Unofficial translation /Ministry of Social Affairs and Health

No. 548/2008

Government Decree on Narcotics Control

Issued in Helsinki on 28 August 2008

Section 1

Scope of application

This Decree lays down provisions on the licence administration, operations subject to authorisation and their supervision under the Narcotics Act (373/2008).

Section 2

Quotas

For confirming of the quotas for Finland the National Agency for Medicines shall annually submit to the International Narcotics Control Board estimates of the amounts of substances included in schedules I and II of the 1961 Single Convention on Narcotic Drugs that are needed for medical and scientific research purposes for the next year.

In case granting an import authorisation would lead to exceeding the quota the National Agency shall submit to the International Narcotics Control Board an additional estimate for confirming a new quota. Authorisation cannot be granted until a new quota has been confirmed.

Section 3

Import and export licence

The import and export licence for a narcotic drug (below: *drug*) must specify the name of the drug and its possible international usual name, the amount of the drug concerned, the names and addresses of the importer and consigner or exporter and consignee, the prescribed time within which the import or export must take place, as well as the conditions defined on the basis of section 13 (2) and section 14 (3) of the Narcotics Act. The export licence must, in addition, specify the number and date of the import authorisation, as well as the authority that has issued it.

If the drug is imported or exported in the form of a preparation, the licence must also specify the name of the preparation, in case there is a name for it, and the dosage form.

In connection with import and export of drugs the customs authority must record on the import or export licence issued by the National Agency for Medicines the number of the consignment note or trade invoice regarding the consignment, the signature of the customs officer, clarification of signature, the date, and the stamp of the customs office.

The authorisation holder shall return to the National Agency, besides the licence, also a copy of the consignment note or trade invoice recorded on the licence.

Section 4

Conditions to be appended to the import authorisation and returning of documents

A condition that any import to a customs warehouse in Finland is forbidden must be appended to the import authorisations. For particular reasons this condition need not be appended to import authorisations for drugs other than those included in schedule I of the Convention on Psychotropic Substances, in which case approval of import to a customs warehouse must be separately recorded on the authorisation.

When a drug requiring import authorisation has been imported or the period of time determined for the import has expired, the National Agency for Medicines must return a copy of the export authorisation to the competent authority of the country of export, on which the date of import and the amount of the imported drug is recorded.

Section 5

Identification data on the labelling of the drug

The name of the substance must appear from the labelling of the drug in the form it is given in the schedules of the 1961 Single Convention on Narcotic Drugs or the Convention on Psychotropic Substances. In addition, the drug content of the substance or preparation intended for sale must appear from its labelling.

Section 6

Storage and safekeeping of drugs

A pharmaceutical plant and a pharmaceuticals wholesaler may not stock a greater amount of a drug than what is necessary for customary use or marketing taking into account the prevalent market conditions.

Preparations containing substances included in schedules III and IV of the Convention on Psychotropic Substances shall be kept in a place to which access by outsiders is hindered as efficiently as possible.

Section 7

Disposal of drugs

Minutes shall be drawn up regarding the disposal of substances and preparations included in schedules I, II and IV of the 1961 Single Convention on Narcotic Drugs and in schedules I–III of the Convention on Psychotropic Substances, specifying the name, amount and batch number of the drug. Two persons, one of whom is the person responsible for the disposal, shall sign the minutes. A note of the disposal shall be made in the record of drugs and the minutes shall be appended to the record.

Section 8

Keeping of a record by pharmacies

Pharmacies shall keep a record of the substances and preparations included in schedules I, II and IV of the 1961 Single Convention on Narcotic Drugs and in schedules I–III of the Convention on Psychotropic Substances.

The following information shall appear from the record of drugs:

1) the name of the drug or preparation;

2) the amount purchased to be kept in stock, date of purchase and place of purchase;

3) the amount supplied from stock, the date, and the recipient or patient;

4) the volume of the stock;

5) the name of the physician prescribing the medicine;

6) the number of the prescription register or of the manufacturing lot; and

7) the initials of the person who made the entries, and the date.

