MEDICINES DECREE

Unofficial translation; Amendments up to 69/2011 included

Manufacture, importation and wholesaling of medicinal products

Section 1 (803/2009)

(1) When applying to the Finnish Medicines Agency for a licence to manufacture medicinal products industrially under section 8 of the Medicines Act (395/1987), the following must be enclosed with the application:

1) the applicant's articles of association or similar document and a trade register extract for the applicant or, in the case of a foreign business that has a registered branch in Finland, the branch;

2) details of the medicinal products, active substances and pharmaceutical forms that the medicinal product manufacturer intends to manufacture;

3) details of the medicinal product manufacturer's estimate of production quantity;

4) details of the medicinal product manufacturer's location and premises and the equipment used in production and quality control;

5) details of production quality control;

6) details of the medicinal product manufacturer's personnel and

7) details of the accountable director and person meeting qualifications referred to in section 9 of the Medicines Act.

(2) A licence granted by the Finnish Medicines Agency applies only to the pharmaceutical forms and active substances specified in the licence. The production of other pharmaceutical forms or active substances requires an amendment to the existing licence. Amendments must be applied for separately from the Finnish Medicines Agency. Amendment applications must include the documentation referred to in subsection 1, as appropriate. The Finnish Medicines Agency must be notified of any material changes in production or quality control made by medicinal product manufacturers.

(3) When an application is made for a licence referred to in section 8 of the Medicines Act in order to carry out duties related to the quality control of medicinal products as contract analyses, documentation referred to in subsection 1 must be appended to the application as appropriate. Licences granted to units or laboratories carrying out duties in the sphere of quality control of medicinal products only apply to the techniques of analysis listed in the licence granted by the Finnish Medicines Agency. What is provided in subsection 2 applies as appropriate to applications and notifications concerning amendments to licences and changes in operations.

Section 1a (312/2004)

Accountable directors of units and laboratories carrying out duties in the sphere of quality control of medicinal products must have an appropriate higher first degree, sufficient experience on analytics relating to quality control and the qualifications otherwise laid down in section 9(2) and section 9(3) of the Medicines Act. If the duties of the unit or the laboratory do not include approval of consignments of medicinal products for use, it does not need to employ the person meeting qualifications referred to in section 9(2) and section 9(3) of the Medicines Act.

Section 2 (803/2009)

(1) When applying to the Finnish Medicines Agency for the licence referred to in section 32 of the Medicines Act, the following must be enclosed with the application:

1) the applicant's articles of association or similar document and a trade register extract for the applicant or, in the case of a foreign business that has a registered branch in Finland, the branch;

2) details of the medicinal product wholesaler's estimate of the extent of product distribution;

3) details of the medicinal product wholesaler's location, premises and equipment;

4) details of the medicinal product wholesaler's personnel;

5) details of the medicinal product transport arrangements;

6) details of active substance handling and quality control;

7) details of the accountable director referred to in section 33 of the Medicines Act; and

8) details of the contingency plan referred to in section 7a of this Decree.

(2) In addition to what is laid down in subsection 1, holders of a medicinal product wholesaling licence granted in a state belonging to the European Economic Area in accordance with Community provisions who wish to engage in medicinal product wholesaling in Finland must enclose with the application details of the licence granted by the other state belonging to the European Economic Area.

(3) The Finnish Medicines Agency must be notified of any material change made in the medicinal product wholesaler's operations.

Section 2a (312/2004)

(1) Decisions on applications for licences referred to in section 8, 15a or 32 of the Medicines Act must be made within 90 days of the arrival of the licence application at the Finnish Medicines Agency. (803/2009)

(2) Decisions on applications to amend a licence referred to in section 1(2) and section 1(3) above must be made within 30 days of the arrival of the application. The processing period for amendment applications may be extended by up to 60 days if there is a special reason, notification of which must be given to the applicant prior to the conclusion of the period stated above.

(3) Time reserved for submitting additional documentation or for supplying an explanation is not included in the processing periods referred to in this section.

