

No. 373/2008

Narcotics Act

(Amendments up to 539/2014 followed)

Issued in Helsinki on 30 May 2008

Chapter 1

General provisions

Section 1

Objectives of the Act

The objectives of this Act are to prevent illicit import to and export from Finland of narcotic drugs (hereinafter 'drugs'), and their illicit manufacture, distribution and use.

Section 2

Scope

This Act is applied to the control of drugs. It is also applied to the control of drug precursors in addition to what is provided regarding it in the Regulation on intra-Community trade in drug precursors and the Regulation on extra-Community trade in drug precursors and their implementing Regulation.

Section 3

Definitions

For the purposes of this Act:

1) *drug conventions* mean:

a) the Single Convention on Narcotic Drugs (Treaty Series of the Statute Book of Finland 43/1965) adopted in New York on 30 March 1961 as amended by the Protocol adopted in Geneva on 25 March 1972 amending the Single Convention on Narcotic Drugs (Treaty Series 42/1975) (*the 1961 Single Convention on Narcotic Drugs*);

b) the Convention on Psychotropic Substances (Treaty Series 60/1976) adopted in Vienna on 21 February 1971 (*the 1971 Convention on Psychotropic Substances*); and

c) the United Nations Convention against Illicit Trafficking in Drugs and Psychotropic Substances adopted in Vienna on 20 December 1988 (Treaty Series 44/1994) (*the 1988 Convention against Illicit Trafficking in Drugs and Psychotropic Substances*);

2) *the Regulation on intra-Community trade in drug precursors* means the Regulation No. 273/2004 (EC) of the European Parliament and of the Council on drug precursors;

3) *the Regulation on extra-Community trade in drug precursors* means the Regulation No. 111/2005 (EC) of the Council laying down rules for the monitoring of trade between the Community and third countries in drug precursors;

4) *the Regulation implementing the Regulations on drug precursors* means the Commission Regulation No. 1277/2005 (EC) laying down implementing rules for Regulation of the

European Parliament and of the Council No. 273/2004 (EC) on drug precursors and for Regulation No. 111/2005 (EC) of the Council laying down rules for the monitoring of trade between the Community and third countries in drug precursors (*the implementing Regulation*);

5) *drug* means:

a) substances and preparations included on lists I–IV in the 1961 Single Convention on Narcotic Drugs;

b) substances and preparations included on lists I–IV in the 1971 Convention on Psychotropic Substances;

c) substances that are decided to be made subject to control in accordance with the Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances; (322/2011)d) khat plant (*Catha edulis*), cactus plants containing mescaline, and Psilocybin mushrooms; and (322/2011)

e) substances used for the purpose of intoxication that are harmful to health and that have been notified to be made subject to control measures in accordance with the Council Decision referred to under c) above or that are in regard to their pharmacological properties medicinal substances comparable to drugs; (322/2011)

6) *drug precursor* means the scheduled substances referred to in article 2 (a) of the Regulation on intra-Community trade in drug precursors and in article 2 (a) of the Regulation on extra-Community trade in drug precursors;

7) *manufacture of drugs* means, except for production, any method by which drugs can be prepared, and purification of drugs and conversion of a drug into another drug; and

8) *drug production* means separating opium, coca leaves, cannabis or cannabis resin from the plants from which they are derived.

Further provisions as to what substances, preparations and plants are to be considered as drugs referred to in paragraph 1 (5) are laid down by Government decree.

Section 3 a (322/2011)

Evaluation of the properties of intoxicating substances

The intoxicating properties and the dangers of the substances referred to in section 3(1)(5)(e) shall be evaluated by the Finnish Medicines Agency together with the National Institute for Welfare and Health, the police and the Customs. The Finnish Medicines Agency shall send the evaluation to the Ministry of Social Affairs and Health and append it to its proposal for action, which is based on whether the substance occurs or is likely to occur in Finland, before a decision can be made on making the substance subject to control measures in accordance with the Council Decision referred to in section 3(1)(5)(c).

Section 3 b (322/2011)

Industrial use of intoxicating substances

If the substances referred to in section 3(1)(5)(e) can be assumed to have industrial use or if it is question of a medicinal substance, the manufacturers of the substance or medicinal substance or the bodies representing them that are known shall be provided an occasion to give their opinion on the evaluation and proposal for action. Provisions on minor exceptions to the ban on handling the substance in industrial use can be laid down by Government decree if the substance has legitimate use in industrial activity.

Section 4

Other Acts

Drugs and drug precursors that are medicinal products are, in addition, subject to what is provided regarding them in the Medicines Act (395/1987) and elsewhere in law.

Provisions on prevention of drug use and welfare for drug abusers are laid down in the

Temperance Work Act (828/1982) and the Act on Welfare for Substance Abusers (41/1986).

