VELFERÐARRÁÐUNEYTIÐ

Ministry of Welfare

REGULATION
on habit-forming and narcotic substances and other controlled substances, No. 233/2001,
as amended by Regulations No. 848/2002, No. 480/2005, No. 789/2010, No. 513/2012 and No. 624/2012.

CHAPTER I
General provisions.

Article 1

Habit-forming and narcotic substances.

Habit-forming and narcotic substances shall be understood to mean:

1. substances, which are included in lists I-IV of the Single Convention on Narcotic Drugs of 1961, as subsequently amended, classed as N I – N IV in Appendix I to this Regulation;
2. substances, which are included in lists I-IV of the Convention on Psychotropic Substances of 1971, together with annexes, classed as P I – P IV in Appendix I to this Regulation;
3. substances which can be used for the illegal cultivation, production or preparation of habit-forming and narcotic substances and other controlled substances, included in lists I-II of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, classed as D I – D II in Appendix II of this Regulation.

In addition, any salts, esters, amides, peptides and any sort of derivative (isomer) of the substances listed in Appendices I and II, including isomers which differ from the original substance (the reference substance) with regard to the structure of the chemical group or groups on carbon, nitrogen, oxygen and/or sulphur.

It shall also apply to pharmaceutical forms of the above-listed chemical compounds (e.g. tablets, capsules, injections) as well as other pharmaceuticals which can be abused in a similar manner and can have detrimental effects on human health.

The term habit forming and narcotic substances applies also to habit forming and narcotic pharmaceuticals.

Habit forming and narcotic pharmaceuticals are those drugs that can be expected, due to their properties, to cause their user to become dependent upon them by habit or addiction

Article 2

The import, export, sale, purchase, exchange, delivery, reception, production, preparation and storage of habit-forming and narcotic substances, marked with an x in column B in Appendix I, is prohibited within Icelandic territorial jurisdiction.

The Minister of Health and Social Security may grant exemptions from this prohibition for scientific research or for other special reasons. Should the rules or conditions set by the Minister for such exemptions not be satisfied, the Minister may immediately cancel or restrict such exemptions.

CHAPTER II
Control and procedures for disposal.

Article 3

Control.

Medicinal products are controlled if, due to their characteristics, they may present a risk of abuse.

The substances classed as N I – N IV and P I – P III in Appendix I are controlled.

The Icelandic Medicines Control Agency may, after consultation with the Directorate of Health, add to the control list or exempt from control specific medicinal products, pharmaceutical forms or concentrations. Special rules apply concerning prescribing, dispensing, reception and recording of information for controlled drugs.

Article 4

In granting a marketing authorisation for a drug covered by the provisions of Article 3, the Icelandic Medicines Control Agency shall provide for its control. In the case of a drug in ATC classifications N 05 B A and N 05 C, the amount which may be prescribed in each instance shall be restricted and based on the provisions of Article 10 of this Regulation.

The Icelandic Medicines Control Agency must publish in an accessible manner information on the control of a drug in granting a marketing authorisation.

Article 5

Disposal of controlled drugs from pharmacy stocks.

Outdated or unusable controlled drugs from pharmacy stocks must be sent to the Icelandic Medicines Control Agency for disposal by registered mail or delivered to an employee of the Agency. An accompanying letter must specify what drugs are concerned and in what quantities, in addition to indicating the date and sender. The Icelandic Medicines Control Agency shall confirm in writing having received the controlled drugs for disposal.

Notwithstanding the provisions of the first paragraph, outdated controlled drugs may be returned to the medicinal products wholesaler if a full or partial refund is available. The confirmation of the wholesaler of receipt of the drugs must be preserved in the pharmacy for at least two years.

The Icelandic Medicines Control Agency may authorise that controlled drugs be disposed of by pharmacies. Such an authorisation must be made in writing and conditions may be set for its implementation and other aspects deemed necessary by the Agency. Controlled drugs which are returned to a pharmacy must be sent in a secure manner for disposal with other drugs.

Habit-forming and narcotic substances may not be disposed of except in consultation with the Icelandic Medicines Control Agency in the presence of a pharm-a-ceutical inspector.

Parties responsible for the storage and handling of substances as provided for in this Regulation must provide annual reports concerning the substances in question on special forms provided for the purpose by the Ministry of Health and Social Security. Furthermore, they must provide at any time such reports and information as the Ministry deems necessary for surveillance.

CHAPTER III
Import and export.

Article 6

Import and export of habit-forming and narcotic substances.