Section 3 (803/2004)

If the accountable director or person meeting qualifications of a medicinal product manufacturer, a unit manufacturing medicinal products for clinical trials or a unit or laboratory carrying out duties in the sphere of quality control as contract analyses is replaced, the Finnish Medicines Agency must be notified without delay.

Section 4 (803/2009)

If the accountable director of a medicinal product wholesaler is replaced, the Finnish Medicines Agency must be notified without delay.

Section 5 (1184/2002)

Medicinal product manufacturers must keep a sales register indicating the medicinal products sold and their quantity, buyer and date of sale.

Section 5a
Repealed by Decree 1184/2002.

Section 6 (803/2009)

(1) Importers referred to in section 17 of the Medicines Act must keep a register of medicinal product imports indicating the product imported and its quantity, country of origin, supplier and date of import.

(2) Active substance importers referred to in section 17(4) of the Medicines Act must also submit notification of the active substances imported to the Finnish Medicines Agency without delay. The notification must include information on the quantity and quality of the imported substance and it purpose of use.

Section 6a (312/2004)

(1) Importers of medicinal products must make sure that medicinal products imported from countries outside the European Economic Area have been manufactured by legal manufacturers of medicinal products in compliance with at least the good manufacturing practice for medicinal products laid down in European Union provisions.

(2) Apart from the above, importers of medicinal products with marketing authorisation must make sure that each consignment of medicinal products imported from countries outside the European Economic Area has undergone a quality control inspection in Finland or in another country belonging to the European Economic Area in accordance with the requirements of the marketing authorisation for the medicinal product. In Finland the inspection must take place in a laboratory approved by the Finnish Medicines Agency. (803/2009)

(3) The inspection referred to in subsection 1 above may be waived if the European Community and the country of origin of the import have agreed the necessary arrangements to ensure that the manufacturer of the medicinal product complies at least

with the good manufacturing practice for medicinal products referred to in the provisions of the European Community, and that the quality control measures are performed in the country of origin of the import.

(4) The provisions laid down in section 10 of the Medicines Act apply, where appropriate, to commissioning inspections from an outside party.

Section 7

(1) The register of purchases, sales, imports and storage of medicinal products kept by a medicinal product wholesaler under section 36 of the Medicines Act must indicate the trade name of all medicinal products and their quantity, the name and address of the seller or buyer and the date of purchase or sale. (1184/2002)

(2) In the register of sales referred to in subsection I above, it must be possible to itemize sales of medicinal products to buyers referred to in section 34 of the Medicines Act. (1490/1993)

(3) Medicinal product wholesalers must submit notification to the Finnish Medicines Agency twice a year on the sale or other supply of active substances to buyers referred to in section 34(2) of the Medicines Act. (803/2009)

Section 7a
Repealed by Decree 1184/2002.

Section 8 (1604/1993)

Medicinal product manufacturers and medicinal product wholesalers may sell or otherwise supply narcotic drugs referred to in lists I, II and IV of the 1961 Single Convention on Narcotic Drugs (Finnish Treaty Series 43/1965) and lists I and II of the Convention on Psychotropic Substances (Finnish Treaty Series 60/1976) to hospital pharmacies, dispensaries, military pharmacies and veterinary surgeons only on the basis of a separate written order.

Marketing authorisation and special permits for medicinal products (118412002)

Section 9 (803/2009)

(1) In connection with granting a marketing authorisation for a medicinal product, the Finnish Medicines Agency must decide whether the medicinal product may be sold or otherwise released for consumption only on the basis of a prescription.

(2) The Finnish Medicines Agency may alter a decision referred to in subsection 1 on the basis of new information received on the medicinal product affecting its supply classification.

Section 10

Repealed by Decree 1184/2002.

Section 10a (803/2009)

(1) Applications concerning authorisations and registrations referred to in chapter 4 of the Medicines Act must be processed by the Finnish Medicines Agency within the following time limits:

1) 210 days in the case of marketing authorisations and registrations;

2) 130 days in the case of parallel import marketing authorisations; and

3) 30 days in the case of special authorisations.