Section 5 (322/2011)

General prohibitions

Production, manufacture, import to the territory of Finland, export from the territory of Finland, transportation, transit through the territory of Finland, distribution, trade, handling, possession and use of drugs is prohibited. Deviation from the prohibition is allowed for medicinal, research, control and industrial use purposes as specifically laid down regarding them in this Act or elsewhere in law.

Section 6

Transit of drugs

Drugs may be transported without storing them through the territory of Finland to another country if the operator has export authorisation granted by the competent authority of the country of origin and import authorisation granted by the competent authority of the country of reception.

Those transporting drugs on the basis of paragraph 1 shall submit a notification of the transit of the drugs to the customs authorities and present the export authorisation and import authorisation for the consignment before arrival of the drug consignment in the country.

Section 7

Prohibition against cultivation of certain plants and mushrooms

It is prohibited to cultivate Khat plant (*Catha edulis*), Psilocybin mushrooms and coca bush. It is prohibited to cultivate opium poppy, hemp and cactus plants containing mescaline for use as drugs or in manufacture or production of drugs.

Section 8

Obligation to hand over drugs

Anyone who has got possession of a drug without being entitled to possess it shall hand it over immediately to the police or the customs or border control authorities.

Chapter 2

Activity subject to authorisation

Section 9

Granting of authorisation

The Finnish Medicines Agency (Fimea) may grant authorisation for manufacture, import to Finland, export from Finland, and handling of drugs. (775/2009)

Authorisation can be granted a private entrepreneur, legal person, or university or other research institute:

4

1) for production of medicinal products and for other medicinal purposes if the operator is authorised to import to Finland medicinal products on the basis of section 17 (1) of the Medicines Act;

2) for manufacture, import, export or handling of substances, preparations and test systems used for detecting drugs if they contain drugs; 3) for scientific research, and for research, quality assurance research and product development for medicinal purposes; or

4) for industrial use of the drug as referred to in section 3(1)(5)(e) if the industrial use of the substance is permitted on the basis of section 3 b. (322/2011)

Section 10

Scope of authorisation

The authorisation holder under this Act, the staff of the authorised establishment when carrying out job tasks and those carrying out the assignments assigned by the authority entitled to the authorisation have the right to keep in possession and transport as necessary the amount of drugs defined in the authorisation.

An authorisation under this Act does not exempt the authorisation holder from complying with the requirements laid down for the operation and the provisions on them elsewhere in law.

Authorisation may not be granted for a greater amount of drugs mentioned on lists I and II in the 1961 Single Convention on Narcotic Drugs than what has been notified according to the said Convention to the International Narcotics Control Board to be used in the said year for the purposes referred to.

Further provisions on setting the quotas referred to in paragraph 3 and on fulfilment of the obligations arising out of the Convention may be given by Government decree.

Section 11

Conditions for granting authorisation

The conditions for granting the authorisation referred to in section 9 (1) are:

1) the authorisation holder has the personnel required by the quality and scope of the operation, an adequate number of persons responsible for the operation referred to in section 16, as well as appropriate facilities, devices and equipment;

2) the private entrepreneur, persons who are members of the management boards of the authorisation applicant and the managing director, in a partnership the co-partners, in a limited partnership the responsible partners, and in universities and other research institutes the person holding a managerial post in the unit:

a) are of age;

b) are known to be honest and reliable; and

c) are not subject to bankruptcy and their competence to act has not been limited;

3) the authorisation holder has appropriate prerequisites for fulfilling the obligations laid down in sections 25, 26 and 30 and for ensuring that the substances subject to authorisation will not be used as drugs or drug precursors.

The Finnish Medicines Agency may consider that the authorisation applicant fulfils the conditions laid down in paragraph 1, without their being investigated separately, if the applicant on a regular basis applies for authorisations under sections 12–15 from the Agency and the Agency has during the preceding twelve months considered that the operations of the applicant comply with the conditions laid down in paragraph 1. (322/2011)

Section 12

Manufacturing authorisation

A manufacturing authorisation for a drug may be granted for a maximum of one calendar year at one time. A manufacturing authorisation is not required for manufacturing the pharmaceutical preparations referred to in the Medicines Act. A manufacturing authorisation may not be granted for a drug with no medicinal use.

Notwithstanding what is laid down in paragraph 1, a university or other research institute may however be granted authorisation to manufacture a drug for use in scientific research if the institute concerned has the handling authorisation referred to in section 15. Notwithstanding what is laid down in paragraph 1, authorisation for manufacture of a drug referred to in section 3(1)(5)(e) may be granted if the authorisation applicant has the handling authorisation for industrial use referred to in section 15. A manufacturing authorisation may not be granted for a period longer than the validity of the handling authorisation. (322/2011)

Conditions related to storing, safekeeping, transportation, monitoring and disposal of substances or to other comparable circumstances may be appended to a manufacturing authorisation, as necessary.

Further provisions on details of the conditions for authorisation may be given by Government decree.