Substances which are classed as N I - N IV, P I - P IV and D I in Appendices to this Regulation may only be imported or exported, produced or sold in wholesale after receiving a licence for such from the Minister of Health and Social Security.

Anyone intending to import or export substances as provided for in the first paragraph, whether in the form of raw materials or in pharmaceutical form, must apply for an import permit to the Ministry of Health and Social Security in each instance, before making an order.

The application must state:

1. the name and address of the applicant;
2. the name and address of the vendor/purchaser;
3. the name and quantity of the substance concerned (INN name);
4. the purpose for which the substance is to be used.

Article 7

Import and export of substances which can be used for the illegal cultivation, production or preparation of habit-forming and narcotic substances and other controlled substances.

Substances which are classed as D II in Appendix II may only be imported or exported, produced or sold in wholesale after receiving a permit for such from the Minister of Health and Social Security, which shall be restricted to each individual substance. Parties responsible for the storage and handling of these substances must follow the provisions on registering delivery of controlled substances in accordance with more detailed rules in this regard. An importer must have an import licence from the Minister of Health and Social Security and produce the same for the customs authorities upon demand.

Anyone intending to import substances as referred to in the first paragraph, whether in the form of raw materials or in pharmaceutical form, must apply for an import permit to the Ministry of Health and Social Security each time an order is made, in the case of substances which are classed as D I and, in the case of substances which are classed as D II, if the quantity exceeds the maximum specified in Appendix II. The application shall state the same details provided for in the second paragraph of Article 6.

Licence holders may only deliver the substances in question to other parties holding a permit from the Minister for their storage, handling or sale. This provision shall not apply to dispensing by pharmacies and other parties licensed to sell medicinal products.

Article 8

In order for substances covered by Article 7 to clear customs, the archives of the importer or exporter concerned must contain a licence issued by the Minister of Health and Social Security. The consignment must include information on the names of substances which must be in accordance with the import or export licence; such information shall not, however, be on the outer packaging of the consignment. As soon as an importer has received a substance, he must record the date, name and quantity of the substance received on his copy of the import licence and send the copy to the Ministry.

Article 9

The import licence shall as a rule be valid for four months unless otherwise authorised by the Ministry. If the issued licence is not used such must be notified in writing to the Ministry no later than the day upon which it expires. If unprocessed or semi-processed raw materials are involved, the authorised quantity must be imported in a single instance.

The same provisions as listed above for import shall also apply in the case of export.

These provisions on import and export shall not apply to those habit-forming and narcotic substances which, in accordance with current rules, are to be found in the medical chests of vessels or aircraft, nor to medicinal products transported by individuals resident in a State which is a member to the Schengen Agreement, for their own use and which have been prescribed in legitimate manner, for up to a 30-day dosage, if the instructions of the physician are followed. In the same way, individuals resident in States which are not members to the Schengen Agreement, are allowed to transport medicinal products for their own use, and which have been prescribed in a legitimate manner, for up to a 14 day usage, if the instructions of the physician are followed, cf. Regulation on individual's transport of drugs for own use.

CHAPTER IV
Drugs which may be prescribed in limited quantity.

Article 10

Drugs in ATC classifications N 05 B A and N 05 C, which are classed as P IV in Appendix I, may only be prescribed in a quantity representing a 30-day dosage based on their Defined Daily Dose (DDD).

In granting a marketing authorisation for the above drugs the Icelandic Medicines Control Agency shall determine the quantity which may be prescribed in each instance, taking into consideration the packages for which the marketing authorisation is being granted. The general rule shall be to authorise a smaller rather than a larger quantity.

The Icelandic Medicines Control Agency can, in co-operation with the Director General of Health, permit that certain drugs, drug forms or strengths are prescribed in larger quantities than for 30 days normal use.

Information on the quantities which may be prescribed shall be published in the Register of Proprietary Medicinal Products, while the Icelandic Medicines Control Agency must publish in an accessible manner information on the permitted maximum quantity per prescription in granting a marketing authorisation.

[Exceptions may be made from Paragraphs 1 and 2, if a physician requests for it on a prescription that these drugs should be dosed in special dose-boxes, along with other prescription medicinal products, *cf.* provisions of Regulation on preparation and signing of prescriptions, No. 111/2011.][1)]

[1)] *Regulation No. 848/2002, Article 1.*

Article 11

If no defined daily dosage has been determined for a drug covered by Article 10, the Icelandic Medicines Control Agency shall, in granting a marketing author-isa-tion, decide the maximum quantity which may be prescribed in each instance.

