be mentioned. (853/2005)

(2) Repealed by Act 853/2005.

(3) Medicinal product advertising must not include groundless statements concerning health or be targeted at children. Neither must medicinal product advertising otherwise give an exaggerated or misleading picture of the effects of a medicinal product.

(4) It is forbidden to distribute medicinal product samples to the general public for sales promotion purposes.

Section 91b (700/2002)

(1) Medicinal products referred to in section 91a(1) may be marketed to persons entitled to prescribe or supply medicinal products. Such marketing can take place only in medicinal product demonstrations arranged for persons entitled to prescribe or supply medicinal products, in publications intended for them and in electronic communication media. Electronic marketing must be carried out in protected form to prevent it from reaching third parties.

(2) Advertising targeted at persons authorised to prescribe or supply medicinal products must include essential information on the medicinal product and its use. Reminder advertising of a medicinal product constitutes an exception, however. In reminder advertising, only the name of the medicinal product, its international generic name or trademark and, in addition, the holder of the marketing authorisation or registration, may be mentioned. (853/2005)

Section 91c (1112/2010)

Holders of marketing authorisation or registration and other parties engaging in the marketing of medicinal products must keep available for public review an up-to-date list of all direct and indirect financial and comparable support which they have given to associations in the fields of medicine and health care and to patient organisations.

Section 92 (296/2004)

(1) Medicinal product sales promotion targeted at health care personnel and veterinary surgeons, such as various benefits and gifts, must be modest in terms of economic value and must be related to their professional activities. In the case of sales promotion events, hospitality must be moderate and secondary in relation to the purpose of the event, and it

must not extend beyond health care personnel. Sales promotion must not be inappropriate or of such a nature that it can be considered to endanger public trust in the impartiality of prescription, use or supply of medicinal products. Hospitality at purely professional or scientific events must always be moderate and remain secondary in relation to the main scientific purpose of the event and it must not be extended to other than health care professionals.

(2) Persons entitled to prescribe or supply medicinal products must not ask for or accept any inducement, benefit or gift prohibited in subsection 1 or otherwise in violation of what is provided therein.

Section 92a (296/2004)

(1) Further provisions on the marketing restrictions laid down in sections 91–92 above may be issued by Government decree.

(2) The Finnish Medicines Agency monitors the appropriateness of medicinal product advertising. For the purposes of such monitoring, all parties marketing and advertising medicinal products must provide the Finnish Medicines Agency with documentation and notifications on marketing and advertising as provided by Government decree. (773/2009)

(3) The National Supervisory Authority for Welfare and Health and the Regional State Administrative Agencies must supervise the observance of the prohibition in section 92 by the health care professionals referred to in the Act on Health Care Professionals (559/1994) who have the right to prescribe or supply medicinal products. The provisions of the Act on Health Care Professionals apply to such supervision. (1546/2009)

Section 93 (1112/2010)

(1) If provisions laid down in sections 91, 91a, 91b or 92 or under section 92a have been violated in marketing a medicinal product, the Finnish Medicines Agency may forbid continuation or renewal of the marketing. The Finnish Medicines Agency may also order a party thus forbidden to correct the marketing if this is definitely considered necessary in terms of risk to medicinal product safety. The Agency may order the list referred to in section 91c to be published within a deadline set by the Agency.

(2) A prohibition or an order to correct marketing material or publish the list can be backed up with a conditional fine. If necessary, a new conditional fine may be imposed in order to make a prohibition more effective.

(3) If requested by the Finnish Medicines Agency, a Regional State Administrative Agency will order payment of the conditional fine to make the prohibition more effective.

Section 93a (1546/2009)

(1) The Finnish Medicines Agency may also take the action referred to in section 93(1–2) upon application by a competent authority or organisation of another state referred to in section 2 of the Act on cross-border prohibition procedures (1189/2000) if action originating in Finland is contrary to the provisions of Council Directive 92/28/EEC on the advertising of medicinal products for human use or the provisions of article 14 of Council Directive 89/552/EEC on the coordination of certain provisions laid down by Law,

Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities, in the form in which they are implemented nationally in the legislation to be applied.

(2) Upon application by the Finnish Medicines Agency or a competent authority or organisation of another state, a Regional State Administrative Agency will order payment of a conditional fine imposed to make a prohibition ordered under subsection 1 above more effective.

Section 93b (773/2009)

The right of the Finnish Medicines Agency to take legal action for a prohibition in another state belonging to the European Economic Area is laid down in the Act on cross-border prohibition procedures.

