VELFERÐARRÁÐUNEYTIÐ

Ministry of Welfare

Medicinal Products Act, No. 93/1994,

as amended by Act No. 122/1994, No. 131/1994, No. 55/1995, No. 118/1995, No. 153/1996, No. 10/1997, No. 82/1998, No. 77/2000, No. 108/2000, No. 173/2000, No. 16/2001, No. 63/2002, No. 76/2002, No. 93/2002, No. 164/2002, No. 89/2003, No. 83/2004, No. 58/2005, No. 76/2005, No. 40/2007, No. 57/2007, No. 167/2007, No. 88/2008, No. 97/2008, No. 112/2008, No. 120/2008, No. 146/2008, No. 28/2009, No. 132/2009, No. 162/2010, No. 42/2011, No. 126/2011, No. 177/2011, No. 34/2012, No. 45/2012, No. 105/2012, No. 130/2012, No. 20/2013, No. 42/2014, No. 52/2015, No. 53/2015, No. 13/2016 and No. 59/2016.

SECTION I
Objectives and administrative structure.

Article 1

The objective of this Act is to ensure that the people of Iceland have a sufficient supply of necessary medicinal products, as efficiently distributed as possible on the basis of fair and equitable competition, and in accordance with the rules which apply in the European Economic Area [or under the European Free Trade Association (EFTA) Treaty].[1)] Where trade in medicinal products is concerned, it must always be borne in mind that the distribution of medicinal products is an integral part of health services and those employed in the distribution of medicinal products are to work with other professions of the health services towards fulfilling current health service objectives. It is, furthermore, the objective of this Act to ensure as far as possible the quality and safety of medicinal products and services, increase public information on the use of medicinal products, counter their excessive use and keep costs to a minimum.

[The Minister][2)] shall supervise the implementation of this Act. At [the Ministry][3)], the Director of Medicinal Affairs is responsible for administering medicinal product matters on behalf of the Minister. The Director shall be a qualified pharmacist and may not have personal interests at stake in the manufacturing, importation or distribution of medicinal products. The Director of Medicinal Affairs, [the Environment Agency of Iceland],[4)] the Director of Health, [the Icelandic Medicines Agency],[5)] [the Medicinal Products Pricing Committee][6)] and [the Icelandic Food and Veterinary Authority][7)] shall advise the Minister on the implementation of this Act.

[1)] Act No. 76/2002, Article 24. [2)] Act No. 126/2011, Article 197. [3)] Act No. 162/2010, Article 64. [4)] Act No. 164/2002, Article 18. [5)] Act No. 108/2000, Article 1. [6)] Act No. 83/2004, Article 1. [7)] Act No. 167/2007, Article 74.

Article 2

[The Icelandic Medicines Agency is under the aegis of [the Minister].[1)]

The Minister shall appoint the Director of the Icelandic Medicines Agency for a five-year term. The Director shall have a university degree and knowledge of the Agency's field of operation. The Director shall be responsible for administering the Agency, be responsible for day-to-day operations and ensure that it operates in accordance with all currently applicable laws and regulations.

Neither the Director nor any other staff of the Agency may have any personal interests at stake in the production, importation or distribution of medicinal products.

Independent laboratories in Iceland or abroad may be entrusted with research on behalf of the Agency.][2)]

[1] Act No. 162/2010, Article 64. [2] Act No. 108/2000, Article 2.

Article 3

[The role of the Icelandic Medicines Agency shall be as follows:

1. To evaluate medicinal products and other products covered by this Act in accordance with applicable rules in the European Economic Area [and under the European Free Trade Association (EFTA) Treaty].[1]
2. [To issue, amend, cancel and revoke marketing authorisations and authorisations for parallel importation of medicinal products, in accordance with the rules which apply in the European Economic Area.][2]
3. To process applications for authorisation to import and sell by prescription medicinal products that do not have marketing authorisation in Iceland.
4. To issue authorisations for research on medicinal products (clinical trials of medicinal products and research on the bioavailability of pharmaceuticals) [and to monitor the implementation of such trials].[3]
5. To handle recording of adverse reactions to medicinal products and the provision of information on medicinal products in collaboration with the Director of Health.
6. To provide professional inspection of the import of medicinal products, pharmaceutical substances and raw materials for the manufacture of medicinal products, or any other products subject to the authority of the Agency.
7. To carry out professional inspection of activities of pharmacies, wholesalers of medicinal products and manufacturers of medicinal products, and inspect holders of marketing authorisations for medicinal products and their agents and other enterprises, institutions and individuals who sell, manufacture, import or package medicinal products and related products. The Minister may, in regulations, appoint the Icelandic Medicines Agency to inspect other enterprises or other products than medicinal products and related products, if special circumstances call for such action and such inspection is connected with the function of the Agency under this Act.

[8. To carry out, in Iceland and abroad, quality audits and certification of enterprises' manufacturing procedures, at their request and in accordance with this Act and the rules applying in the European Economic Area and in accordance with the Convention Establishing the European Free Trade Association.][4]

[9.][4] To monitor advertising of medicinal products and ensure that the promotion and distribution of medicinal products complies with current laws and regulations.

[[9.][10] To provide special monitoring of medicinal products containing narcotic drugs or psychotropic substances in connection with the delivery, preparation and signing of prescriptions and the dispensing of medicinal products containing narcotic drugs or psychotropic substances by pharmacies. Regulations on narcotic drugs or psychotropic substances and other substances subject to monitoring shall provide in detail for the implementation of such monitoring. [The Icelandic Medicines Agency shall also grant authorisation and exemptions under the Act on narcotic drugs and psychotropic substances.][5]][6]

[[11.][4] To carry out surveillance of the activities of blood banks with respect inter alia to the handling, storage and processing of blood and blood products. [Surveillance of the activities of blood banks by the Director of Health is subject to Section VI of the Health Service Act and to the Act on the Director of Health and Public Health.][7] The Minister may make further provision in Regulations[8] for the activities of blood banks, recording of adverse reactions, the practice of surveillance, etc.][3]

[12.][4] [To examine applications for, and issue, pharmacy licences in accordance with Section VII, importing and wholesaleing licences under Section XII, manufacturing licences under Section XIII and importing and manufacturing licences for medicated animal feeds under Section XVI.][9]][10]

[13.][4] Other matters concerning the implementation of this Act, including collaboration with bodies abroad in the field of medicinal products, [such as the European Medicines Agency (EMA).][3]

In accordance with the rules of the European Economic Area [and in accordance with the European Free Trade Association (EFTA) Treaty],[1] manufacturers of medicinal products or their agents shall provide the Icelandic Medicines Agency with all new information on medicinal products under consideration by the Agency as it becomes available. The same shall apply to medicinal products for which marketing authorisations have been granted.