Section 9

Keeping of a record by hospitals and health centres

Hospital pharmacies and medicine dispensaries shall keep a record of the substances and preparations included in schedules I–IV of the 1961 Single Convention on Narcotic Drugs and in schedules I–III of the Convention on Psychotropic Substances. The corresponding data shall appear from the record of drugs as is laid down in section 8 (2). Instead of the name of the patient and physician, the department or the care unit to which the drug or preparation has been delivered shall be entered on the record.

When a hospital pharmacy or medicine dispensary delivers to a department or other care unit, or when a pharmacy delivers on the basis of a written order for medicines such substances and preparations as are included in schedules I, II and IV of the 1961 Single Convention on Narcotic Drugs or in schedules I–III of the Convention on Psychotropic Substances, a package-specific consumption card must be attached. The consumption card must specify the name, amount and date of delivery of the preparation, and the name of the department or care unit. The name of the patient, the dose taken, the name of the physician and the signature of the giver of the preparation used as medicine and the date shall be recorded on the consumption card.

Once the preparation has been used up, the consumption card with entries of possible loss in measure shall be returned to the hospital pharmacy, medicine dispensary or pharmacy signed by the physician in charge at the department or care unit.

Section 10

Keeping of a record by wholesalers of medicinal products and by pharmaceutical plants

Wholesalers of medicinal products and pharmaceutical plants shall keep a record of the substances and preparations included in schedules I–IV of the 1961 Single Convention on Narcotic Drugs and in schedules I–III of the Convention on Psychotropic Substances. Pharmaceutical plants shall, in addition, keep a record of the substances included in schedule IV of the Convention on Psychotropic Substances, from which the amounts of drugs used for manufacture appear. A pharmaceutical plant's duty to keep a record also applies to those preparations containing psychotropic substances that have been exempted from being subject to authorisation.

The following information shall appear from the record of drugs kept by wholesalers of medicinal products and by pharmaceutical plants:

1) the name of the drug or preparation;

2) the amount purchased to be kept in stock and the place of purchase;

3) the amount supplied from stock and place of consignment;

4) the volume of the stock; and

5) the initials of the person who made the entries of changes, and the date.

Pharmaceutical plants shall also keep a record of the amounts manufactured and any losses in the course of the manufacture process.

Section 11

Keeping of a record by authorities and holders of handling authorisation

The authorities that have the right to keep drugs in stock and the holders of handling authorisation for drugs shall keep a record of drugs in the same way as is laid down in regard to wholesalers of medicinal products in section 10. Instead of the place of consignment, information on the purpose of use must be given.

The minutes drawn up by an authority of seized drugs shall be regarded as the keeping of a record referred to in paragraph 1.

Section 12

Keeping of a record by drug importers and drug exporters

Drug importers and drug exporters shall keep a record of the substances and preparations included in schedules I–IV of the 1961 Single Convention on Narcotic Drugs and in schedules I–III of the Convention on Psychotropic Substances. The amounts of drugs contained in preparations whose import or export has been exempted from being subject to authorisation shall also appear from the record.

The following information shall appear from the record kept by drug importers and drug exporters:

1) the name and amount of the drug;

2) to which countries the drug has been exported or from which countries the drug has been imported;

3) the date of import and export; and

4) the number of the import or export authorisation.

The note of the amount of the drug and other notes regarding customs clearance with dates made by the customs shall appear from the record.

Section 13

Keeping of a record by veterinaries

Veterinaries shall keep a record of the substances and preparations included in schedules I–IV of the 1961 Single Convention on Narcotic Drugs and in schedules I–III of the Convention on Psychotropic Substances.

The following information shall appear from the record of drugs kept by veterinaries:

1) the name of the drug or preparation;

2) the amount purchased to be kept in stock or supplied from stock and the date;

3) the volume of the stock; and

4) a specification of the drug that has been used or supplied.

Section 14

Entry into force

This Decree enters into force on 1 September 2008.