Section 13

Import authorisation

An import authorisation for a drug may be granted for a maximum of six months. An import authorisation is granted separately for every consignment, except for authorisation concerning a drug intended for industrial use referred to in section 3(1)(5)(e) or a substance, preparation or testing system containing a drug that is used for detecting a drug. (322/2011)

Conditions relating to the mode of importation, and to the amount, storing, safekeeping, transportation, monitoring and disposal of the drug may be appended to the import authorisation.

Besides each decision on import authorisation the applicant is issued an import licence for applying for an export authorisation from the competent authority of the country from which the drug is imported. The authorisation holder shall submit a notification of the arrival of the drug in the country and present the import licence to the customs authority. The customs authority will make the necessary notes in the licence and, if necessary, append to it other information related to the customs clearance.

The authorisation holder shall return the licence to the Finnish Medicines Agency immediately after the import to Finland has taken place, in any case at the latest when the validity of the authorisation expires. (775/2009)

Further provisions on details of the conditions for authorisation referred to in paragraph 2 and on details of the content of the import licence and the notes to be made in them may be given by Government decree.

Section 14

Export authorisation

An export authorisation for a drug may be granted for a maximum of six months. The term may not be longer than the validity of the import authorisation issued by the country to which the export from Finland takes place. An export authorisation is granted separately for every consignment, except for authorisation concerning a drug intended for industrial use referred to in section 3(1)(5)(e) or a substance, preparation and testing system that is used for detecting a drug. (322/2011)

When applying for an export authorisation for a drug, the applicant must present the import authorisation issued by the competent authority of the country to which the export is to take place, or a comparable certificate according to which the import of the consignment intended to be exported to the country is permitted.

6

Conditions relating to the mode of exportation and to the amount, storing, safekeeping, transportation, monitoring and disposal of the drug may be appended to the export authorisation.

Besides each decision on export authorisation the applicant will be issued an export licence. The authorisation holder shall submit a notification that the drug has been taken out of the country and present the export licence to the customs authority. The customs authority will make the appropriate notes in the licence and, if necessary, append to it other information related to the customs clearance.

The authorisation holder shall return the licence to the Finnish Medicines Agency immediately after the export from Finland has taken place, in any case at the latest when the validity of the authorisation expires. (775/2009)

Further provisions on details of the conditions for authorisation referred to in paragraph 3 and on details of the content of the export licence and the notes to be made in them may be given by Government decree.

Section 15

Handling authorisation

A handling authorisation for a drug may be granted for a maximum of three years at one time for scientific research or research for medicinal purposes, quality control research or product development. A handling authorisation for industrial use of a drug referred to in section 3(1)(5)(e) can only be granted if the industrial use of the substance is permitted under section 3 b. (322/2011)

A handling authorisation for drugs is not required for the handling and possession of medicinal products classified as drugs when it takes place for medicinal purposes referred to in the Medicines Act, the Health Care Professionals Act (559/1994) or the Veterinary Practice Act (29/2000) or a decree issued in virtue of them or when the official laboratory of the competent authority is carrying out its statutory tasks. (322/2011)

Conditions relating to the type, amount, purpose of handling, storing, safekeeping, transportation, monitoring and disposal of the drug may be appended to the handling authorisation.

Further provisions on details of the conditions for authorisation may be given by Government decree.

Section 16

Requirements for the person responsible and his or her substitutes

Every establishment where operations subject to authorisation under this Act are carried out shall have a person responsible for the operations and a necessary number of substitutes that the authorisation holder appoints. The person responsible and his or her substitutes must be of age and suitable for their task. They must also have the powers required for the duty and adequate professional qualifications acquired through education or experience.

A person is unsuitable as the person responsible or his or her substitute if the person, due to abuse of drugs or other intoxicating substances, a drug offence committed during the preceding ten years or offences or defaults committed against this Act during the preceding three years, obviously is not capable of attending to the task. A person who is subject to bankruptcy or whose competence to act has otherwise been restricted is likewise unsuitable for the task.

Section 17 (775/2009)

Approval of the person responsible

The Finnish Medicines Agency approves the persons responsible and their substitutes that are together with the authorisation holder responsible for seeing to it that the establishment complies with the provisions of this Act and the conditions for the authorisation.

When submitting the application for authorisation the applicant must also submit to the Agency an application for approval of the person responsible and his or her substitutes appointed by the applicant. Operations subject to authorisation may not be commenced before a person responsible for the operation has been approved.

In case the person responsible or his or her substitute resigns or otherwise ceases to attend to the task a new person responsible or substitute shall be appointed to replace him or her, and approval must be applied for that person within seven days.

Section 18 (775/2009)

Withdrawal of the approval of a person responsible

The Finnish Medicines Agency shall withdraw the approval of a person responsible or his or her substitute if the authorisation holder so requests.