[Applicants for pharmacy licences, licences for the importation of fully prepared medicinal products and/or medicinal product substances for wholesale distribution, licences to manufacture medicinal products and licences for the importation and/or manufacture of medicated animal feeds shall pay the Icelandic Medicines Agency a fee to meet the cost of processing the application. Applicants shall also pay the Icelandic Medicines Agency a fee to meet the cost of the necessary auditing of the proposed activities.][4]

[An applicant for a marketing authorisation and authorisation for parallel importation under indent 2 of paragraph 1 shall pay the Icelandic Medicines Agency a fee which shall cover the cost of evaluation under indent 1 of paragraph 1, and the cost incurred under indent 2 of paragraph 1 in case of changes on marketing authorisation or dispensing authorisation for parallel importation of medicinal products. The fee shall also cover the cost of issuing marketing authorisation and authorisation for parallel importation of medicinal product.][2]

Holders of marketing authorisations shall pay an annual fee to the Icelandic Medicines Agency which shall cover the costs of maintaining medicinal product registers, recording adverse reactions to medicinal products, and dissemination of information on medicinal products with marketing authorisation in Iceland, as well as costs resulting from necessary co-operation with foreign agencies concerning medicinal products for which marketing authorisation has been granted in Iceland.

[An applicant for professional evaluation on whether a procuct can fall within the terms of definition of a medicinal product under Article 5, shall pay the Icelandic Medicines Agency a fee to cover the cost of the evaluation.][2]

[Pharmaceutical companies shall pay the Icelandic Medicines Agency a fee for the issue of certificates of a marketing authorisation for a medicinal product for which they intend to apply for market authorisation in other countries (Certificate of Pharmaceutical Product), also Certificates of Authorisation for Manufactures of Medicinal Products regarding good practice, and certificates regarding a medicine is on Icelandic market (Statements of Licensing Status of Pharmaceutical Products). The fee shall take account of the work contributed by experts in issuing them.

The Icelandic Medicines Agency may collect a special fee with respect to scientific advice regarding marketing authorisation (Scientific Advice) requested by a manufacturer of a medicinal product. [The Icelandic Medicines Agency may furthermore collect a special fee for quality audits and certification of enterprises' manufacturing procedures, in Iceland or abroad, at their request and in accordance with this Act and the rules applying in the European Economic Area and in accordance with the Convention Establishing the European Free Trade Association.][4)][3]

[The Icelandic Medicines Agency shall be paid a fee for granting exemptions under paragraph 7 of Article 7 for medicinal products which do not have marketing authorisations in Iceland, for granting authorisations for carrying out clinical trials of medicinal products under Article 9 [for evaluation of officinal formulae under Article 5 and for granting authorisations and exemptions under the Act on narcotic drugs and psychotropic substances, *cf.* [indent 10][4] of paragraph 1.][5]][11]

The Minister shall, after receiving the proposals of the Icelandic Medicines Agency, set a tariff for activities referred to in [paragraphs 3–9.][4] It shall take into consideration the costs of services and implementation of individual projects. The tariff shall be based on the Agency's operating budget, giving grounds for the figures upon which the determination of fees are based.

The Icelandic Medicines Agency shall levy an annual inspection fee on the parties subject to its regular inspection, which shall cover the cost of inspection by the Agency. Parties subject to inspection are as follows:

1. holders of pharmacy licences,
2. physicians' dispensaries,
3. local authorities' dispensaries,
4. manufacturers of medicinal products, [including activities of blood banks],[3)]
5. wholesalers of medicinal products,
6. enterprises representing manufacturers of medicinal products,
7. veterinarians,
8. health institutions, hospitals and primary health care centres,
9. medical centres.

[10. importers and manufacturers of medicated animal feeds.][9)]

The inspection fee shall be determined in the following manner:

1. Concerning the activities of holders of pharmacy licences, physicians' dispensaries and dispensaries of local authorities, 0.3% of the total amount of payments from [the Icelandic Health Insurance][12)] to such parties for sales of medicinal products during the year preceding the year of assessment, but of the total amount of purchases of medicinal products by these parties (wholesale price excluding value-added tax), if that amount exceeds the payments from [the Icelandic Health Insurance].[12)] The amount of the inspection fee shall, however, never be lower than [ISK 176,000][9)] per year.
2. Concerning the activities of manufacturers of medicinal products [including the activities of blood banks],[3)] medicinal product wholesalers and representatives of manufacturers of medicinal products, 0.3% of the total sales of medicinal products [in Iceland][3)] (wholesale price excluding value-added tax) during the year preceding the year of assessment. The amount of the inspection fee shall, however, never be lower than [ISK 82,000][9)] per year.
3. Concerning the activities of veterinarians, health institutions, hospitals, primary health care centres and medical centres, 0.3% of the total amount of purchases of medicinal products (wholesale price excluding value-added tax) during the year preceding the year of assessment. The amount of the inspection fee shall, however, never be lower than [ISK 17,500][9)] per year.

[4. Concerning the activities of importers and manufacturers of medicated animal feeds, 0.3% of the total amount of purchases of medicinal products for use in feeds. The inspection fee may not, however, be lower than ISK 82,000 per year.][9)]

[The amounts provided for in indents 1–4 of [paragraph 12][4)] are based on price levels as of December 2012.][9)] The amount of the minimum inspection fee for medicinal products shall be adjusted once each year, on 15 January, with 70% of the fee reflecting the wage index and 30% the consumer price index.

[The Icelandic Health Insurance][12)] and parties subject to inspection must provide the Icelandic Medicines Agency with all the information necessary for assessing the inspection fee for medicinal products.

If the parties subject to inspection fail to provide the necessary information the Icelandic Medicines Agency may estimate their inspection fees. The base of the fee shall be estimated so liberally as to preclude any risk of underestimating the actual amounts, and the inspection fee then determined on the basis of that estimate. The levy may be reviewed if the base for assessment changes.

The Minister may make, in regulations, further provision for the implementation of collection of monitoring fees.

The inspection fee shall be levied each year in arrears. The due date for payment shall be 30 days from the date of the invoice, with penalty interest calculated after the due date.

The Icelandic Medicines Agency shall collect the fees under this Article. The fees are enforceable by execution.][13)]

[1)] Act No. 76/2002, Article 25. [2)] Act No. 42/2014, Article 1. [3)] Act No. 58/2005, Article 1. [4)] Act No. 59/2016, Article 1. [5)] Act No. 42/2011, Article 3. [6)] Act No. 89/2003, Article 1. [7)] Act No. 40/2007, Article 39. [8)] Regulation No. 441/2006, cf. No. 1024/2007, No. 411/2010 and No. 625/2012 and No. 216/2016. [9)] Act No. 20/2013, Article 1. [10)] Act No. 97/2008, Article 1. [11)] Act No. 83/2004, Article 2. [12)] Act No. 112/2008, Article 62. [13)] Act No. 108/2000, Article 3.