Section 94 (853/2005)

Holders of marketing authorisations for medicinal products or of registrations of traditional herbal medicinal products must have a scientific service unit responsible for the information given in marketing the medicinal product.

Sale of medicinal gases

Section 95 (773/2009)

In derogation to what is provided in this Act on the sale of medicinal products by medicinal product manufacturers or wholesalers, a manufacturer or importer of medicinal gases may, after being granted a licence under section 8 or section 32, also sell medicinal gases to relevant patients and for the purposes of patient transport. The Finnish Medicines Agency may issue further regulations and guidelines on the procedures of supplying medicinal gases.

Veterinary surgeons' right to supply medicinal products (700/2002)

Section 95a (700/2002)

(1) Veterinary surgeons are entitled to supply medicinal products for veterinary medication. Veterinary surgeons must not, however, supply medicinal products with alcohol content that can be used for purposes of intoxication or medicinal products containing narcotic drugs as referred to in section 2 of the Narcotics Act. Veterinary surgeons may supply medicinal products to owners or keepers of animals only after examining the animal or having in some other reliable manner ascertained justification for the necessity of the medication. Veterinary surgeons may not charge more for the medicinal products they supply than the amount they themselves have paid to the pharmacy or medicinal product wholesaler. A veterinary surgeon means a person with an authorisation to practise veterinary medicine under the Act on Practising Veterinary Medicine (29/2000).

(2) The Ministry of Agriculture and Forestry may generally restrict supply of a medicinal product to the owner or keeper of an animal if the medicinal product may cause significant harm to animals, humans or the environment or some other significant harm.

Section 95b (700/2002)

(1) Veterinary surgeons must provide the owner or keeper of an animal with instructions for use of the medicinal product supplied.

(2) Veterinary surgeons must comply with instructions given concerning proper safe-keeping and storage of the medicinal products they have procured from a pharmacy or a medicinal product wholesaler, and must ensure that expired medicinal products are not kept in stock.

(3) Veterinary surgeons must keep records of the medicinal products they procure and supply.

(4) Further provisions concerning the procedures veterinary surgeons are to comply with in storing and supplying medicinal products procured from a pharmacy or a medicinal product wholesaler and the bookkeeping and notification requirements related to the procurement and supply of medicinal products will be issued by Ministry of Agriculture and Forestry decree.

Section 95c (1546/2009)

(1) Supervision of compliance with provisions on veterinary surgeons' rights to supply medicinal products for veterinary medication falls within the purview of the Finnish Food Safety Authority and the Regional State Administrative Agencies. The Finnish Food Safety Authority may issue provisions concerning individual cases that are necessary for such supervision by the Regional State Administrative Agencies.

(2) The Finnish Food Safety Authority and the Regional State Administrative Agencies are entitled to receive free of charge all information necessary for supervision from veterinary surgeons, the Finnish Medicines Agency, medicinal product wholesalers and pharmacies, notwithstanding what is provided on confidentiality elsewhere in legislation.

(3) Provisions concerning procedure in cases where a veterinary surgeon violates or abuses the right to procure or supply medicinal products are laid down in the Act on Practising Veterinary Medicine.

Chapter 11 — Sanctions, appeals and authorisation to issue decrees

Penalties

Section 96 (411/2002)

(1) Punishment for medicinal product offences violating this Act or provisions issued by the European Community on supervision of the medicinal products referred to in this Act or provisions or regulations issued thereunder is laid down in Chapter 44, section 5, of the Criminal Code (39/1889).

(2) Punishment for practising medicinal product wholesaling or operating a pharmacy without a licence required under this Act is laid down in Chapter 44, section 3, of the Criminal Code.

Section 97 (643/1995)

The penalty for breach of the confidentiality obligation laid down in section 90 shall be imposed according to Chapter 38, sections 1 or 2, of the Criminal Code, unless the act is punishable under Chapter 40, section 5, of the Criminal Code or a more severe penalty is laid down elsewhere by law.

Section 98 (296/2004)

(1) Whoever, either intentionally or through negligence, violates a provision concerning supervision of medicinal products laid down in a decree issued under this Act or under article 95 or article 308 of the Treaty establishing the European Community or thereunder or a general provision or a provision concerning an individual case by

1) manufacturing, importing, storing, carrying for sale or supplying medicinal products referred to in this Act,

2) neglecting to make a notification, provide information or keep records concerning medicinal products referred to in this Act or

3) failing to comply with a prohibition issued by Finnish supervisory authorities or the Commission of the European Communities or the European Union Council concerning the medicinal products referred to in this Act,

4) violating provisions issued in this Act on the marketing of medicinal products, or

5) asking for, accepting or receiving inducements, benefits or gifts prohibited in section 92,

must be sentenced to pay a fine for a *medicinal product offence*, unless a stricter punishment is prescribed elsewhere in law.

