REGULATION

on the importation by individuals of medicinal products for their own use.

Article 1

Scope.

This Regulation applies to the importation into Iceland, by individuals (natural persons), of medicinal products for their own use. The importation of medicinal products, pharmaceutical substances, intermediate substances and drug precursors by legal persons is subject to the Medicinal Products Act, No. 100/2020, and other regulations issued thereunder. The importation of food additives, including unlawful food supplements which contain medicinal products, is subject to the Foodstuffs Act, No. 93/1995.

Article 2

Definitions.

Defined daily dose (DDD): The average daily treatment dose of a specific medicinal product used for its most common indications in adults. The average daily treatment dose is stated in the marketing licence for the medicinal product or is in accordance with information published by the World Health Organisation.

Registered domicile: Domicile registered in the National Register.

Article 3

General.

Medicinal products may be imported into Iceland for the importer's own use, with the restrictions set out in this Regulation, providing that these are medicinal products that have been legally obtained for human use with the restrictions stated in this Regulation.

On arrival in Iceland, individuals shall present to the customs authorities a medical certificate or prescription together with instructions for use, or an instruction label providing fully satisfactory proof that a prescription medicinal product has been obtained in a lawful manner and that the product is necessary for the bearer in the quantity stated. This provision shall apply solely to prescription medicinal products.

The customs authorities may obtain the opinion of other public institutions, healthcare professionals or other specially qualified persons if there is a suspicion that documents presented under the second paragraph are incorrect or have been forged.

Article 4

Importing of medicinal products by individuals.

On arrival in Iceland from states within the European Economic Area (EEA), individuals may be in possession of ordinary medicinal products for their own use in quantities corresponding to one year's use in accordance with the instructions for use from a physician or the marketing licence holder or manufacturer of the product. If the individual is arriving from a state outside the EEA, the permitted amount shall be restricted to 100 days' dose.

Individuals may import into Iceland, by post or goods consignments, from EEA states medicinal products for their own use in quantities corresponding to 100 days' use in accordance with the instructions for use from a physician or the marketing licence holder or manufacturer of the product. Medicinal products may not be imported into Iceland by post or goods consignments from states outside the EEA.

Article 5 applies to the importation of habit-forming and narcotic drugs by individuals.

Article 5

Importation by individuals of habit-forming and narcotic drugs.

Individuals may bring with them into Iceland medicinal products for their own use which contain, in part, substances that are listed in Appendix 1 to Regulation No. 233/2001, on habit-forming and narcotic drugs and other controlled substances, with the following restrictions:

1. Individuals whose registered domicile is in Iceland may, on arrival in the country, be in possession of medicinal products according to this paragraph in quantities corresponding to 30 days' doses if the medicinal product were originally obtained in Iceland. Individuals shall present documents demonstrating that the drugs were obtained in Iceland.
2. Individuals whose registered domicile is in Iceland may, on arrival in the country, be in possession of medicinal products according to this paragraph in quantities corresponding to 7 days' dose, according to the defined daily dose (*cf.* Article 2), if the medicinal products were obtained abroad.
3. Individuals whose registered domicile is in Iceland may, on arrival in the country, be in possession of medicinal products according to this paragraph in quantities corresponding to 30 days' dose, according to the defined daily dose (*cf.* Article 2), if the medicinal products were obtained abroad, if the person concerned is in possession, on arrival in Iceland, of a declaration from a physician with a valid licence to practice in Iceland stating that the medicinal products are necessary for the person concerned for a medical purpose.
4. Individuals whose registered domicile is not in Iceland may, on arrival in the country, be in possession of medicinal products according to this paragraph in quantities corresponding to 30 days' dose, according to the defined daily dose (*cf.* Article 2).
5. Individuals travelling between the jurisdictions of signatories of the Schengen Agreement, or within their jurisdictions, may be in possession of medicinal products according to this paragraph in quantities necessary for their medical treatment, providing that they present a certificate issued by a competent authority in their country of residence (*cf.* Article 75 of the Schengen Agreement). Such certificates are valid for a maximum of 30 days from the date of issue.

Individuals shall be obliged to present documents in accordance with the requirements of the second paragraph of Article 3 on arrival in Iceland.

Habit-forming and narcotic drugs may not be imported by post or in goods consignments.

Importation that is not in conformity with the authorisations of this Article shall be subject to the Act on Habit-Forming and Narcotic Substances, No. 65/1974.

Article 6

Medicinal products and pharmaceutical substances on the Prohibited List of the World Anti-Doping Agency.

In cases involving medicinal products containing substances included in sections S1 (anabolic agents) and S2 (peptide hormones, growth factors, related substances and mimetics) of the Prohibited List of the World Anti-Doping Agency (WADA), individuals shall only be permitted to import into Iceland for their own use quantities corresponding to 30 days' use according the instructions for use from a physician or the marketing licence holder or manufacturer of the product.

Medicinal products covered by this Article may not be imported by post or in goods consignments.

Article 7

Exemptions.

The Icelandic Medicines Agency may grant exemptions from the provisions of this Regulation when it is demonstrated that restrictions on the importation of medicinal products for personal use may jeopardise the health or life of an individual.

The Icelandic Medicines Agency shall set procedural rules covering exemptions under this Article and publish them on the agency's website. In the case of medicinal products covered by Article 5, an

exemption decided by the Icelandic Medicines Agency shall have been issued before the individual concerned arrives in Iceland.

Article 8
Commencement.

This Regulation, which is issued under the authorisation in the third paragraph of Article 31 (*cf.* Article 109) of the Medicinal Products Act, No. 100/2020, shall take immediate effect. As of the same date, Regulation No. 212/1998, on the importation by individuals of medicinal products for their own use, shall stand repealed.

Ministry of Health, 7 November 2022.

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