Article 4

[The Medicinal Products Committee of the Icelandic Medicines Agency shall be the advisory committee of the Agency on issues concerning medicinal products.

The Committee shall comprise five persons with the broadest possible expertise in medicine and pharmacy. The Minister shall appoint its chair. The Minister shall appoint other members of the Committee, as well as five alternates, in consultation with the chair. When veterinary medicinal products are dealt with, the Committee shall be joined by the Chief Veterinary Officer, and a veterinarian appointed by the Minister in consultation with the chair of the Committee. Alternates shall be appointed in the same manner. The Committee shall be appointed for a four-year term.

The Director of the Icelandic Medicines Agency may request the services of experts and representatives of professional associations as consultants to the Agency when necessary.][1)]

[1)] Act No. 108/2000, Article 4.

SECTION II

[**Definitions.**][1)]

[1)] Act No. 58/2005, Article 3.

Article 5

[For the purposes of this Act the following meanings shall apply:

1. *Proprietary medicinal products*: All medicinal products, ready for use or nearly so, for which a marketing authorisation has been granted, under a special name and in the special packaging of the manufacturer (holder of the marketing authorisation).
2. [*Medicinal products*: Any substance or combination of substances said to have properties which are useful in the treatment of diseases in humans or animals, or for prevention of disease, or any substance or combination of substances that may be used for human beings or animals or administered to them, either with the objective of restoring, correcting or modifying physiological functions by means of pharmacological, immunilogical or metabolic effects, or in order to confirm a medical diagnosis.][1)]
3. *Substance*: Any matter irrespective of origin, from:
   - humans, e.g. blood and human blood products;
   - animals, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products, etc.;
   - plants, e.g. micro-organisms, plants, parts of plants, plant secretions, extracts, etc.;
   - other chemicals, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical reaction or synthesis.
4. *Magistral formula*: All medicinal products prepared in a pharmacy in accordance with a prescription by a physician for an individual patient.
5. [*Officinal formula*: All medicinal products prepared in a pharmacy or medicinal product manufacturing facility in accordance with a formula approved by the Icelandic Medicines Agency, and dispensed in pharmacies. A medicinal product manufacturing facility is a location where medicinal products are manufactured in accordance with Good Manufacturing Practice (GMP) and which has been granted a licence under the provisions of Section XIII of this Act.][2)]

If there is doubt as to whether individual substances or compounds are medicinal products the Icelandic Medicines Agency shall decide the matter. [In case of doubt as to whether a product can, taking into account all its properties, fall within the terms of definition of a medicinal product, and the definition of a product subject to other legislation, the provisions of this Act shall apply.][1)]

The Minister shall issue regulations[3)] on further definitions of medicinal products and the concept of a medicinal product in accordance with the rules of the European Economic Area [and in accordance with the European Free Trade Association (EFTA) Treaty].[4)]

[The Minister shall issue regulations[5)] which shall stipulate when substances which may originate in nature are deemed to be medicinal products. They shall also stipulate the daily doses of vitamins and/or

minerals, intended for consumption by human beings or animals, which are deemed to be medicinal products.][2)]

...[6)]][7)]

[1)] Act No. 58/2005, Article 2. [2)] Act No. 83/2004, Article 3. [3)] Regulation No. 141/2011, cf. No. 1021/2011, No. 484/2012 and No. 943/2012. [4)] Act No. 76/2002, Article 26. [5)] Regulation No. 142/2011. [6)] Act No. 16/2001, Article 15. [7)] Act No. 108/2000, Article 5.

SECTION III
Pharmacopoeia.

Article 6

Iceland is a signatory to the European Pharmacopoeia (Ph. Eur.), including annexes. The English edition of the pharmacopoeia is valid for Iceland.

Other requirements regarding the form, quality and purity of medicinal product substances and excipients in the manufacturing of medicinal products, as well as the methods of analysis and determination of these substances shall be in accordance with legal advertisements regarding the validity of Nordic and other European standards in Iceland.

Iceland is a signatory to the Pharmaceutical Inspection Convention (PIC). Guidelines regarding Good Manufacturing Practice in the medicinal product industry, the GMP rules, *cf.* European Commission Directives [and the European Free Trade Association Treaty],[1)] as well as other guidelines issued by these parties, shall apply in Iceland.

[1)] Act No. 76/2002, Article 27.

SECTION IV
[Marketing authorisation for medicinal products. Evaluation of medicinal products. Clinical trials of medicinal products.][1)]

[1)] Act No. 108/2000, Article 10.

Article 7

[Fully prepared medicinal products (medicinal products, ready for use og nearly so) may only be imported to Iceland, sold or dispensed, following the issue of marketing authorisation of authorisation for parallel importation.][1)]

An application for a marketing authorisation, together with the necessary documentation, shall be submitted to the Icelandic Medicines Agency. [The period of validity of a marketing authorisation is five years, with the exceptions stated in this paragraph. A marketing authorisation for a medicinal product may be renewed after that time, on the basis of the Icelandic Medicines Agency's reassessment of risk-benefit balance. Before the reassessment the holder of the marketing authorisation shall, at least six months before the expiry of the marketing authorisation, have submitted to the Icelandic Medicines Agency sufficient and updated data on the quality, safety and effect of the medicinal product. When the marketing authorisation of a medicinal product has been renewed once, it shall be valid indefinitely, unless the Icelandic Medicines Agency determines, on valid grounds, with respect to pharmacovigilance, that it should be renewed only for five years. The marketing authorisation is invalidated if the medicinal product for which the marketing authorisation is granted has not been placed on the market within three years of the granting of the authorisation, or if a medicinal product for which authorisation has been granted, and which has been placed on the market, has not in fact been on the market for a continuous period of three years. The Icelandic Medicines Agency may grant exemptions from this provision in special circumstances, and for reasons relating to public health. Such exemptions shall be supported by valid reasons.][2)]

The Icelandic Medicines Agency may use a marketing authorisation granted in another member state of the European Economic Area Agreement as the basis for recognition of a medicinal product for which marketing authorisation is sought.

The Icelandic Medicines Agency may approve an application from the holder of a marketing authorisation for a major or minor amendment to the terms of a marketing authorisation.