(2) Whoever, either intentionally or through negligence, fails to comply with the medicinal products price list referred to in section 58, must also be convicted for a medicinal product offence.

Section 99

Repealed by Act 893/2001.

Section 100

Repealed by Act 411/2002.

Certain prohibitions and revocations (1046/1993)

Section 101 (773/2009)

The Finnish Medicines Agency has the right to prohibit the import, manufacture, distribution, sale or other release for consumption of a medicinal product if it becomes apparent, or there is reason to suspect, that the conditions for granting the marketing authorisation or for registration no longer exist or if the requirements and obligations concerning manufacture or import of the medicinal product are no longer met.

Section 101a (773/2009)

The Finnish Medicines Agency may revoke in part or in full a licence granted for practising the manufacture or wholesaling of medicinal products if any of the requirements for granting the licence are no longer met or if an obligation essential to safety or quality has not been met.

Appeals and the correction of factual errors in specific cases

Section 102 (773/2009)

(1) Appeals can be made against decisions given by the Finnish Medicines Agency under this Act as provided in the Administrative Judicial Procedure Act (586/1996). Decisions by administrative courts settling matters referred to in sections 40, 41, 52 or 54 may, however, be appealed to the Supreme Administrative Court only if the Supreme Administrative Court grants leave to appeal. No appeal may be made against decisions by administrative courts concerning the requirement to provide information referred to in section 89.

(2) Leave to appeal can be granted if:

1) it is important to submit the matter to the Supreme Administrative court in view of application of the law in other similar cases or for reasons of consistency in legal practice;

2) there is special reason to submit the matter to the Supreme Administrative Court as a result of an obvious error in the matter; or

3) there is some other weighty reason for granting leave to appeal.

(3) In addition, the Finnish Medicines Agency is entitled to appeal against decisions made by administrative courts following an appeal if the decision on the matter under appeal was made by the administrative court.

(4) Decisions made by the Finnish Medicines Agency under sections 2(4), 59, 66, 80, 80a, 87, 87c, 88a, 93, 94 and 101 must be complied with regardless of whether an appeal has been made, unless the appeal authority orders otherwise. Decisions made by the Agency under sections 40, 41, 52 and 54 must not be implemented until they have become legally effective. (1112/2010)

(5) Notwithstanding what is provided in the Administrative Procedure Act (434/2003) on correcting an error of substance, the Finnish Medicines Agency may revoke its decision on granting a marketing authorisation for a medicinal product, on modifying a medicinal

product, on revocation of an authorisation granted or on prohibiting release of a medicinal product for consumption, and re-decide the matter if a decision made by an institution of the European Union in the matter referred to above so requires.

Authorisation to issue decrees

Section 103 (700/2002)

Further provisions concerning the implementation of this Act will be issued by Government decree.

Chapter 12 — Entry into force and transitional provisions

Entry into force

Section 104

(1) This Act enters into force on January 1, 1988.

(2) This Act repeals the Act on the Pharmacy System of January 4, 1928 (4/1928), as amended, and the Pharmaceutical Preparations Act of December 5, 1935 (374/1935), as amended.

(3) Measures necessary for the implementation of this Act may be taken before the Act's entry into force.

Rights and licences valid at the time of the entry into force of this Act

Section 105

Whoever, at the time of the entry into force of this Act, is in possession of a licence for the industrial manufacture of pharmaceutical supplies for sale or has a licence to operate in the pharmaceutical supplies trade will continue to be entitled to manufacture medicinal products industrially at a medicinal product manufacturer's facility or engage in wholesaling medicinal products without the licence laid down in this Act. However, a new licence referred to in sections 8 and 32 of this Act must be applied for within three years of the entry into force of this Act, under threat that the previous licence will otherwise be considered to have expired.

Section 106

Whoever, at the time of the entry into force of this Act, has the right to operate a pharmacy business in a pharmacy or subsidiary pharmacy will continue to have this right.