(2) If Commission Regulation 1084/2003/EC concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State applies to amending a marketing authorisation, the application for such an amendment must be processed in accordance with the periods laid down in the said Regulation. In addition, amendments to the package inserts and labelling of these medicinal products must be processed within 90 days if the amendment does not affect the approved summary of product characteristics. The processing time for applications for amending marketing authorisations and registrations concerning other medicinal products may be longer than the above.

(3) Renewals of marketing authorisations and registrations must be processed within 180 days.

(4) The time limits referred to in subsections 1–3 are calculated from the submission of the relevant application including necessary specifications to the Finnish Medicines Agency. If the Finnish Medicines Agency requests additional specifications from the applicant, the time spent in giving the additional specifications concerned is not included in the processing period.

(5) Where recognition of a marketing authorisation decision made by competent authorities in another state in compliance with European Community Law is concerned, the Finnish Medicines Agency must approve an evaluation statement drawn up by a Reference Member State, the summary of product characteristics, labelling and package insert within 90 days of receiving the application and inform the Reference Member State of its approval or otherwise measures must be taken during the said period to submit it for processing by the European Medicines Agency in the manner required by European Community Law. When the Reference Member State gives a notification that an understanding concerning the procedure stated in this subsection has been reached, the Finnish Medicines Agency must grant a marketing authorisation within 30 days of such notification.

(6) Matters concerning the granting of marketing authorisations, changes to medicinal products and revocation of granted marketing authorisations or prohibition of the release of a medicinal product for consumption in which an institution of the European Union has made a decision in compliance with European Community Law must be resolved within 30 days of such a decision.

Section 10b (1184/2002)

(1) The Finnish Medicines Agency may grant a special authorisation referred to in section 21f of the Medicines Act if no other means is available to treat an individual patient or animal or group of animals, or if an available treatment would not yield the desired result. A special authorisation may also be granted when a medicinal product with marketing authorisation is not available to treat a group of patients or the population or to prevent an illness, and there are particularly weighty reasons for granting the special authorisation. When granting a patient group-specific special authorisation, the Finnish Medicines Agency must have regard to any statement on the matter issued by the European Medicines Agency's Committee for Medicinal Products for Human Use. (803/2009)

(2) When a medicinal product is supplied under a special authorisation, the supplier must, for his part, ensure that the user of the product receives sufficient instructions on the correct and safe use of the product, and storage and other instructions.

Section 10c (1184/2002)

(1) Special authorisations are applied for in writing from the Finnish Medicines Agency. A special authorisation 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 and the Finnish Food Safety Authority. Applications for special authorisations must state: (803/2009)

1) the identity of the applicant;

2) the name of the medicinal product, its strength, the pharmaceutical form, the active substance, the quantity of the medicinal product, the manufacturer, the importer, the medicinal product wholesaler and the party releasing it for consumption;

3) the patient's personal data, unless the product is used by a hospital, health centre or private health care provider in conjunction with examining or treating a patient;

4) an explanation by the prescriber of the medicinal product on the special needs which warrant the treatment of the illness with this product;

5) in the case of an individual patient, a copy of the prescription; and

6) a summary of the product characteristics or corresponding documentation on a new special authorisation product.

(2) When a special authorisation for a veterinary medicinal product is applied for, an account of the species for the treatment of which the application is made and a veterinary surgeon's account of the veterinary treatment reasons for the medicinal product will be given in place of the information indicated in subsection 1(3–5).

Section 10d (1184/2002)

Separate special authorisations must be applied for in the case of products which contain the same active substance but have a different pharmaceutical form or strength. However, a single special authorisation application for medicinal products intended for veterinary medication may be used to apply for special permits for products with different quantities or concentrations of the medicinal product's active substances.

Section 10e (1184/2002)

Special authorisations are granted for a maximum treatment period of one year. Special authorisations remain in force for one year after the decision was issued.