The Icelandic Medicines Agency may revoke, [invalidate, cancel temporarily or amend][2)] a marketing authorisation if:

a. it transpires that a medicinal product on the market in Iceland does not conform to current law or rules on medicinal products or does not meet requirements for marketing authorisation;
b. the medicinal product is no longer considered to fulfil requirements for quality, safety and efficacy;
c. information which was provided in connection with an application is incorrect;
d. quality control in accordance with the requirements of a currently applicable quality description is not carried out as prescribed by the rules;
e. the obligations to make necessary changes to production or supervision or to the summary of product characteristics (SPC), are not fulfilled;
f. the time which must elapse until the utilisation of animal products may begin once more after administration of a medicinal product is no longer considered long enough to ensure that the animal products contain no residues harmful to consumers;
g. new representation has not been notified within the specified time limits, provided the parties have been warned that exceeding such time limits would result in revocation of the marketing authorisation.

Rules on the revocation of market authorisation shall also apply to special marketing authorisations, as applicable.

The holder of a marketing authorisation may request that the Icelandic Medicines Agency cancel the marketing authorisation.

The Icelandic Medicines Agency may, under exceptional circumstances, grant a physician, upon his/her personal responsibility, an exemption from paragraph 1 for medicinal products which do not have marketing authorisation in Iceland. In granting such exemptions, care shall be taken to ensure that the amount of the medicinal products is limited to the needs of those for whom they are intended.

The Icelandic Medicines Agency may refuse an application for a marketing authorisation [or marketing][2)] for a vaccine, serum or other immunological veterinary medicinal product if its registration is contrary to law or if it is intended for use against a disease which is unknown in animals in Iceland.

[The Minister shall, in regulations,[3)] make provision for the granting of marketing authorisations for proprietary medicinal products, homeopathic medicines and natural medicinal products, vitamins and minerals, and for the granting of authorisations for parallel imported medicinal products.][1)] Provision shall also be made for the processing of applications, [recognition of central marketing authorisations from the European Medicines Agency (EMA), duration of protection of data from preclinical and clinical trials],[2)] recognition based on marketing authorisations granted in other member states of the European Economic Area Agreement, amendment to the terms of marketing authorisations, revocation and cancellation of marketing authorisations and exemptions for medicinal products which do not have marketing authorisation in Iceland.][4)]

[1)] Act No. 42/2014, Article 2. [2)] Act No. 58/2005, Article 4. [3)] Regulation No. 141/2011, cf. No. 1021/2011, No. 484/2011, No. 943/2012, No. 923/2014, No. 1006/2014, No. 118/2015, No. 654/2015, No. 891/2015, No. 1007/2015 and No. 993/2016. Regulation No. 142/2011. Regulation No. 340/2016. [4)] Act No. 108/2000, Article 6.

Article 8

[The granting of marketing authorisation for a medicinal product][1)] may be limited to use in hospitals, specified wards, and/or for prescription by specialists in specific branches of medicine.

[The Icelandic Medicines Agency may, on the basis of a marketing authorisation in another member state of the European Economic Area Agreement and upon the fulfilment of the requirements of this Act concerning the granting of a marketing authorisation, issue a marketing authorisation for a medicinal product which has been removed from the registry or for which a marketing authorisation has not been sought if the Agency deems justifiable, due to considerations of public health or public interests, to have the medicinal product in question on the market. [If the Icelandic Medicines Agency intends to exercise this right, it must notify the holder of the marketing authorisation in the country in which the medicinal

product is registered of its intent, requesting a copy of the evaluation report and the valid marketing authorisation for the medicinal product from the authorities in that country. The Minister shall provide in detail for the implementation of this provision in regulations.][2)]][3)]

[The Icelandic Medicines Agency may authorise temporary distribution of a medicinal product which has not been granted a marketing authorisation, if it is for protection against pathogens, toxic substances, chemical agents or nuclear radiation which are believed or known to have spread, or to be likely to do so.

The Icelandic Medicines Agency may grant a veterinarian, having received his/her reasoned application, and on his/her own responsibility, permission to use out-of-label a medicinal product, with or without marketing authorisation in Iceland, or use it for another animal species than that for which the medicinal product is intended. Further provision shall be made for such cases in regulations on veterinarians' authority to prescribe medicinal products.][2)]

[1)] Act No. 108/2000, Article 7. [2)] Act No. 58/2005, Article 5. [3)] Act No. 83/2004, Article 5.

Article 9

[A clinical trial of a medicinal product is a systematic testing of a medicinal product intended to discover or confirm its effect and/or to discover any adverse reactions to the medicinal product and/or to investigate the absorption, distribution, metabolism and excretion of the medicinal product for the purposes of evaluating its safety and effectiveness.

The Minister shall issue regulations[1)] with further provisions on the definition of clinical trials of medicinal products, the granting of permits for such, and for their monitoring and implementation in accordance with rules on Good Clinical Practice (GCP), the Helsinki Convention, codes of ethics and the Patients' Rights Act.][2)]

[1)] Regulation No. 443/2004, cf. No. 907/2004 and No. 1099/2010. Regulation No. 893/2004, cf. No. 1100/2010. [2)] Act No. 108/2000, Article 8.

Article 10

[The Icelandic Medicines Agency supervises publication of a registry of proprietary medicinal products, listing the proprietary medicinal products with marketing authorisation in Iceland by medicinal product categories or in a similar manner. The registry shall include, for instance, clinical indications, contra-indications, dosages, the main adverse reactions and the maximum price of medicinal products, *cf.* [Article 43.][1)]][2)]

[1)] Act No. 89/2003, Article 4. [2)] Act No. 108/2000, Article 9.

SECTION V
Prescription of medicinal products. Prescription forms and dispensing of prescriptions. Labelling of medicinal products.

Article 11

[The Icelandic Medicines Agency shall decide whether a medicinal product shall be subject to prescription, what quantity of a medicinal product may be dispensed on the basis of a prescription, and how often on the same prescription. The Agency shall also decide when exemptions from prescription status may be granted.][1)]

[A prescription form is a prescription for a medicinal product issued by a physician or dentist holding a valid licence to practice medicine in the European Economic Area. A prescription form is furthermore a prescription issued by a vet holding a valid licence to practice medicine in Iceland.][2)] In emergency cases, pharmacists are authorised to dispense a medicinal product in the smallest available packaging without a prescription.

The person issuing a prescription shall sign it in his/her own hand and indicate his/her professional status (physician, dentist, veterinarian) or communicate by telephone in such a manner as to make his/her identity clear. A prescription may be sent by fax or by computer file transmission in any standardised format which enables the receiver to verify the identity of the sender. The person issuing the prescription

thus verifies having him/herself prescribed for the specified individual or his/her guardian the stated medicinal product in the stated quantity, specifying dosage or use.