Section 107

A municipality or municipal federation which, at the time of the entry into force of this Act, has a Government-issued licence to operate a special pharmacy in a hospital that it maintains shall, without a different licence, have the right to continue to operate a hospital pharmacy referred to in this Act. A municipality or municipal federation which, at the time of entry into force of this Act, has a licence under the Act on the Pharmacy System for a hospital or health centre that it maintains to otherwise prepare and distribute medicinal products may, notwithstanding this Act's provisions on the qualifications of a dispensary manager, continue to distribute medicinal products from a dispensary referred to in this Act. Private nursing institutions and institutions caring for the mentally handicapped that, at the time of the entry into force of this Act, have the previously mentioned licence to prepare and distribute medicinal products may continue to distribute medicinal products from a dispensary referred to in this Act.

Section 108

A proprietary medicinal product for which the licence granted under the Pharmaceutical Preparations Act to sell or otherwise release it for consumption is valid at the time of the entry into force of this Act may continue to be sold or otherwise released for consumption as a medicinal product referred to in section 20 of this Act. The provisions of this Act shall otherwise also apply to such products.

Section 109

Products for which the licence granted under section 10f of the Pharmaceutical Preparations Act to sell or otherwise release them for consumption is valid at the time of the entry into force of this Act, and products for which a semimedicinal use has been approved in accordance with separate provisions, may continue to be sold to the general public as semimedicinal products referred to in this Act.

Scale of charges, pharmacopoeia and pharmaceutical supplies list valid at the time of the entry into force of this Act

Section 110

The latest approved scale of charges and pharmacopoeia to be complied with in pharmacies at the time of the entry into force of this Act will continue to be followed until a new scale of charges for medicinal products and a pharmacopoeia are approved under this Act for pharmacies to comply with. The National Board of Health must approve the medicinal products list no later than one year after the entry into force of this Act, until which time the pharmaceutical supplies list referred to in the Pharmaceutical Preparations Act shall remain in force.

Section 111

Matters referred to in the Act on the Pharmacy System or in the Pharmaceutical Preparations Act which are being processed by a State Provincial Office, the National Board of Health or the Ministry of Social Affairs and Health at the time of the entry into force of this Act will be dealt with and resolved in accordance with the provisions valid at the time of entry into force of this Act.

Government proposal 87/1986, Economic Committee report 1311986, Committee for Social Affairs report 272/1986.

Entry into force and application of amendment statutes

81/1991:
This Act enters into force on March 1, 1991.
Government proposal 233/1990, Committee for Social Affairs report 44/1990, Committee for Social Affairs report 227/1990.

1162/1992:
This Act will enter into force on a date laid down by Decree.
Matters being processed by the National Agency for Welfare and Health at the time of the entry into force of this Act shall be dealt with and resolved in accordance with the provisions valid at the time of entry into force of this Act, with the exception of the provisions of sections 21(1)(4) and of 26(1), under which a change in the price of a product for which a marketing authorisation has been received requires an application to the National Agency for Welfare and Health.
Measures necessary for the implementation of this Act may be taken before the Act's entry into force.
Government proposal 118/1992, Socials Affairs and Health Committee report 30/1992, Grand Committee report 5/1992.

248/1993:
This Act enters into force on March 15, 1993.
Government proposal 374/1992, Social Affairs and Health Committee report 1/1993.

939/1993:
This Act enters into force on January 1, 1994.
Measures necessary for the implementation of this Act may be taken before the Act's entry into force. Government proposal 171/1993, Social Affairs and Health Committee report 19/1993.

1046/1993:
1. This Act will enter into force on a date laid down by Decree. (Act 1046/1993 entered into force on January 1, 1994, as laid down by Decree 1447/1993.)
2. This Act repeals the Act amending the Medicines Act, of November 27, 1992 (1162/1992).
3. Matters being processed by the Finnish Medicines Agency at the time of the entry into force of this Act shall be dealt with and resolved in accordance with the provisions valid at the time of entry into force of this Act, with the exception of the provisions of sections 21(1)(4) and of 26(1), under which a change in the price of a product for which a marketing authorisation has been received requires an application to the Finnish Medicines Agency, and the provisions of Chapter 8.
4. Homeopathic and anthroposophic products that fulfil the requirements laid down in section 21a(1-2) of this Act for which the licence granted under section 69(1) or under section 10f of the Pharmaceutical Preparations Act to sell or otherwise release them for consumption is valid at the time of the entry into force of this Act, will, when the Act enters into force, be designated as registered products referred to in section 21a of the Act.
5. Products other than those referred to above for which the licence granted under section 69(1) or under section 10f of the Pharmaceutical Preparations Act to sell or otherwise release them for consumption is valid at the time of the entry into force of this Act, and products for which a semimedicinal use has been approved in accordance with separate provisions, will, when the Act enters into force, be designated as herbal medicinal products referred to in section 21(2) of this Act with a marketing authorisation and with approved uses for the products.
6. Sales package labelling of products designated as registered products or products with a marketing authorisation in accordance with the above must be adapted, within two years of the entry into force of this Act, to conform with provisions issued by the Finnish Medicines Agency under section 21a and section 30 of the Medicines Act and section 30 of the Medicines Decree.
7. Notwithstanding the provisions of section 24(1) on the validity period of marketing authorisations and the renewal of marketing authorisations, the Finnish Medicines Agency shall