The approval of a person responsible or his or her substitute can be withdrawn wholly or for a fixed period of time if the person or substitute:

- 1) no more fulfils the conditions laid down in section 16;
- 2) has been sentenced by a court judgment that has gained legal force for an offence that indicates that he or she is obviously unsuitable as the person responsible; or
- 3) has essentially acted erroneously in the capacity of the person responsible or his or her substitute.

The Agency may, in cases referred to in paragraph 2, instead of withdrawing the approval issue an admonition to the person responsible or his or her substitute in case a withdrawal of approval would be unreasonable considering the circumstances.

The Agency shall inform the authorisation holder of the withdrawal of approval for the person responsible or his or her substitute and of issuing an admonition to the person responsible or his or her substitute employed by the authorisation holder.

Section 19

Information needed for consideration of granting authorisation

An application for authorisation under this Act shall include the following information:

- 1) the applicant's name or firm, contact information and business identity code;
- 2) the applicant's suitability for pursuing the operation subject to authorisation;
- 3) every establishment in which operations subject to authorisation are intended to be carried out;
- 4) the drugs subject to authorisation and their use and amount;
- 5) the persons who are members of the management boards of the authorisation applicant and the managing director, in a partnership the co-partners, in a limited partnership the responsible partners, and in universities and other research institutes the person holding a managerial post in the unit;
- 6) the persons responsible and their substitutes in every establishment, and of their reliability, qualifications and experience in regard to handling the substances subject to authorisation;
- 7) the control methods of every establishment to prevent the use of the substances as drugs or drug precursors; and
- 8) other comparable investigations and measures that are needed to achieve the objectives of this Act and for control purposes.

The operator need not present the information referred to in paragraph 1, subparagraphs 2 and 3 and 5–7 if the operator:

8

1) on a regular basis applies for authorisations under sections 12–15 from the Finnish Medicines Agency; and

2) has furnished the Agency with the information concerned, which has not changed, during the preceding six months in connection with another application for authorisation and the Agency has not had anything to remark against it. (775/2009)

The authorisation holder shall inform the Agency of any changes to the information given in the context of applying for authorisation under paragraph 1 that have taken place after the granting of authorisation and that affect the conditions for granting authorisation. (775/2009)

Further provisions on the content of the information to be appended to the application for authorisation may be issued by Government decree.

Section 20

Restrictions on supplying drugs to others

The authorisation holder may supply drugs only to another authorisation holder or to someone who is even otherwise entitled to acquire, possess or handle the substances to be supplied.

The receiver shall inform the supplier of the use of the drug to be supplied, which must be that referred to in section 9 (2).

Section 21 (775/2009)

Sanctions for violations in the context of operations subject to authorisation

The Finnish Medicines Agency shall withdraw the authorisation in accordance with this Act if:

- 1) the authorisation holder so requests; or
- 2) the operation subject to authorisation has been terminated.

The Agency may withdraw the authorisation granted under this Act for a fixed period of time or wholly if:

- 1) obligations or prohibitions prescribed in this Act or in provisions laid down in virtue of it or elsewhere in law have essentially been violated;
- 2) the authorisation holder has essentially violated the conditions for authorisation;
- 3) the conditions laid down for granting authorisation in sections 9 and 11 do not exist any more;

4) the authorisation holder does not have a person responsible referred to in section 16 or the person responsible or a person who is a member of the boards of management of the authorisation holder and the managing director, in a partnership the co-partners, in a limited partnership the responsible partners, or in universities or other research institutes a person holding a managerial post in the unit has been sentenced by a court judgment that has gained legal force for an offence that indicates that the person is unsuitable for attending to the duty; or

5) the information given when applying for authorisation has been essentially incorrect in regard to the information on the control of drugs.

Unless it is question of an urgent case the Agency shall, in situations referred to in paragraph 2, before withdrawal of the authorisation issue a written admonition and set a deadline for the authorisation holder for correcting or remedying the defects in operations.

The Agency may also issue an admonition or written warning to the authorisation holder if the defects, violations or defaults can be remedied or they are of minor significance.

The withdrawn authorisation shall be returned to the Agency.

Chapter 3

Substances and preparations exempt from being subject to authorisation

Section 22

Pharmaceutical preparations needed in first aid

An import or export authorisation in accordance with this Act is not needed for pharmaceutical preparations containing drugs meant to be used in first aid that are included in the medicinal supplies of vessels and aircrafts used in international traffic and of ambulances and vehicles used in humanitarian aid operations.

The pharmaceutical preparations referred to in paragraph 1 shall be kept in a sealed first aid kit in a locked medicine chest. The person responsible for them is the master of the vessel, and in an aircraft, ambulance and vehicle used in humanitarian aid operations the person responsible for medicinal supplies.

Section 23

Certain substances, preparations and testing systems

An import or export authorisation in accordance with this Act is not needed for the pharmaceutical preparations containing a drug mentioned on list III in the 1961 Single Convention on Narcotic Drugs or for the substances, preparations and testing systems containing a drug that are used for detecting drugs in which the amount of the drug is insignificant or which have been composed so that the drug cannot be isolated easily or which may involve a risk of abuse that is insignificant in view of the extensive medicinal use of the substance.