The Director of Health monitors physicians' prescriptions and the dispensing of medicinal products by pharmacists in emergency cases. [[The Icelandic Food and Veterinary Authority][3)] monitors the prescribing of veterinary medicinal products.][4)]

[1)] Act No. 108/2000, Article 11. [2)] Act No. 13/2016, Article 6. [3)] Act No. 167/2007, Article 74. [4)] Act No. 131/1994, Article 1.

Article 12

The Minister shall issue regulations[1)] concerning prescription forms and the prescribing of medicinal products, their dispensing and labelling. These regulations shall provide, for instance, for the following matters:

1. prescription forms,
2. the prescription of medicinal products,
3. ...[2)]
4. how containers (dispensing containers) of ready-to-use medicinal products shall be labelled,
5. prescription of medicinal products by telephone, fax or via computer,
6. prescription of medicinal products containing narcotic drugs or psychotropic substances,
7. prescription of medicinal products for use aboard ship or in aircraft,
8. the right of medical students and physicians without a licence to practice to prescribe medicinal products,
9. term of validity of prescriptions,
10. labelling of medicinal products.

[1)] Regulation No. 539/2000, cf. No. 912/2000, No. 14/2008, No. 1069/2008, No. 392/2012, No. 931/2012 and No. 661/2015. Regulation No. 233/2011, cf. No. 490/2001, No. 248/2002, No. 848/2002, No. 480/2005, No. 516/2006, No. 789/2010, No. 513/2012, No. 624/2012 and No. 138/2017. Regulation No. 1077/2006, cf. No. 874/2010 and No. 343/2016. Regulation No. 421/2017. Regulation No. 422/2017. [2)] Act No. 108/2000, Article 12.

SECTION VI

[Advertising and promotion of medicinal products.][1)]

[1)] Act No. 52/2015, Article 1.

Article 13

Advertising of medicinal products of any kind is prohibited, with the exceptions provided in this Section.

[[Advertising, by means of text or illustrations, directly or indirectly, that a product which has not been approved as a medicinal product has preventive effects, cures or alleviates diseases, disease symptoms or pain, or has effects on physiological functions, is also prohibited.][1)] Under exceptional circumstances, the Icelandic Medicines Agency may grant exemptions from this paragraph.][2)]

[1)] Act No. 63/2002, Article 1. [2)] Act No. 108/2000, Article 13.

Article 14

[Medicinal products which have marketing authorisations in Iceland][1)] may be advertised and promoted in Icelandic in journals and newsletters of health professions which prescribe or distribute medicinal products.

[Advertisements for medicinal products shall state the name of the marketing authorisation holder, the name of the product, its active ingredients and principal indications and contraindications for the use of the product in question. Information on package sizes, the prices, dosages and other principal details regarding use and adverse effects shall be stated in the product advertisement; alternatively, a reference to the insert with the product and/or a summary of the properties of the product on the website of the Icelandic Medical Agency may be displayed.][2)] The afore-mentioned information must always be indicated clearly and legibly and be in accordance with that contained in pharmacopoeia.

[An advertisement may include only the name of a medicinal product if the intent of the advertisement is solely to draw attention to the name. This provision applies only to the advertisement of non-prescription medicinal products.][1)]

[1)] Act No. 108/2000, Article 14. [2)] Act No. 53/2015, Article 1.

Article 15

Prescription medicinal products may be promoted among the health professions prescribing or distributing medicinal products, by such means as will make it unlikely that such advertisements will reach the general public.

Article 16

Non-prescription medicinal products, i.e. medicinal products for which a prescription is not required, may be promoted and advertised to the general public. …[1)] Advertisements of non-prescription medicinal products shall be in accordance with the rules applying in the European Economic Area, as prescribed in more detail in regulations.

Pharmacies may advertise and promote their services, such as home delivery service, the price of non-prescription medicinal products and general discounts.

Information given in advertisements must always be clear and legible and be in accordance with that contained in pharmacopoeia, with regulations concerning prescription forms and the prescribing of medicinal products, their dispensing and labelling, and any other instructions in this regard.

[Holders of marketing authorisations, or their agents, may convey general information on diseases and the use of specific medicinal products to patients by means of brochures. All information included in such brochures shall be in accordance with an approved Summary of Product Characteristics (SPC) and the Icelandic Medicines Agency shall be sent copies of the brochures.][2)]

[1)] Act No. 53/2015, Article 2. [2)] Act No. 108/2000, Article 15.

Article 17

It is permissible to deliver personally to a physician, dentist or veterinarian a medicinal product sample in the smallest package size without charge, provided that it is a newly registered medicinal product, not deemed narcotic drug or psychotropic substance, being introduced on the market in Iceland. Such supply is only authorised if the physician has signed and dated a request to this effect.

Any other delivery or mailing of medicinal product samples for advertising purposes is unauthorised.

Article 18

[The Icelandic Medicines Agency monitors advertisements of medicinal products. The Agency may prohibit and/or order the withdrawal of specific advertisements that provide false or inadequate information on medicinal products. The Agency may also require that the advertiser publish corrections or additional information in a comparable manner. This also applies to substances which have not been approved as medicinal products, *cf.* paragraph 2 of Article 13. The Icelandic Medicines Agency shall refer decisions on advertisements of medicinal products to the Competition and Fair Trade Authority in cases where there are reasons to suspect that an advertisement of a medicinal product violates provisions of the Competition Act. Advertisers shall keep records of all advertisements, indicating where and when they were published. The records are to be preserved for two years and be accessible to the Icelandic Medicines Agency.][1)]

[The Icelandic Medicines Agency can require individuals and legal entities to provide written information with respect to suspected violation of the provisions of Articles 13–17, and this shall be provided within a reasonable period allowed by the Agency. The Icelandic Medicines Agency can, in investigation of suspected violations of the provisions of Articles 13–17, make necessary inspections of the working premises or the location where data are stored, provided that there is probable cause to believe that the provisions have been violated. In the implementation of measures, the provisions of legislation on [criminal][2)] procedure shall be followed with respect to search and seizure of objects.

The Icelandic Medicines Agency may pass to authorities of other members of the European Economic Area information and data deemed necessary in the implementation of the provisions of Articles 13–17 in accordance with Iceland's obligations under the European Economic Area Agreement.

In handing over information and data, the conditions shall be required that:

1. the information and data be treated as confidential by the recipient,
2. the information and data will only be used for the purpose stated in the European Economic Area Agreement and in accord with a request for information,
3. the information and data will only be passed to other parties with the consent of the Icelandic Medicines Agency, and for the purpose specified in the statement of consent.][3)]

[1) Act No. 108/2000, Article 16. 2) Act No. 88/2008, Article 234. 3) Act No. 57/2007, Article 9.

[SECTION VI A
Pharmacovigilance.][1)]

[1) Act No. 52/2015, Article 2.