Section 10f (1184/2002)

The Finnish Medicines Agency may also, without separate application, issue a fixed-term special authorisation for a medicinal product, on the basis of which the product may be released for consumption even if it does not have the marketing authorisation referred to in section 21(1) of the Medicines Act.

Pharmacies, subsidiary pharmacies, pharmacy service points and online pharmacy services (69/2011)

Section 11 (69/2011)

(1) When a pharmacy licence becomes available or a decision is taken to establish a new pharmacy, the Finnish Medicines Agency must invite applications for the licence by placing a public notice in the Official Gazette. The notice must include information on the location of the pharmacy. Applications for the pharmacy licence must be made within 30 days of publication of the notice.

(2) Applicants for a pharmacy licence must enclose with their application the information required to meet the licence-granting preconditions referred to in section 43 of the Medicines Act, but not including such information on the competence of the applicant that the authority can obtain under the Act on the Population Information System and Certificate Services of the Population Register Centre (661/2009).

Section 12 (249/1993)

Repealed by Decree 69/2011.

Section 13 (69/2011)

A licensed pharmacist must notify the Finnish Medicines Agency in advance of the date on which he/she will begin operating a pharmacy business or keeping a subsidiary pharmacy.

Section 14

Repealed by Decree 1184/2002.

Section 15 (803/2009)

(1) Pharmacies must have:

1) customer space that is suitable for instructions to be given on the use of medicinal products as referred to in section 57 of the Medicines Act and that meets the requirements of the provisions on confidentiality;

2) sufficient and appropriate storage space;

3) a separate area for preparing medicinal products and for quality control; and

4) sufficient other working space as required for the range of operations of the pharmacy.

(2) Before new pharmacy premises are opened to the general public or significant changes made affecting pharmacy spaces referred to in subsection 1, the licensed pharmacist must notify the Finnish Medicines Agency of the new premises or the changes made.

Section 16

Repealed by Decree 1184/2002.

Section 17

Repealed by Decree 69/2011.

Section 18

Repealed by Decree 1184/2002.

Section 19

When a pharmacy business is transferred to another licensed pharmacist, the documents that are required to be retained must be given without charge to the new manager of the pharmacy business.

Section 20 (1184/2002)

(1) A licensed pharmacist who keeps a subsidiary pharmacy must appoint a manager for the subsidiary pharmacy. Under section 52 of the Medicines Act, the manager of a subsidiary pharmacy must be a certified Master of Pharmacy or a certified Bachelor of Pharmacy. The manager of a subsidiary pharmacy of the University of Helsinki's licensed pharmacy must, however, be a Master of Pharmacy. The Finnish Medicines Agency must be notified of the names of subsidiary pharmacy managers. (803/2009)

(2) The subsidiary pharmacies and pharmacy service points of a pharmacy must be inspected at least once each year by the licensed pharmacist or a certified Master of Pharmacy assigned by the licensed pharmacist. A record must be made of the inspection and the record must be signed by the party that carried out the inspection. A copy of the inspection record must be supplied to the manager of the subsidiary pharmacy and the pharmacy service point. (69/2011)

(3) In addition to the provisions laid down in this section, the provisions laid down in sections 14, 15, 17 and 19 of this Decree also apply to subsidiary pharmacies.

Section 20a

Repealed by Decree 1184/2002.

Section 21 (69/2011)

Applications made to the Finnish Medicines Agency for an authorisation to maintain a pharmacy service point as referred to in section 52a of the Medicines Act must include the following information:

1) identity of the applicant;

2) location of the pharmacy service point in a sparsely populated area of village centre in the location area of the pharmacy or the area of an adjoining municipality;

3) verification that the area does not provide an operating base for a subsidiary pharmacy;

4) address of the service point;

4) facilities reserved for the service point;

5) intended opening hours of the service point;

7) intended medicinal product selection of the service point;

8) whether the service point is intended to supply prescription medicines, and the manner in which the supply of prescription medicines will take place;

9) the medicinal product advisory service plan under section 52a of the Medicines Act;

10) the intended management of the service point;

11) the special reasons for the establishment of the service point when the pharmacy service point is established to safeguard the availability of medicinal products in the manner referred to in section 52a of the Medicines Act.

