

Velferðarráðuneytið

Ministry of Welfare

REGULATION

on importation by individuals of medicinal products for personal use, No. 212/1998

as amended by Regulation No. 230/2001.

General provisions.

Article 1

Individuals may import into the country medicinal products for their personal use with the restrictions provided for in this Regulation.

Article 2

Individuals may import medicinal products for their personal use, provided these medicinal products have been acquired by legitimate means for human use.

An individual must be able to produce a physician's certificate, a prescription or other written declaration, together with instructions for use, which provide satisfactory proof that the medicinal products have been acquired by legitimate means and that they are necessary to the individual in the amount specified.

Importation of medicinal products from European Economic Area states.

Article 3

An individual may take along, when entering Iceland, or import through the mail from European Economic Area (EEA) states, medicinal products for his/her personal use in a quantity equivalent to no more than 100 days' use.

Importation of medicinal products from states outside the European Economic Area.

Article 4

An individual may take along, when entering Iceland from states outside the EEA, medicinal products for his/her personal use in a quantity equivalent to no more than 100 days' use.

Medicinal products may not be imported through the mail from states outside the EEA.

Restrictions.

Article 5

[In the case of medicinal products covered by the provisions of the Act and Regulations on Habit Forming and Narcotic Substances, and which are included on lists N-I, N-II, N-III and N-IV of the Convention on Narcotic Drugs of 1961 and lists P-I, P-II and P-III of the International Convention on Psychotropic Substances of 1971 to which Iceland is a party, the following shall apply to their importation.

An individual who is resident in a country which is a member of the Schengen Treaty may take along medicinal products, *cf.* paragraph 1, for personal use and which have been prescribed in a legitimate manner, equivalent to up to 30 days' use, in accordance with provisions of Article 75 of the Schengen Treaty, *cf.* also the provisions of the currently applicable Regulation on Habit Forming and Narcotic Substances and other substances subject to surveillance.

The same shall apply to individuals resident outside the Schengen area, except that they may only take along medicinal products for 14 days' use.

Medicinal products covered by these provisions may not be imported through the mail.]¹⁾ *Regulation No. 230/2001, Article 1.*

Article 6

Medicinal products of the anabolic steroid type (anabolica) and similar substances covered by *item* c of the International Olympic Committee's list, or pituitary and hypothalamic hormones, i.e. growth hormones and comparable substances covered by *item* f in the International Olympic Committee's list of medicinal products which are prohibited in sports, may not be imported either as personal baggage or by other means in excess of the quantity required by an individual for a maximum of 30 days.

Customs authorities may demand that an individual in possession of medicinal products covered by paragraph 1 produce satisfactory proof that these medicinal products are necessary to the individual in the quantity specified, e.g. by means of a physician's certificate.

Penalties.

Article 7

Violations against the provisions of this Regulation shall be liable to penalty as provided for in Article 43 of the Medicinal Products Act, No. 93/1994, *cf.* Article 2 of Act No. 55/1995, unless provision is made for more severe punishment in other Acts.

Legal basis and entry into force.

Article 8

This Regulation is set by authority of Article 44 of the Medicinal Products Act, No. 93/1994, and shall enter into force upon publication.

Provisions in the Regulation are based on EU Directive 92/26/EBE, granting individuals the right to take along or have sent a reasonable quantity of medicinal products, acquired by legitimate means for their personal use, from another state in the European Economic Area.

Ministry of Health and Social Security, 26 March 1998.

Ingibjörg Pálmadóttir.

Davíð Á. Gunnarsson.

[This translation is published for information only.

The original Icelandic text is published in the Law Gazette.

In case of a possible discrepancy, the original Icelandic text applies.]