[Article 19

The Icelandic Medicines Agency shall operate a pharmacovigilance system to monitor medicinal product security; it shall maintain a register of adverse reactions reported to it. The Agency may release information on reported adverse reactions to the Director of Health, patients' associations that are operated in Iceland, the European Medicines Agency, the European Commission, the legally-competent authorities in the field of medicinal products in the Member States of the European Economic Area and holders of marketing authorisations.][1)]

[1) Act No. 52/2015, Article 2.

[Article 19 a

Marketing authorisation holders shall be obliged to:

a. Operate pharmacovigiliance systems with the aim of monitoring the safety of medicinal products, assessing the possibility of minimising and preventing risks and taking appropriate measures when necessary.
b. Have accurate descriptions of their pharmacovigilance systems in their pharmacovigilance system master file dealing with adverse reactions and grant the Icelandic Medicines Agency access to the description if so requested. This shall not apply, however, to medicinal products for veterinary use.
c. Maintain a register of adverse reactions that are suspected of being connected with medicinal products and have the register accessible by the Icelandic Medicines Agency.
d. Report adverse reactions that are suspected of being connected with medicinal products to the Icelandic Medicines Agency or the European Medicines Agency.
e. Compile and submit summaries on medicinal product safety and submit them to the Icelandic Medicines Agency.
f. Have in their service a person responsible for pharmacovigilance. This person shall be domiciled in, and shall operate within, the European Economic Area.

The Icelandic Medicines Agency may demand that the holder of a marketing authorisation for a medicinal product for human use nominate a contact person in Iceland who will appear on behalf of the person responsible for pharmacovigilance referred to in indent f of the first paragraph.

The Icelandic Medicines Agency shall monitor to ensure that the marketing authorisation holder discharges its obligations under the first paragraph. Marketing authorisation holders shall be obliged to provide the Icelandic Medicines Agency with all materials and information which the Agency considers necessary in order to exercise its monitoring function. Marketing authorisation holders shall also be obliged to grant the Icelandic Medicines Agency access to their premises for the same purpose if this proves necessary in the assessment of the Icelandic Medicines Agency.

The Icelandic Medicines Agency shall inform the European Medicines Agency, the European Commission, the legally-competent authorities in the field of medicinal products in the other Member

States of the European Economic Area and the marketing authorisation holder if the conclusion of monitoring is that the marketing authorisation holder does not meet the requirements of the pharmacovigilance system as described in the pharmacovigilance system master file (*cf.* indent b of the first paragraph.][1)]

[1) Act No. 52/2015, Article 2.]

[Article 19 b

Holders of marketing authorisations for medicinal products for human use may not publish information on product safety from the pharmacovigilance system without notifying the Icelandic Medicines Agency, the European Medicines Agency and the European Commission, either beforehand or at the time of publication.

Holders of marketing authorisations for medicinal products for veterinary use may not publish information on product safety from the pharmacovigilance system without notifying the Icelandic Medicines Agency, either beforehand or at the time of publication.

Marketing authorisation holders shall ensure that information referred to in the first and second paragraphs is presented in an impartial manner and that it is not misleading.

The Icelandic Medicines Agency may demand that holders of marketing authorisations for medicinal products for human use publish product information concerning patient safety, including information on adverse effects which are suspected of being connected with products, or that they disseminate such information to a specific group of healthcare workers.

The Icelandic Medicines Agency may issue provisions on the form and content of the information referred to in the fourth paragraph. In addition, the Icelandic Medicines Agency may set time limits regarding the publication or dissemination of such information.][1)]

[1) Act No. 52/2015, Article 2.]

[Article 19 c

The Minister may issue regulations specifying in further detail the demands made of marketing authorisation holders in connection with pharmacovigiliance in accordance with the EEA rules on pharmacovigilance.

The Minister may issue regulations stating the obligation of healthcare workers to inform the Icelandic Medicines Agency of adverse effects which are suspected of being connected with medicinal products, including information from patients' medical records and registers of deceased persons.

The Minister may issue regulations stating the right of patients, close family members and animal owners to inform the Icelandic Medicines Agency of adverse effects which are suspected of being connected with medicinal products.][1)]

[1) Act No. 52/2015, Article 2.]

SECTION VII
The establishment of pharmacies and pharmacy licences.

Article 20

Only those parties who have received a licence for such from [the Icelandic Medicines Agency][1)] are authorised to sell medicinal products. [But it is permissible to sell outside pharmacies fluoride medicines and the smallest packages and lowest doses of nicotine medicines which are not prescription-only. Sale of nicotine and fluoride medicines is subject to the provisions of paragraphs 1 and 7 of Article 8 of the Tobacco Control Act and paragraph 2 of Article 62 of Regulations on pharmacy licences and pharmacies. Monitoring, coercive measures and penalties are subject to the provisions of the Health and Safety and Pollution Control Act.][1)]

[The Icelandic Medicines Agency][1)] shall issue a pharmacy licence to a party fulfilling the following conditions who applies for such licence:

1. Is a pharmacist licensed to practice in Iceland, *cf.* [the Healthcare Practitioners Act.][2)]

2. Has worked as a pharmacist for three years. Exceptions may be made from this requirement under special circumstances.
3. ...[3)]

Applications for new pharmacy licences shall be referred by [the Icelandic Medicines Agency][1)] to the local authority concerned for an opinion. Consideration of the application shall, among other things, take into account the number of inhabitants to be served by the pharmacy and its distance from the next pharmacy. If the party giving the opinion opposes the granting of a new licence, [the Icelandic Medicines Agency][1)] may refuse the application. [Applications for pharmacy branches shall be sent to the local authorities for their opinion in the same manner.][3)]

[Before the pharmacy may commence activities, it must be confirmed that the premises, facilities and staff meet the Medicine Control Agency's criteria.][1)]

[The Icelandic Medicines Agency][1)] may provide for an obligation for holders of pharmacy licences to provide after-hours services.

[The Icelandic Medicines Agency may assign responsibility for the operation of a pharmacy to the director of a primary health care centre if no pharmacy operates in the health care district.][1)] [The director of a primary health care centre][4)] which has been assigned responsibility for the operation of a pharmacy may make a contract with an external holder of a pharmacy licence regarding its services, including the operation of a pharmacy, *cf.* [Article 38.][5)]

…[6)]

[1)] Act No. 97/2008, Article 2. [2)] Act No. 34/2012, Article 34. [3)] Act No. 108/2000, Article 19. [4)] Act No. 83/2004, Article 6. [5)] Act No. 89/2003, Article 4. [6)] Act No. 59/2016, Article 2.