Section 21a (69/2011)

Licensed pharmacists must notify the Finnish Medicines Agency of the start and termination of the operations of a pharmacy service point and of any material changes in the operations.

Section 21b (69/2011)

(1) Licensed pharmacists must attend to the proper storage and transportation conditions of medicinal products supplied via an online pharmacy service.

(2) Pharmacies may charge from customers only such actual additional costs as arise from proper packing and transportation.

Section 21c (69/2011)

(1) Online pharmacy service customers must have access to the advisory services on medicinal products referred to in section 57 of the Medicines Act before orders placed via the online service are paid for or otherwise confirmed.

(2) If it emerges, due to the advisory services referred to in section 57 of the Medicines Act, that the customer does not need a medicinal product for which he/she has paid, the payment must be refunded if the medicinal product has not yet been shipped to the customer.

Hospital pharmacies, dispensaries and military pharmacies (1184/2002)

Section 22 (1184/2002)

(1) Applications for a licence to set up a hospital pharmacy or a dispensary, referred to in section 61(3) of the Medicines Act, must include the following information:

1) identity of the applicant;

2) scope of the activities and number of hospital beds for which the hospital pharmacy or the dispensary supplies medicinal products;

3) the premises and equipment of the hospital pharmacy or dispensary;

4) the estimated scale of medicinal product preparation and the pharmaceutical forms to be produced;

5) execution of medicinal products distribution; and

6) the manager and other staff of the hospital pharmacy or dispensary.

(2) The Finnish Medicines Agency must be notified of any material changes in the operations of hospital pharmacies and dispensaries, including replacement of the manager in charge. The Finnish Medicines Agency must be notified without delay of the start of operations of a hospital pharmacy or dispensary after the licence referred to in section 62 of the Medicines Act has been granted, and of the interruption or termination of these operations. (803/2009)

Section 23 (1184/2002)

Applications for a permit referred to in section 62 of the Medicines Act to supply medicines from a hospital pharmacy or dispensary must include an explanation of the manner in which the medicines will be supplied and the impact of the permit on pharmacy services in the area.

Section 24 (803/2009)

A permit from the Finnish Medicines Agency is required to set up a military pharmacy referred to in section 67 of the Medicines Act. Permit applications must include the information laid down in section 22, as appropriate.

Marketing of medicinal products (1184/2002)

Section 25 (1184/2002)

(1) The marketing of medicinal products means all publicity, marketing and promotional activities intended to promote the prescription, supply, purchase or use of medicinal products. This includes advertising directed at the general public, advertising directed at persons entitled to prescribe or supply medicinal products, sales promotion and the activities of medicinal product sales representatives. Marketing also includes the distribution of samples of medicinal products.

(2) The following are not considered to be marketing as defined in the Medicines Act and Decree:

1) labelling and package inserts of medicinal products;

2) correspondence engaged in for a purpose other than sales promotion;

3) information bulletins and other similar material pertaining to, for example, packaging changes, or warnings concerning adverse effects as part of general safety measures for medicinal products;

4) product catalogues and price lists, provided that they do not contain claims concerning medicinal products;

5) articles on human health or disease, provided that they are not intended to increase the sales of a medicinal product even indirectly; and

6) informing the general public about vaccination campaigns approved by the authorities.

Section 25a (1184/2002)

(1) Information provided in conjunction with the marketing of medicinal products must comply in all respects with the special information listed in the summary of product characteristics approved in conjunction with the marketing authorisation, including any amendments later approved. Marketing material may not include obsolete information nor omit an essential detail the omission of which could give a false impression of a medicinal product, the composition of a medicinal product or its origin, medicinal value or quality.

(2) Marketing may not refer to any clinical trial in a way that misrepresents the conclusions, extent or significance of the trial.