If the Icelandic Medicines Control Agency considers that a drug, which is not covered by Article 10, may have a habit-forming or dependency risk, the Agency shall determine the quantity which may be prescribed in each instance, based on the general provisions of Article 10.

Article 12

In granting authorisation for the use of a medicinal product which has no marketing authorisation in Iceland, the Agency shall determine its control and limits to the quantity prescribed in accordance with the provisions of this Regulation.

CHAPTER V
Surveillance, penalties and entry into force.

Article 13

The prescription of controlled drugs and other habit forming and narcotic drugs is under special surveillance, cf. Art. 3. The Icelandic Medicines Control Agency shall notify the Directorate of Health if there is any suspicion of abnormal prescribing by physicians or dentists of habit-forming and narcotic drugs, and notify the Chief Veterinary Officer if there is suspicion of abnormal prescribing of habit-forming and narcotic drugs by veterinarians.

The Icelandic Medicines Control Agency shall monitor that the provisions of this Regulation are complied with. The Icelandic Medicines Control Agency must be provided with any data or information which the Agency deems necessary for its surveillance, cf. The Medicinal Products Act No. 93/1994, Art. 42.

Article 14

Violations of this Regulation shall be liable to fines or imprisonment of up to six years, unless more severe punishment is provided for by law. Any attempt to com-mit, or complicity in, a violation is punishable in accordance with Chapter III of the Criminal Code.

Habit-forming and narcotic substances and other controlled substances, which have been obtained by illegitimate means or which are otherwise in illegal custody, shall be confiscated on behalf of the National Treasury. Furthermore, receipts from ille-gitimate sale of habit-forming and narcotic substances, as well as any and all ob-jects which have been used or intended for use in illegal treatment of the sub-stances, may also be confiscated on behalf or the National Treasury.

Article 15

This Regulation, which is set by authority of Article 12 of the Medicinal Products Act, No. 93/1994, as subsequently amended, and Article 2 of the Act on Habit-forming and Narcotic Substances, No. 65, of 21 May 1974, as subsequently amended, shall enter into force 1 January 2001. At the same time Articles 15-21 and 43 of Regulation No. 421/1988, concerning prescription forms and the prescribing of medicinal products, their dispensing and labelling, shall be repealed. The Regulation on the sale and handling of habit-forming and narcotic substances, No. 16/1986, as

subsequently amended, shall be repealed as of that date, together with Advertisement No. 84/1986, on restrictions to physicians' prescribing of amphetamines and several other drugs, and Advertising No. 314/1981, prohibiting the storage and handling of habit-forming and narcotic substances.

[Appendix I

Notes:

B	Substances which are prohibited in Icelandic territorial jurisdiction, cf. Article 2 of the Act on Habit-forming and Narcotic Substances, No. 65/1974, as subsequently amended, and Article 1 of this Regulation.
N-I – IV	Substances included in Appendices I-IV of the Single Convention on Narcotic Drugs of 1961, and the Protocol of 25 March 1972 amending the Single Convention on Narcotic Drugs of 1961.
P I – IV	Substances included in Appendices I-IV of the Convention on Psychotropic Substances 1971, as subsequently amended.
Unsorted substances	Substances which are either known derivatives of substances on INCB-lists or substances that cause addiction or are addictive.

Substance	Other name	Internetional Agreements	Banned	Exemptions and Comments
(1-phenyl-1-piperidyl-(2)-methyl)acetat			x	
1,4-butandiol			x	
2C-B	4-bromo-2,5-dimethoxyphenethylamine	P II	x	
2C-E	4-ethyl-2,5-dimethoxyphenethylamine		x	
2C-I	4-jodo-2,5-dimethoxyphenethylamine		x	
2C-P	2,5-dimethoxy-4-propylphenethylamine		x	
2C-T-2	2,5-dimethoxy-4-ethylthiophenethylamine		x	
2C-T-7	2,5-dimethoxy-4-(n)-propylthiophentylamine		x	
3-methylfentanyl		N I+IV		
3-methylthiofentanyl		N I+IV		
4-fluoroamphetamine			x	
4-methylaminorex		P I	x	
4-MTA	α-methyl-4-methylthiophenethylamine	P I	x	
5-(1,1-dimethylhexyl)-2-((1R,3S)-3–hydroxycyclohexyl)-phenol	CP47, 497-C6		x	
5-(1,1-dimethylheptyl)-2-((1R,3S)-3–hydroxycyclohexyl)-phenol	CP47, 497-C7		x	
5-(1,1-dimethyloctyl)-2-	CP47, 497-C8		x	