An import or export authorisation in accordance with this Act is not needed for the combination preparations containing a psychotropic substance other than that mentioned on list I in the 1971 Convention on Psychotropic Substances or for the preparations that contain the medicinal substance referred to in section 3(1)(5)e) in which the amount of the drug is insignificant or which have been composed so that the drug cannot be isolated easily or which may involve a risk of abuse that is insignificant in view of the extensive medicinal use of the substance. (322/2011)

Further provisions on substances, preparations and testing systems exempt from being subject to authorisation may be given by Government decree.

Section 23 a (322/2011)

Substances defined as drugs nationally

An authorisation in accordance with this Act is not needed for the drug referred to in section 3(1)(5)(e) if it is on reasoned grounds contained in another substance or preparation and the risk of abuse involved is considered insignificant because of the small amount of the substance or because it has been composed so that the drug cannot be used or isolated easily.

Section 24 (322/2011)

Importation and exportation of personal medication

The provisions on import and export of drugs in this Act are not applied to such pharmaceutical preparations containing substances referred to on lists I–III in the 1961 Single Convention on Narcotic Drugs or on lists II – IV in the 1971 Convention on Psychotropic Substances or to the pharmaceutical preparations containing the medicinal substance referred to in section 3 (1)(5)(e) that passengers use for their personal medication. In that respect the provisions of section 19 of the Medicines Act and those laid down in virtue of it shall be observed.

Chapter 4

Responsibilities of operators

Section 25

Identification data in import and export documents and on labelling

The manufacturer, importer, exporter and those involved in transportation and storage of drugs shall see to it that the import and export documents and the labelling with which the substance or preparation is supplied have the necessary identification data.

Further provisions on the identification data referred to in paragraph 1 may be given by Government decree.

Section 26

Storage and safekeeping of drugs

Drugs shall be stored and even otherwise kept in a separate locked place to which outsiders have no access.

Further provisions on the storing and safekeeping of drugs as referred to in paragraph 1 and on those pharmaceutical preparations that need not be kept in the manner laid down in paragraph 1 may be given by Government decree.

Section 27

Transportation of drugs

Necessary care and caution shall be exercised in the context of transportation of drugs and related measures, taking into account the substance to be transported, its amount and form of transportation.

Those involved in the transportation and storage of drugs shall see to it that seizure and other illegal use of the drugs are prevented.

Further provisions on transportation and related handling of drugs referred to in paragraph 1 may be given by Government decree.

Section 28 (663/2011)

Disposal of drugs as hazardous waste

Those entitled to handle drugs are responsible for delivering all medicinal products classified as drugs and other drugs for which there is no more any use permitted under this Act for disposal.

The substances and preparations referred to in paragraph 1 may only be disposed of at a hazardous waste treatment plant. The provisions of the Waste Act (646/2011) and the Environmental Protection Act (527/2014) shall be observed in the disposal of hazardous waste. (539/2014)

Paragraph 1 notwithstanding, the disposal of the drugs referred to in section 3 (1)(5)(e) whose industrial use the Government has approved are subject to the provisions of the Waste Act and the Environmental Protection Act.

Further provisions on the disposal of substances and preparations referred to in paragraph 1 may be given by Government decree.

Section 29 (775/2009)

Notification of changes

The authorisation holder shall immediately notify the Finnish Medicines Agency of the following:

- 1) closing down of an establishment and change of address of an establishment;
- 2) change of a member of the management boards or of the managing director, in a partnership of a co-partner, in a limited partnership of the responsible partner, and in universities and other research institutes of a person holding a managerial post in the unit;
- 3) closing down of the operations or suspending of the operations for a period exceeding one month;
- 4) if the person responsible referred to in section 16 or his or her substitute ceases to attend to the task; and
- 5) other changes essentially affecting the conditions for granting authorisation that have taken place after its granting.

Section 30

Duty to keep a record

Authorisation holders under this Act and operators referred to in section 15 (2) shall keep a record of the drugs they manufacture, export, import and handle. The duty to keep a record however does not apply to medicinal products considered as drugs that have been prescribed for personal medication. The records shall be retained for at least six years counting from the end of the year during which they were drawn up. The Finnish Medicines Agency is entitled to have access to the records on drugs referred to in this paragraph. The Food Safety Authority and the Regional State Administrative Agencies are entitled to have access to the drug records of veterinarians. (1568/2009)

A note of disposal of drugs shall be made in the drug record. Separate provisions apply to the disposal of medicinal products brought by customers to pharmacies and to the duty to keep a record of them.

Further provisions regarding the keeping of a record of drugs and the drug records referred to in this paragraph and how to retain them may be given by Government decree.