determine the period within which holders of marketing authorisations for herbal medicinal products for which the marketing authorisation was received in conformity with the above must apply for renewal of the authorisation.
8. Those who manufacture herbal medicinal products and homeopathic and anthroposophic products referred to above industrially in Finland must, within a year of the entry into force of this Act, submit an application for the licence referred to in section 8 of the Medicines Act to the Finnish Medicines Agency.
9. Wholesalers of herbal medicinal products referred to above must, within a year of the entry into force of this Act, apply to the Finnish Medicines Agency for the licence or recognition referred to in section 32.
10. Measures necessary for the implementation of this Act may be taken before the Act's entry into force.
Appendix II of the EEA agreement: Council Directives (65/65/EEC, 75/318/EEC, 75/319/EEC, 87/21/EEC, 81/851/EEC, 81/852/EEC, 85/432/EEC and 91/356/EEC), Government proposal 101/1993, Social Affairs and Health Committee report 29/1993.

416/1995:
This Act enters into force on April 1, 1995.
Measures necessary for the implementation of this Act may be taken before the Act's entry into force.
Government proposal 337/1994, Social Affairs and Health Committee report 52/1994, Council Regulation (EEC) 2309/93; OJ L214, August 24, 1993, p.1, Council Directive 93/39/EEC; OJ L214, August 24, 1993, p.22, 93/40/EEC; OJ L214, August 24, 1993, p.31, 81/851/EEC; OJ L317, November 6, 1981, p. 1.

643/1995:
This Act enters into force on September 1, 1995.
Government proposal 94/1993, Legal Committee report 22/1994, Grand Committee report 10/1994.

282/1996:
This Act enters into force on May 1, 1996 and remains in force until December 31, 1996.
Notwithstanding the provisions of sections 4 and 6(1) of the Act on Central Government Transfers to Local Government (688/1992), the level of central government transfers to local government for social and health care for 1996 will be increased by the total amount of additional costs incurred by municipalities as a result of the entry into force of this Act.
Government proposal 13/1996, Social Affairs and Health Committee report 5/1996, Parliament's reply 35/1996.

895/1996:
This Act enters into force on January 1, 1997.
Pharmacy location regulations and pharmacy licence conditions under section 43(3) of the Medicines Act which state that the pharmacy licence incorporates an obligation to keep a subsidiary pharmacy shall cease to be valid no later than three years after the entry into force of this Act, when the Finnish Medicines Agency will determine the area in which a pharmacy shall be located, as referred to in section 40 of this Act. If a condition referred to in section 43(3) of the Medicines Act is incorporated into the pharmacy licence for a pharmacy located alone in a municipality, the condition shall cease to be valid when this Act enters into force.
Measures necessary for the implementation of this Act may be taken before the Act's entry into force.
Government proposal 118/1996, Social Affairs and Health Committee report 19/1996, Parliament's reply 129/1996, Council Directive 83/189/EEC; OJ L109, April 26, 1983, p.8, amended 88/182/EEC; OJ L81, March 26, 1988, p. 75, amended 94/10/EC; OJ L100, April 19, 1994, p.30.

898/1996:

This Act enters into force on January 1, 1997 and remains in force until December 31, 1998. (1135/1997)
Notwithstanding the provisions of Chapter 2 of the Act on Central Government Transfers to Local Government (1147/1996), the level of central government transfers to local government for social and health care for 1997 and 1998 will be increased by the total amount of additional costs incurred by municipalities as a result of the entry into force of this Act. (1135/1997)
Government proposal 167/1996, Social Affairs and Health Committee report 25/1996, Parliament's reply 143/1996,

999/1997:
This Act enters into force on March 1, 1998.
Government proposal 124/1997, Social Affairs and Health Committee report 1511997, Parliament's reply 129/1997.