Article 21

[Each pharmacy licence shall be restricted to the operation of one pharmacy and the licence-holder him/herself shall be professionally responsible for the pharmacy's operation. A pharmacist may only be issued one pharmacy licence at any time, but the licence-holder may apply for a licence to operate a branch of the pharmacy in a community where no pharmacy is operated. In the absence of the licence-holder a pharmacist shall be entrusted with the daily operation of the pharmacy in consultation with the Icelandic Medicines Agency. Pharmacy branches shall be classified in accordance with the nature and the scope of the services they are authorised to provide. The Minister shall, in regulations, make detailed provision for the classification of pharmacy branches. If a pharmacy branch is operating in a community where no pharmacy exists, authorisation to operate another branch with a lower level of service shall not be granted. ...[1)] [The Minister may make further provisions on conditions and implementation of mail order of medicines and postal deliveries of medicines in regulations[2)] on pharmacy licences and pharmacies.][1)]

[Should a pharmacy be operated by a person other than the holder of a pharmacy licence, this licence holder must obtain authorisation from [the Icelandic Medicines Agency][1)] for the operation. The holder of an operating licence shall be responsible, together with the holder of the pharmacy licence, for ensuring compliance with this Act. [The Icelandic Medicines Agency][1)] may revoke the operating licence of the holder if he/she violates the provisions of this Act.][3)]

Practising physicians, dentists, and veterinarians may not own such extensive holdings in pharmacies, medicinal product manufacturers or wholesalers of medicinal products that this has a significant impact on their personal finances. The same shall apply to their spouses and children under 18 years of age. Sale of medicinal products by veterinarians is subject to [paragraph 6 of Article 33.][4)] The Minister may make further provision in regulations regarding this paragraph, including for instance exceptions from this prohibition in the case of spouses where no alternative is available.][5)]

[1)] Act No. 97/2008, Article 3. [2)] Regulation No. 1065/2008. [3)] Act No. 63/2002, Article 2. [4)] Act No. 89/2003, Article 4. [5)] Act No. 108/2000, Article 20.

Article 22

A pharmacy licence shall be cancelled:

1. if the licence-holder has his/her pharmacist's licence revoked ...;[1)]
2. at the end of the year the licence-holder reaches the age of 70; after that time the licence may be extended for a one-year period at a time ...;[2)]
3. if a licence-holder ceases work;
4. upon the death of a licence-holder. The estate of a deceased licence-holder may, however, operate the pharmacy for six months under the professional administration of a pharmacist, after receiving the agreement of [the Icelandic Medicines Agency].[1)]

[The Icelandic Medicines Agency][2)] may withdraw pharmacy licence if the pharmacy licence-holder violates the provisions of this Act or others and the violation is of such nature that the licence-holder must be deemed unfit to sell medicinal products. The provisions of [Healthcare Practitioners Act][3)] shall apply to the loss of professional licence.

A retiring licence-holder, or the estate of a deceased licence-holder, may sell the operations to a pharmacist who has acquired a pharmacy licence under the provisions of this Act.

[1)] Act No. 108/2000, Article 21. [2)] Act No. 97/2008, Article 4. [3)] Act No. 34/2012, Article 34.

SECTION VIII
Operation of pharmacies.

Article 23

A pharmacy shall be clearly designated as such. Holders of pharmacy licences are permitted to call their pharmacies, and them alone, lyfjabúðir or apótek.

Article 24

Pharmacy licence holders must offer for sale those medicinal products which may be sold in the country, keep sufficient stocks of medicinal products to meet foreseeable prescription needs from the doctors, dentists and veterinarians practising in the area and obtain medicinal products which they do not have in stock as quickly as possible. Pharmacies shall, furthermore, have for sale as far as possible essential medicinal product supplies and equipment for nursing and medical treatment.

Pharmacy licence holder must provide [the Icelandic Medicines Agency][1)] with information on their activities and keep records thereof, provided that such actions are not in violation of other laws. [Pharmacy licence holders are furthermore obliged to deliver to [the Icelandic Health Insurance][2)] in electronic format all information indicated on prescription forms on the dispensing of medicinal products with personal information encrypted, fulfilling the require-ments of the Act on the Protection of Privacy as regards the Processing of Personal Data. The Director of Health is responsible for the encryption and decryption of these data.][3)]

Pharmacy licence holders must provide consumers and health care professionals with information on medicinal products, their use and proper storage. They must furthermore provide information on the utilisation of medicinal products and pharmaceutical care in co-operation with other health professions with the objective of reducing the risk of diseases and promoting general health.

Pharmacy licence holders shall keep computerised records of all information regarding their prescriptions in a format which has been approved by the Director of Health and [the Data Protection Authority, *cf.* the Act on the Protection of Privacy as regards the Processing of Personal Data].[4)] The Director of Health can require such information to be produced for a period of up to one year retroactively.

[1)] Act No. 97/2008, Article 5. [2)] Act No. 112/2008, Article 62. [3)] Act No. 89/2003, Article 2. [4)] Act No. 77/2000, Article 46.

[SECTION IX
Databases.][1)]

[1) Act No. 89/2003, Article 3.

[Article 25

Two databases shall be operated, a statistical database and a medicinal products database, containing information which [the Icelandic Health Insurance][1)] collects from pharmacies, *cf.* paragraph 2 of Article 24. The objective of operating the databases is to enable [the Icelandic Health Insurance][1)], the Director of Health and the Icelandic Medicines Agency to carry out their mandated monitoring of the prescribing of medicinal products containing narcotic drugs or psychotropic substances and of prescriptions in general, as well as to monitor the cost of medicinal products and process statistical data on national consumption of medicinal products.

The Data Protection Authority shall, in accordance with its role under the Act on the Protection of Privacy as regards the Processing of Personal Data, monitor the security of personal information in the statistical database and the medicinal products database and their operation in other respects.][2)]

[1) Act No. 112/2008, Article 62. 2) Act No. 89/2003, Article 3.

[Article 26

For the purposes of monitoring the cost of medicinal products and to process statistical data on national consumption of medicinal products, [the Icelandic Health Insurance][1)] shall operate a database on dispensing of medicinal products to patients, *cf.* paragraph 2 of Article 24, to collect statistical information on medicinal products, prescribing and use of medicinal products, and their cost.

Personal identification of patients and physicians shall be removed before encrypted data from pharmacies are entered into the statistical database. [The Icelandic Health Insurance][1)] shall ensure that this is done within one month of receipt of data by the Institution.

[The Icelandic Health Insurance][1)], the Icelandic Medicines Agency and the Directorate of Health may obtain information from the database for purposes of instruction and research. Other parties may obtain information from the database for the same purpose. The Minister shall issue regulations on the use of the information and on access to the database.][2)]

[1) Act No. 112/2008, Article 62. 2) Act No. 89/2003, Article 3.