Section 31 (775/2009)

Notification duty

The authorisation holder shall submit to the Finnish Medicines Agency by the end of January every year:

- 1) a notification of drugs and of substances and preparations containing drugs that were manufactured, purchased for stock, kept in stock and supplied from stock the previous year and of their amounts and the amount that was used for manufacturing medicinal products;
- 2) a notification of the drugs disposed of in the previous year; and
- 3) a preliminary estimate of demand for the next year.

Furthermore, the authorisation holder shall submit to the Agency every fourth month a notification of the substances imported to Finland and exported from Finland that are included on the lists in the 1961 Single Convention on Narcotic Drugs and on lists I–III in the 1971 Convention on Psychotropic Substances.

Further provisions on the notification duty referred to in this paragraph may be given by Government decree.

The Agency may, as necessary, issue further rules on how to make the notifications.

Section 32

Monitoring certain medicinal products classified as drugs

Pharmacies shall monitor the dispensing of substances and preparations on lists I, II and IV in the 1961 Single Convention on Narcotic Drugs and on lists I and II in the 1971 Convention on Psychotropic Substances, and the dispensing of pentazocine and buprenorphine and keep a record of it.

Pharmacies shall monthly submit the data on the monitoring of medicinal products classified as drugs to the Finnish Medicines Agency. (775/2009)

The data on monitoring and keeping of a record referred to in paragraph 1 is confidential.

Further provisions on the monitoring of medicinal products classified as drugs, disposal of the monitoring data on them and the pharmacies' duty to submit the monitoring data to the Agency may be given by Government decree. (775/2009)

Section 33

Duties of operators based on the Regulations on intra-Community trade and extra-Community trade in drug precursors

The placing on the market according to the Regulation on intra-Community trade in drug precursors, the import and export according to the Regulation on extra-Community trade in drug precursors as well as the transmitting operations related to them and the duties of operators are governed by the provisions of the said Regulations and their implementing Regulation.

Chapter 5

Guidance and general supervision

Section 34 (775/2009)

Authorisation and supervisory authorities

The supreme leadership and guidance of compliance with this Act and the provisions and regulations issued in virtue of it is the responsibility of the Ministry of Social Affairs and Health.

The authorisation and supervisory authority under this Act and the competent authority referred to in the Regulation on intra-Community trade in drug precursors and the Regulation on extra-Community trade in drug precursors and their implementing Regulation is the Finnish Medicines Agency, unless otherwise provided.

Furthermore, the Agency shall:

- 1) keep databases on drugs; and
- 2) be responsible for the data collection duties under this Act, as far as they are not assigned to the National Institute for Health and Welfare under section 35.

Veterinarians are furthermore supervised by the Food Safety Authority and the Regional State Administrative Agencies. (1568/2009)

Further provisions on the duties of the Finnish Medicines Agency referred to in paragraph 3 may be given by Government decree.

Section 35 (775/2009)

Data collection duties of the National Institute for Health and Welfare

The National Institute for Health and Welfare shall:

- 1) collect, produce and obtain information on drugs and on measures to prevent their illicit use for the purposes of statistics and research; and
- 2) act as the representative of Finland in the European information network on drugs and drug addiction (Reitox) in issues regarding data collection within the scope of application of this Act. Further provisions on the data collection duties of the National Institute under this Act

may be given by Government decree.

Section 36 (775/2009)

Right to inspect

An inspector appointed and employed by the Finnish Medicines Agency is entitled to inspect the premises and facilities where drugs or drug precursors are produced, manufactured, stored, kept or handled in some other way. The right to inspect also applies to the advance inspection covered by the authorisation and control operations of the Agency in order to ensure that the conditions for granting authorisation are fulfilled.

The inspector referred to in paragraph 1 must be provided access to all premises and facilities of the establishment. Inspections referred to in this section may not be carried out in premises used on a permanent basis for housing.

The Agency is entitled to executive assistance from the police and the customs and border control authorities for performing its duties under this Act.

Section 37

Inspection material

In addition to what is provided on inspections in the Administrative Procedure Act (434/2003), all the documents and other material requested by an inspector referred to in section 36 (1) that is necessary for carrying out the inspection must be presented at the inspection. The inspector shall be given, free of charge and notwithstanding the provisions on confidentiality, the copies he or she requests of any documents necessary for the inspection.

In the context of the inspection the inspector is entitled to take free samples of drugs and narcotic preparations in the establishment for a more specific analysis. Furthermore, the inspector is entitled to take during the inspection photographic records that are necessary for carrying out the inspection.

Section 38 (775/2009)

Right of access to information from operators and authorities

Notwithstanding the provisions on confidentiality, the Finnish Medicines Agency has the right of access, free of charge, to information necessary for carrying out the authorisation and control duties prescribed in this Act from entrepreneurs and other operators referred to in this Act and the Medicines Act as well as from state and municipal authorities.