(3) No therapeutic indication must be claimed in the marketing of homeopathic products covered by registration. (868/2005)

Section 25b (1184/2002)

(1) In marketing directed at the general public, advertisements must clearly indicate that they concern a medicinal product. Advertisements must include the information required for the correct and safe use of the medicinal product, such as indications and important medicinal safety information on the safety precautions and interactive and adverse effects.

(2) Marketing directed at the general public may not contain material that:

1) gives the impression that visiting a physician or treatment recommended by a physician is not necessary;

2) suggests that the effects of taking the medicine are guaranteed or that there will be no adverse effects or that the effects are as good as or better than those of another treatment or medication;

3) suggests that the health of a person may be improved with a medicinal product, or that changes may occur in a person's state of health if the medicinal product is not taken, with the exception, however, of the vaccination campaigns referred to in section 25(2)(6);

4) is directed solely or primarily at children;

5) refers to recommendations made by scientists, health care professionals or public figures;

6) suggests that a medicinal product is a foodstuff, cosmetic or other consumer product;

7) suggests that the efficacy of a medicinal product or its safety is based on the product's natural origin;

8) could, in self-care, lead to an incorrect diagnosis or treatment on account of the inclusion of a detailed case description;

9) refers to claims of recovery with inappropriate, alarming or misleading expressions;

10) contains inappropriate, alarming or misleading pictorial representations of the changes a disease or injury causes to the human body or of the effect of a medicinal product on the human body or part thereof; or

11) states that the medicinal product has been granted a marketing authorisation.

Section 25c (1184/2002)

(1) The provisions laid down in this Decree on the marketing of medicinal products also apply as appropriate to the marketing of medicinal products prepared in a pharmacy and intended for supply to patients served by the pharmacy. The marketing of self-care and prescription medicinal products prepared in a pharmacy (ex tempore products) for an individual patient is prohibited, however.

(2) Medicinal products prepared in a pharmacy may be marketed only for purposes for which they are most likely to have an effect based on their medicinal product composition according to prevailing scientific knowledge.

Section 25d (1184/2002)

In addition to what is laid down in this Decree, marketing material concerning veterinary medicinal products must also state the holder of the marketing authorisation for the product, the species approved for the product and the withdrawal period set for the product.

Section 25e (1184/2002)

(1) Marketing material directed at persons entitled to prescribe and supply medicinal products must always include:

1) the essential information from the summary of product characteristics that relates to the intended and recommended uses of the product and its efficacy and safety;

2) legal terms of supply of a medicinal product;

3) indemnity terms of health insurance, average cost of treatment, if possible, and the retail prices of all packaging sizes;

4) the date when an information bulletin was drawn up or revised.

(2) All information given in bulletins used in marketing must comply with the approved summary of product characteristics and be accurate, up-to-date, verifiable and sufficiently complete for the reader to be able to form an opinion of the therapeutic value of the medicinal product. Quotations and tables from medical publications and scientific research or other illustrative material must be reproduced faithfully and their source accurately indicated.

Section 25f (1184/2002)

(1) Sample packs of self-care medicinal products may be handed over only to persons entitled to prescribe and supply medicinal products. Sample packs of prescription medicinal products may be handed over only to persons entitled to prescribe medicinal products. If the marketing authorisation of a medicinal product includes a term restricting supply, sample packs may be handed over only to persons entitled to prescribe this type of product. No more than one sample pack of a medicinal product may be handed over in a calendar year to a person entitled to prescribe or supply medicinal products.

(2) Medicinal product samples may be supplied only on written request, signed and dated. The sample must be exactly identical to the smallest pack on sale. A summary of product characteristics must be supplied with samples.

(3) Medicinal product manufacturers and wholesalers may hand over sample packs of registered homeopathic products and traditional herbal medicinal products that are not restricted to pharmacy sale to retailers of these products. (868/2005)

(4) Narcotics or substances classified as primarily affecting the central nervous system or medicinal products containing a psychotropic substance may not be handed over as a sample pack.

(5) Holders of marketing authorisations must provide the Finnish Medicines Agency annually with a summary of medicinal product samples they have supplied. Summaries must

contain information on the number of samples of each product handed out during the year. (803/2009)

Section 25g (1184/2002)

Starter packs may not be used in the marketing of medicinal products.