1134/1997:
This Act enters into force on January 1, 1998.
Government proposal 175/1997, Social Affairs and Health Committee report 25/1997, Parliament's reply 198/1997.

1135/1997;
This Act enters into force on January 1, 1998.
Government proposal 175/1997, Social Affairs and Health Committee report 25/1997, Parliament's reply 198/1997.

420/1999:
This Act enters into force on April 1, 1999.
Measures necessary for the implementation of this Act may be taken before the Act's entry into force.
The University of Helsinki must transfer its subsidiary pharmacy located in Kuopio to the University of Kuopio no later than six months after the entry into force of this Act. The conditions of the transfer shall be determined in an agreement drawn up between the two universities. If no agreement is drawn up within the specified time period, the Government shall determine the conditions of the transfer.
The Finnish Medicines Agency must grant the University of Helsinki a licence to establish a new, sixteenth, subsidiary pharmacy to replace the subsidiary pharmacy in Kuopio no later than six months after the Kuopio subsidiary pharmacy has been transferred to the University of Kuopio. An area in the cities of Espoo, Helsinki or Vantaa must be determined from the standpoint of pharmaceutical services as the location of the new subsidiary pharmacy,
Government proposal 276/1998, Social Affairs and Health Committee report 42/1998, Parliament's reply 308/1998.

679/1999:
This Act enters into force on December 1, 1999.
Government proposal 30/1998, Administrative Committee report 31/1998, Parliament's reply 303/1998.

1191/2000;
This Act enters into force on January 1, 2001.
Government proposal 178/2000, Economic Committee report 36/2000, Parliament's reply 183/2000, Directive 98/27/EC of the European Parliament and of the Council (31998L0027); OJ L 166, June 11, 1998, p.51.

893/2001:
This Act enters into force on January 1, 2002.
Government proposal 80/2000, Legal Committee report 14/2001, Parliament's reply 94/2001.

411/2002:
This Act enters into force on September 1, 2002.
Government proposal 17/2001, Legal Committee report 5/2002, Parliament's reply 35/2002.

700/2002:
This Act enters into force on January 1, 2003.
This Act repeals the Decree on the right of veterinary surgeons to supply medicinal products for veterinary purposes of December 23, 1987 (113511987), as amended.
Measures necessary for the implementation of this Act may be taken before the Act's entry into force.
Government proposal 46/2002, Social Affairs and Health Committee report 14/2002, Parliament's reply 91/2002.

1081/2002:
This Act enters into force on March 1, 2003.
Government proposal 146/2002, Social Affairs and Health Committee report 32/2002, Parliament's reply 166/2002.

80/2003:
This Act enters into force on April 1, 2003.
Measures necessary for the implementation of this Act may be taken before the Act's entry into force. When supplying medicinal products on the basis of a prescription issued before the entry into force of this Act, the product shall be exchanged in accordance with section 57b if the purchaser wishes the medicinal product to be exchanged for a lower cost product. The purchaser of the medicinal product must be informed of the possibility of exchange under section 57.
Government proposal 165/2002, Social Affairs and Health Committee report 39/2002, Parliament's reply 209/2002.

296/2004:
This Act enters into force on May 1, 2004.
The provisions of this Act must be complied with as appropriate in clinical trials that have been initiated when this Act enters into force.
Measures necessary for the implementation of the Act may be taken before the Act's entry into force,
Government proposal 20/2004, Social Affairs and Health Committee report 5/2004, Parliament's reply 33/2004, Directive 2001/20/EC of the European Parliament and of the Council (32001L0020), OJ L121 May 1, 2001 pp. 34-44, Directive 2001/83/EC of the European Parliament and of the Council (32001L0083), OJ L311 November 28, 2001 pp. 67-128.