Notwithstanding the provisions on confidentiality, the Agency has the right of access to such information on operations regarding drug precursors from the operators referred to in the Regulation on intra-Community trade in drug precursors and in the Regulation on extra-Community trade in drug precursors as is necessary for supervising compliance with the said Regulations.

Section 39 (775/2009)

Access to information from certain registers

Notwithstanding the provisions on confidentiality, the Finnish Medicines Agency has the right of access to such information as is necessary for carrying out its duties under this Act from the customs authority from the foreign trade registers regarding the import to and the export from Finland of drugs and drug precursors. Without permission of the National Board of Customs the information concerned may not be used for any other purpose than for which it has been supplied.

The Agency has the right of access to information needed for carrying out the control under this Act and for granting authorisations referred to in this Act and in the Community legislation on drug precursors from the register of fines referred to in section 46 of the Act on the Enforcement of a Fine (672/2002).

Provisions on the right of access to information from the criminal records are laid down in the Criminal Records Act (770/1993).

Section 40 (775/2009)

Passing information to other authorities

Notwithstanding the provisions on confidentiality, the Finnish Medicines Agency may, on its own initiative, pass such information regarding control under this Act to the police, the customs and border control authorities and the National Supervisory Authority for Welfare and Health as is necessary for the authorities for attending to their statutory duties.

Section 41 (775/2009)

Collecting information for international control authorities for the purpose of statistics and research

The police, the customs authority, the border control authority, other authorities handling drugs and taking measures to prevent illicit drug use, as well as the Ministry for Foreign Affairs and the Ministry of Justice shall give, subject to the provisions on confidentiality, the Finnish Medicines Agency and the National Institute for Health and Welfare such information as is necessary for passing information to international control authorities and bodies collecting information.

Chapter 6

Crime prevention

Section 42 (775/2009)

The police and the customs and border control authorities as competent authorities

Competent authorities are, in addition to the Finnish Medicines Agency, the police in matters relating to combating drug offences, the customs and border control authorities in matters relating to import, export and transit of drugs, and the said authorities in matters governed by article 8 (1) of the Regulation on intra-Community trade in drug precursors, article 8, article 9 (1) and articles 14 and 26 of the Regulation on extra-Community trade in drug precursors, and article 12 (2), articles 13 and 16 and article 23 (2) of the Regulation implementing the Regulations on drug precursors.

Section 43 (836/2011)

Seizure

Officials with powers of arrest shall seize drugs that have been handed over to the police or the customs or border control authorities on the basis of section 8, or whose possession is not otherwise permitted under this Act but whose possession is not punishable. When carrying out the seizure, the provisions on the record in Chapter 7, section 12, and on revocation of seizure in section 14 of the Coercive Measures Act (806/2011) shall be observed.

Section 44

Disposal

Officials with powers of arrest shall verifiably dispose of the seized drug or the drug that has been declared forfeit to the State, or order it to be disposed of. The disposal of and keeping a record of it is subject to the provisions of sections 28 and 30. The substance to be disposed of or a part thereof shall however be stored as long as it is possibly needed as evidence in judicial proceedings.

Officials with powers of arrest may verifiably dispose of, or order to be disposed of, such raw material, other substance, device or equipment intended for illicit production, cultivation, manufacture, possession or use of drugs that may be seized if it is probable that it would be declared forfeit to the State.

Section 45

Promotion of the prevention, disclosure and investigation of drug offences

Permission for import to, export from or transit of drugs through Finland may be granted to authorities engaged in prevention, disclosure and investigation of drug offences by written decision of the chief of the National Bureau of Investigation or the head of the Customs Crime Prevention Unit. (322/2011)

By written decision of a chief referred to in paragraph 1, drugs that have been seized or forfeited to the State and substances, devices and equipment referred to in section 44 (2) may be handed over to authorities for use in the prevention, disclosure and investigation of drug offences, and the authorities may be granted authorisation to possess drugs for that purpose.

The Finnish Medicines Agency shall immediately be informed of the decisions referred to in this section. (775/2009)

Chapter 7

Coercive measures and sanctions

Section 46 (775/2009)

Administrative coercive measures

The Finnish Medicines Agency may prohibit those who violate this Act or provisions of the Regulation on intra-Community trade in drug precursors or the Regulation on extra-Community trade in drug precursors to continue or repeat the illegal action. The Agency may also order those who violate the said provisions to fulfil their obligation in some other manner.

The Agency may reinforce the prohibition or order imposed on the basis of this Act by a default fine or by threat that the measures that have not been undertaken will be ordered taken at the expense of the defaulting party, or by threat that the action will be suspended. Provisions on withdrawal of the authorisation are laid down in section 21.

Payment of the default fine imposed to reinforce the prohibition is ordered by the Regional State Administrative Office at the request of the Finnish Medicines Agency. Matters concerning default fine, threat that the action will be taken at the defaulter's expense and threat of suspension are otherwise subject to provisions of the Default Fine Act (1113/1990). (1568/2009)

A default fine may not, however, be imposed on a natural person to reinforce the information duty laid down in this Act in case there is reason to suspect the person of an offence and the information is related to a matter subject to suspicion of an offence.