Section 25h (1184/2002)

Medicinal product sales representatives must possess sufficient knowledge to provide accurate information that is as complete as possible on the medicinal products they market. Sales representatives must always provide or have available the summaries of product characteristics for the medicinal products they market to their customers, as well as information on prices and reimbursement conditions.

Section 25i (803/2009)

Holders of a marketing authorisation for a medicinal product must provide the Finnish Medicines Agency, upon request, with the material used in marketing and an account of the recipients of the material, the method of its distribution and the starting date for the distribution, as well as other information and documentation that may be needed for supervision of medicinal product marketing as laid down in sections 91, 91a, 91b and 92 of the Medicines Act.

Supervision

Section 26

(1) In the inspections referred to in section 77 of the Medicines Act, special attention must be given to ensuring:

1) that the manufacture, quality control, storage, distribution and sale of medicinal products tally with the licences and authorisations granted on the basis of the provisions of the Medicines Act and this Decree and regulations issued pursuant to them, and that the medicinal product manufacturer, unit manufacturing medicinal products for clinical trials, medicinal product wholesaler, pharmacy, subsidiary pharmacy, pharmacy service point, hospital pharmacy or dispensary meet the requirements imposed when the licence or authorisation was granted; (69/2011)

2) that there are sufficient pharmaceutical and other staff;

3) that the provisions of the Medicines Act and this Decree and regulations issued pursuant to them concerning register-keeping, premises and equipment are complied with; (426/1995)

4) that medicinal products are appropriately manufactured and stored, are of flawless quality and accord with the provisions issued on them; and (426/1995)

5) that active substances with prohibited or restricted use under the Act on veterinary medication (402/1990) are not used in preparing medicinal products in a manner

contrary to that Act or sold or otherwise supplied for purposes contrary to that Act. (426/1995)

(2) In addition, attention must be given during inspections to ensuring that, in the case of substances or products other than medicinal products sold from pharmacies and subsidiary pharmacies, the provisions laid down separately on such substances or products are complied with.

Section 27

(1) A record of inspection must be drawn up and a copy of it submitted within 30 days to the relevant accountable director, licensed pharmacist, hospital pharmacy manager or dispensary manager.

(2) A copy of the record of inspection must be retained for a period of ten years following the inspection.

(3) An inspection is considered to be completed when a copy of the record of inspection has been given for information to the party concerned.

Clinical medicinal product and veterinary medicinal product trials (1184/2002)

Section 28

Repealed by Decree 312/2004.

Section 28a (1184/2002)

(1) The sponsor or the person in charge of the trial must give advance notification to the Finnish Medicines Agency of the clinical trial of a veterinary medicinal product to be carried out for the purposes of obtaining marketing authorisation for the product at least 60 days before the planned commencement of the trial. (803/2009)

(2) If a veterinary medicinal product has the marketing authorisation referred to in section 21 of the Medicines Act, the advance notification referred to in subsection 1 for clinical trials of veterinary medicinal products need only be made if:

1) the trial involves new indications that are not covered by the existing marketing authorisation;

2) the trial is made using a control substance or a placebo;

3) the medicinal product for which the marketing authorisation was given has not been approved for the treatment of or use by the animals or animal groups being studied;

4) pharmaceutical forms, combinations or strengths other than those approved earlier are used in the trial;

5) dosages, methods of administration or durations of treatment that have been previously approved are significantly altered in the trial; or

6) the trial is a multi—centre trial.

Miscellaneous provisions

Section 29 (803/2009)

The Finnish Medicines Agency will define the principles that determine the extent to which medicinal products can be supplied in Finland on the basis of prescriptions written by physicians licensed in Sweden, Denmark, Norway or Iceland and written in those countries for narcotic substances other than those referred to in lists I, H and IV of the 1961 Single Convention on Narcotic Drugs and lists I and II of the Convention on Psychotropic Substances.