853/2005:
(1) This Act enters into force on 7 November, 2005. Section 17(3), however, enters into force on 1 June 2006. The provisions of this Act apply to all authorisation, registration, change and renewal applications made on 30 October 2005 or later.
(2) Measures necessary for the implementation of this Act may be undertaken before the Act's entry into force.
(3) The marketing authorisations granted to medicinal products before the entry into force of this
Act must be renewed in accordance with this Act. If a marketing authorisation expires within six months of the entry into force of this Act, the renewal application may be made in derogation to the fixed period laid down in section 24(2), however at least three months before the expiry. If, at the time this Act enters into force, a valid marketing authorisation has been renewed one or more times before the entry into force of the Act, the Finnish Medicines Agency will issue separate orders concerning specifications and documents to be appended to such a renewal application.
(4) If a medicinal product that is a traditional herbal medicinal product under the definition of

section 5a has a valid marketing authorisation at the time this Act enters into force, the Finnish Medicines Agency must convert the marketing authorisation into a registration under section 22 when it is renewed. If a medicinal product defined in section 5a has been classified as a food product before the entry into force of this Act, registration of the product must be applied for by 31 December 2007. If registration has been applied for by the said time limit, a traditional herbal medicinal product referred to in this subsection may be sold without registration until the Finnish Medicines Agency gives a decision on the application. A marketing authorisation under this Act must be applied for in the case of medicinal products that have been granted marketing authorisations as natural remedies but are not traditional herbal medicinal products referred to in section 5a when marketing authorisations in force at the time of the entry into force of this Act are renewed.

(5) A marketing authorisation must be applied for in the case of medicinal gases that are being marketed at the time of the entry into force of this Act but do not have a marketing authorisation by 31 December 2007. If such an application has been made by the said time limit, the medicinal gas concerned may be sold without a marketing authorisation until the Finnish Medicines Agency gives a decision on the application. The Finnish Medicines Agency may, however, before issuing a decision on the marketing authorisation, prohibit the sale of the medicinal gas on grounds referred to in section 101 of the Medicines Act.

(6) If the European Communities have granted a marketing authorisation to a medicinal product
for which marketing authorisation has been applied on 19 November 2005 or earlier, the time limit referred to in section 21a(1) is ten years. The time limit is six years for other reference medicinal products based on marketing authorisation applications made before the entry into force of this Act. If a marketing authorisation for a reference medicinal product has been applied for before the entry into force of this Act, section 21a(2-4) does not apply to the reference medicinal product's marketing authorisation.

(7) In the case of medicinal products that have been granted a marketing authorisation before the
entry into force of this Act, the fixed period of three years referred to in section 29(1)(3) is calculated from the entry into force of this Act.

(8) The National Veterinary and Food Research Institute Finland, the National Public Health Institute and the Finnish Red Cross may import, manufacture and distribute medicinal products under the provisions in force at the time of the entry into force of this Act until the end of 2007. After this, importing, manufacturing and distributing medicinal products will require an authorisation under this Act. After the entry into force of this Act, importing, manufacturing and distributing of medicinal products by the National Veterinary and Food Research Institute, the National Public Health Institute and the Finnish Red Cross will be supervised in accordance with section 77. Government proposal 108/2005, Constitutional Law Committee report 33/2005, Social Affairs and Health Committee report 17/2005, Parliament's reply 124/2005, Directive 2001/82/EEC of the European Parliament and of the Council (32001L0082); OJ L 311, 6.11.2001 p. 1, Directive 2001/83/EC of the European Parliament and of the Council (32004L0083); OJ L 311, 6.11.2001, p. 67, Directive 2004/24/EC of the European Parliament and of the Council (32004L0024); OJ L 136, 31.3.2004 p. 85, Directive 2004/27/EC of the European Parliament and of the Council (32004L0027); OJ L 136, 31.3.2004 p. 34,Directive 2004/28/EC of the European Parliament and of the Council (32004L0028); OJ L 136, 31.3.2004, p. 58.

22/2006:

(1) This Act enters into force on 1 February 2006.

(2) Measures necessary for the implementation of this Act may be undertaken before the Act's entry into force.

(3) Section 37a of this Act applies only to medicinal products supplied to pharmacies after the entry into force of this Act, In the case of the supply of a medicinal product based on an agreement made before the entry into force of this Act, Section 37a will apply, however six months from the entry into force of the Act.

(4) If a medicinal product has been granted a marketing authorisation before the entry into force of
this Act and the holder of the marketing authorisation submits to the Finnish Medicines Agency within four months of the entry into force of this Act an explanation referred to in section 57c(2)(3) concerning the validity of a patent or a supplementary protection certificate referred to in section 57c(2)(1), a product that has not been defined as comparable and its generic medicinal products must not be defined as comparable during the validity of the patent or the supplementary protection certificate. If a medicinal product is imported by different importers, these same products may, however, be defined as mutually comparable in spite of a valid patent or supplementary protection certificate.
(5) If a medicinal product and its generic medicinal products have been defined as comparable at
the time of the entry into force of this Act, the Finnish Medicines Agency must remove these products from the list of comparable products if the holder of the marketing authorisation submits an explanation referred to in section 57c(2)(3) within four months of the entry into force of this Act. The removal must take place when the list of comparable medicinal products is drawn up following the submission of the explanation concerning a patent or supplementary protection certificate. If a medicinal product is imported by different importers, these same products may, however, be defined as mutually comparable in spite of a valid patent or supplementary protection certificate.
Government proposal 107/2005, Social Affairs and Health Committee report 32/2005, Parliament's reply 196/2005.