Section 47

Offences against the Narcotics Act

Anyone who intentionally or through carelessness

1) neglects to apply for the authorisation laid down in article 3 (2) of the Regulation on intra-Community trade in drug precursors or in article 6 (1) of the Regulation on extra-Community trade in drug precursors;

2) neglects the notification duty under sections 6, 29 or 31, the duty to keep a record under section 30, or the monitoring duty under section 32 of this Act, or the notification duty laid down in article 3 (1) or 8 of the Regulation on intra-Community trade in drug precursors or in article 9 of the Regulation on extra-Community trade in drug precursors;

3) violates his or her obligation regarding the restriction on supplying drugs to others under section 20, or the obligation regarding identification data under section 25, storing and safekeeping under section 26, transportation under section 27 or disposal under section 28 of this Act;

4) gives false information in authorisation or registration matters referred to in sections 12–16 and 19 of this Act, article 3 (1) and (6) of the Regulation on intra-Community trade in drug precursors, article 13 (1) or article 21 (1) of the Regulation on extra-Community trade in drug precursors, or essentially fails to give the necessary information;

5) essentially violates the conditions or restrictions appended to the authorisation referred to in sections 12–15;

6) fails to fulfil the obligation to update the addresses laid down in article 3 (6) of the Regulation on intra-Community trade in drug precursors or in article 7 (1) of the Regulation on extra-Community trade in drug precursors;

7) fails to comply with the provisions on documentation in article 5 of the Regulation on intra-Community trade in drug precursors or in articles 3 and 4 of the Regulation on extra-Community trade in drug precursors;

8) fails to comply with the provisions on labelling in article 7 of the Regulation on intra-Community trade in drug precursors or in article 5 of the Regulation on extra-Community trade in drug precursors; or

9) fails to comply with the provisions on customer declaration referred to in article 5 of the Regulation on intra-Community trade in drug precursors;

shall be sentenced to a fine for *offence against the Narcotics Act*, unless a more severe punishment for the act is prescribed elsewhere in law.

Anyone who violates a prohibition imposed in virtue of this Act that has been reinforced by a default fine may be left unpunished for the same act.

Section 48

Drug offences

Provisions on drug offences are laid down in Chapter 50 of the Penal Code (39/1889).

Chapter 8

Miscellaneous provisions

Section 49 (775/2009)

Appeal

Decisions issued by the Finnish Medicines Agency on the basis of this Act, the Regulation on intra-Community trade in drug precursors and the Regulation on extra-Community trade in drug precursors may be appealed as provided in the Administrative Judicial Procedure Act (586/1996).

Notwithstanding the appeal, a decision of the Agency shall be observed unless the appeal authority otherwise prescribes.

Chapter 9

Entry into force and transitional provisions

Section 50

Entry into force

This Act, below the *new Act*, enters into force on 1 September 2008.

This Act repeals the Narcotics Act (1289/1993) of 17 December 1993, below the *old Act*, as amended.

Measures necessary for the implementation of this Act may be undertaken before its entry into force.

Section 51

Transitional provisions

In case there are references elsewhere in law to the old Act or its provisions, the reference shall be considered to refer to the new Act or the corresponding provisions in it.

An authorisation issued in virtue of the old Act is considered to have been issued in virtue of the new Act, and it will cease to be valid on the date given in the decision on authorisation.

Matters pending at the National Agency for Medicines at the entry into force of the new Act that had been instituted under the old Act will be processed and decided in accordance with provisions of the old Act.

The authorisation holder shall appoint a person responsible referred in section 16 for every establishment covered by this authorisation and submit it to the National Agency for approval within six months from the entry into force of this Act.

Section 52

Complementary provisions

As substances comparable to substances to be made subject to control in accordance with the Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances are considered the substances decided to be taken under control according to Council decisions made in virtue of Joint Action 97/396/JHA concerning the information exchange, risk assessment and the control of new synthetic drugs that was repealed by the said Council Decision. Further provisions on these substances may be laid down, as necessary, by Government decree in the same way as in regard to substances referred to in section 3 (1) 5 (c).

Entry into force and application of amended Acts:

595/2010:

This Act enters into force on 28 June 2010.

322/2011:

This Act enters into force on 1 June 2011.

The substance methylenedioxypropylamphetamine referred to in section 3(1)(5)(d) that was in force at the entry into force of this Act is regarded as the drug referred to in section 3(1)(5)(e) in this Act.

Measures necessary for the implementation of this Act may be undertaken before its entry into force.

663/2011:

This Act enters into force on 1 May 2012.

836/2011:

This Act enters into force on 1 January 2014.

539/2014

This Act enters into force on 1 September 2014.