Section 30 (1184/2002)

Medicinal products needed to commence treatment immediately may be given free of charge to patients who have visited a hospital outpatient department or a health centre physician, until they can be deemed to have reasonable access to a pharmacy to obtain the medication, taking into account the local circumstances. The medicinal product is handed over by the treating physician, who must ensure that the patient receives adequate instructions on the correct and safe use of the product. The medicinal product must be ready for use when it is handed over.

Section 31

Repealed by Decree 1184/2002.

Section 32

This Decree enters into force on January 1, 1988.
Government proposal 193/1986, Public Finance Committee report 259/1986, Committee for Social Affairs report 259/1986, Public Finance Committee report 2/1987.

Entry into force and application of amending provisions

316/1991:
This Decree enters into force on March 1, 1991.

249/1993:
This Decree enters into force on March 15, 1993.

1490/1993:
This Decree enters into force on January 1, 1994.
Whoever, at the time of the entry into force of this Decree, functions as accountable director of a medicinal product manufacturer but does not meet the requirements laid down in section 3(1) of this Decree may, notwithstanding the stated provisions, continue to function as accountable director.
Measures necessary for the implementation of this Decree may be taken before the Decree’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).

1604/1993:
This Decree enters into force on January 1, 1994.

426/1995:
This Decree enters into force on April 1, 1995.
Measures necessary for the implementation of this Decree may be taken before the Decree's entry into force.
Council Directive 93/39/EEC; OJ L214, August 24, 1993, p.22, 93/40/EEC; OJ L214, August 24, 1993, p.31, 85/358/EEC; L191, July 23, 1985, p.46.

904/1996:
This Decree enters into force on January 1, 1997.

1184/2002:
This Decree enters into force on January 1, 2003.
The conversion of hospital pharmacies that received their permit under the provisions existing when this Decree enters into force to become hospital pharmacies of a hospital district as referred to in section 61(1) of the Medicines Act will be considered to constitute the founding of a new hospital pharmacy. A licence shall be applied for such hospital district pharmacies as referred to in section 61(3) of the Medicines Act, as is laid down in this Decree.
Measures necessary for the implementation of this Decree may be undertaken before its entry into force.
Directive 2001/83/EC of the European Parliament and of the Council (32001L0083); OJ L311, November 28, 2002, p.67.

312/2004:
This Decree enters into force on May 1, 2004.
Directive 2001/20/EC of the European Parliament and of the Council (32001L0020), OJ L 121, 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. Directive of the Commission 2003/94/EC (32003L0094), OJ L262, October 14, 2003 pp. 22-26

868/2005:
(1) This Decree enters into force on 14 November 2005. The Finnish Medicines Agency must apply time limits under section 10 of this Decree to all authorisation, registration, change and renewal applications that have been made on 30 October 2005 or later. If an application for renewing a marketing authorisation or registration has been made on 30 April 2006 or previously, the Finnish Medicines Agency must, however, process the application within 90 days in derogation to what is provided in section 10a(3).
(2) Applications for parallel import marketing authorisations submitted to the Finnish Medicines Agency before the entry into force of this Act must be processed within 130 days of the entry into force of this Act.
Directive 2001/82/EC of the European Parliament and of the Council (32001L0082); OJ L 311, 6.11.2011, p. 1, Directive 2001/83/EC of the European Parliament and of the Council (32001L0083), 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, Council Regulation (EC) No 1084/2003 (32003R1084); OJ L 159, 27.6.2003, p. 1.

803/2009:
This Decree enters into force on November 1, 2009.

Measures necessary for the implementation of this Decree may be taken before the Decree's entry into force.

69/2011:
(1) This Decree enters into force on 1 February 2011.
(2) Applications for licenses pending before the entry into force of the Decree are processed in accordance with the provisions in force at the time of entry into force of the Decree.
(3) Medicine chest licences granted before this Decree enters into force remain in force. Medicine chest licences can no longer be renewed after this Decree 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.
(4) Measures necessary for the implementation of this Decree may be undertaken before the Decree's entry into force.