298/2006:
This Act enters into force on 1 May 2006.
Government proposal 203/2005, Agriculture and Forestry Committee report 2/2006, Parliament's reply 31/2006.

62/2007:
This Act enters into force on 1 April 2007.
Measures necessary for the implementation of this Act may be undertaken before the Act's entry into force.
Government proposal 250/2006, Social Affairs and Health Committee report 43/2006, Parliament's reply 216/2006.

803/2007:
This Act enters into force on 1 April 2009.
The National Agency for Medicines will publish no later than on 30 January 2009 the list on mutually comparable medicinal products which takes effect on 1 April 2009.
Measures necessary for the implementation of this Act may be undertaken before the Act's entry into force.
Government proposal 100/2008, Social Affairs and Health Committee report 24/2008, Parliament's reply 138/2008.

311/2009:
This Act enters into force on 18 May 2009. Section 15c, however, enters into force on 1 January 2010.
Measures necessary for the implementation of this Act may be undertaken before the Act's entry into force.
Government proposal 21/2009, Social Affairs and Health Committee report 8/2009, Parliament's reply 32/2009, Regulation (EC) no. 1394/2007 of the European Parliament and of the Council (32007R1394); OJ L. 324, 10.12.2007, p. 121; Directive 2008/97/EC of the European Parliament and of the Council; (32008L0097); OJ L. 318, 28.11.2008, p.9.

595/2009:
This Act enters into force on 1 November 2009.

Measures necessary for the implementation of this Act may be undertaken before the Act's entry into force.
Government proposal 74/2009, Social Affairs and Health Committee report 21/2009, Parliament's reply 96/2009.

773/2009:
This Act enters into force on 1 November 2009. Section 15c, however, enters into force on 1 January 2010.
Measures necessary for the implementation of this Act may be undertaken before the Act's entry into force.
Government proposal 166/2009, Social Affairs and Health Committee report 28/2009, Parliament's reply 122/2009.

1546/2009:
This Act enters into force on 1 January 2010.
Measures necessary for the implementation of this Act may be undertaken before the Act's entry into force.
Government proposal 161/2009, Administration Committee report 18/2009, Parliament's reply 205/2009.

1727/2009:
This Act enters into force on 1 January 2010.
Government proposal 174/2009, Administration Committee report 19/2009, Parliament's reply 223/2009.

435/2010:
This Act enters into force on 1 July 2010.
Measures necessary for the implementation of this Act may be undertaken before the Act's entry into force.
Government proposal 283/2009, Social Affairs and Health Committee report 2/2010, Parliament's reply 32/2010.

699/2010:
This Act enters into force on 1 October 2010.
Measures necessary for the implementation of this Act may be undertaken before the Act's entry into force.
Government proposal 180/2009, Social Affairs and Health Committee report 14/2010, Parliament's reply 102/2010.

1112/2010:
This Act enters into force on 1 February 2011.
Applications for licenses pending before the entry into force of the Act are processed in accordance with the provisions of the Act in force at the time of entry into force of the Act. Medicine chest licences granted before this Act enters into force remain in force. Medicine chest licences can no longer be renewed after this Act enters into force. Pharmacists licensed to maintain a medicine chest may, however, submit to the Finnish Medicines Agency an application to replace the medicine chest licence with a pharmacy service point authorisation if the requirements for a pharmacy service point under section 52a are met. In the event of a change in the licensed pharmacist, the new pharmacist wishing to establish a pharmacy service point must apply for the authorisation referred to in section 52a.
Measures necessary for the implementation of this Act may be undertaken before the Act's entry into force.
Government proposal 94/2010, Social Affairs and Health Committee report 22/2010, Parliament's reply 145/2010.

1340/2010:
This Act enters into force on 1 May 2011.
Measures necessary for the implementation of this Act may be undertaken before the Act’s entry into force.
Government proposal 90/2010, Social Affairs and Health Committee report 40/2010, Parliament’s reply 244/2010.