[Article 27

[The Directorate of Health shall operate a medicinal products database covering prescriptions and dispensed products in order to ensure the quality of the health services and the safety of patients, monitor the prescription of medicinal products by physicians and monitor narcotic drugs and psychotropic substances, and also to convey information on the prescription of medicinal products for individuals in order, amongst other purposes, to increase security in the prescribing of products by physicians and to facilitate supervision of the cost of medicinal products by the Icelandic Health Insurance, in addition to using information from the database in the production of plans covering quality management in the health services and in scientific research.

Personal identification data of patients and physicians shall be encrypted specially in the medicinal products database. Encrypted personal identification data that is more than 30 years old shall be deleted from the database. The Directorate of Health shall be responsible for the encryption of personal identification data, and shall keep one key to it, both for encryption and decoding.

The Icelandic Medicines Agency may apply for access to personal data from the medicinal products database. The Directorate of Health may grant permission for this if:

a. there is reason to suspect that a prescription for narcotic drugs and psychotropic substances has been forged or that it has been obtained by another unlawful manner or
b. there is reason to believe that a prescription for narcotic drugs and psychotropic substances has been wrongly processed.

The Icelandic Health Insurance shall have access to the medicinal products database in accordance with its supervisory function under the Icelandic Health Insurance Act when any of the following conditions is met:

a. When it is necessary to verify information about a patient's history of medicinal products consumption in connection with the monitoring of costs by the Icelandic Health Insurance.
b. In order to examine physicians' prescriptions and their prescription habits in connection with the monitoring of medicinal product costs.

The personal identification data of individual patients shall not be revealed unless this is unequivocally necessary in connection with specific monitoring procedures.

The Directorate of Health shall have access to the medicinal products database in accordance with its supervisory functions under the Health Services Act, the Directorate of Health and Public Health Act and the present Act when any of the following conditions is met:

a. When there is reason to believe that an individual has had a large amount of narcotic substances and psychotropic drugs prescribed by many physicians.
b. When there is reason to believe that a physician has prescribed narcotic substances and psychotropic drugs for himself/herself.
c. When there is reason to believe that an individual has had more narcotic substances and psychotropic drugs prescribed than can be regarded as normal during a specific period.
d. In order to monitor prescriptions for medicinal products in a general way and promote the rational use of medicinal products by the public.

Patients shall have access to their own medicinal products data in the medicinal products database.

Physician who are involved in treating a patient and need access to the patient's medicinal products history in connection with the treatment shall have access to the patient's medicinal products history for the previous three years in the medicinal products database. The provisions of the Medical Practitioners Act, the Patients' Rights Act and, as appropriate, of other relevant statutes, shall apply regarding non-disclosure and confidentiality obligations on the part of physicians as to information to which they have access in the course of their work, including information on medicinal product use.

Data from the medicinal products database may be used in the production of plans on quality development and for scientific research. The provisions of the Patients' Rights Act, the Regulations on scientific research in the health sector and the Data Protection Act shall apply regarding access to data which can be traced to individuals for the purpose of scientific research.

The Directorate of Health shall maintain active monitoring of access to the medicinal products database under this Article. The Directorate of Health shall issue procedural rules regarding access to the medicinal products database. These shall include rules on access control and traceability. If an individual requests information on who has received data from the medicinal products database, the Directorate of Health shall be obliged to provide this information.][1)]][2)]

[1)] Act No. 45/2012, Article 4. [2)] Act No. 89/2003, Article 3.

[**Section X**][1)]
Workplace training of pharmacy students and trainee pharmacy technicians. Obligations of pharmacy employees.

[1)] Act No. 89/2003, Article 3.

[Article 28][1)]

Pharmacies shall provide pharmacy students and trainee pharmacy technicians with practical training in co-operation with the educational institutions concerned.

[1)] Act No. 89/2003, Article 3.

[Article 29][1)]

Pharmacy students, who have completed a four-year programme of studies and two months of workplace training in a pharmacy, may apply to [the Icelandic Medicines Agency][2)] for permission to serve as assistant pharmacists on a temporary basis. In such cases the pharmacology student shall work with and on the responsibility of a pharmacist.

[1)] Act No. 89/2003, Article 3. [2)] Act No. 97/2008, Article 7.

[Article 30][1)]

Employees of pharmacies are shall treat as confidential all knowledge or suspicions which they acquire in the course of their employment concerning illnesses or other private affairs.

The obligation of the afore-mentioned parties to bear legal witness is covered by the provisions of the Act on Legal Procedure.

[1)] Act No. 89/2003, Article 3.

[**SECTION XI**][1)]
Dispensing of medicinal products.

[1)] Act No. 89/2003, Article 3.

[Article 31][1)]

A pharmacist or assistant pharmacist shall be responsible for dispensing a prescription and carry out the final check that it is correctly dispensed in accord with the prescription or request for toxic substance. [During regular business hours and during peak hours outside regular business hours, a pharmacy shall as a rule have no fewer than two dispensing pharmacists at work filling prescriptions and providing guidance and advice on the proper use and handling of medicinal products. [The Icelandic Medicines Agency][2)] may, on receiving an application to such effect, grant permission for only one pharmacist to be employed in a pharmacy, provided that the extent of its activities is limited and that the pharmacist is assisted by pharmacy technicians or other trained staff.][3)] [Furthermore, [the Icelandic Medicines Agency][2)] may, after receiving an application for such, grant temporary permission for only one pharmacist to work in a pharmacy, if there is a risk that the operation of a pharmacy in the area would otherwise cease. The Minister may, in regulations, provide for more than two pharmacists to work as a rule in pharmacies with a high level of activity.][4)]

[The Icelandic Medicines Agency][2)] may grant a pharmacy technician limited authority, restricted to a specific location, to dispense from a pharmacy branch, provided this involves only standardised packages on a list approved by [the Icelandic Medicines Agency][3)] acting on a proposal from [a director of a primary health care centre][5)] and a pharmacy licence-holder. If a pharmacy technician is not available to fulfil such a position in a pharmacy branch the same permission may be granted to another responsible representative whom the pharmacy licence-holder employs for the purpose, subject to the approval of [the Icelandic Medicines Agency].[3)]

[1)] Act No. 89/2003, Article 3. [2)] Act No. 97/2008, Article 8. [3)] Act No. 108/2000, Article 23. [4)] Act No. 63/2002, Article 3. [5)] Act No. 93/2002, Article 14.

[**SECTION XII**][1)]
[**Importation and wholesale of medicinal products. Parallel importation of medicinal products.**][2)]

[1)] Act No. 89/2003, Article 3. [2)] Act No. 83/2004, Article 8.

[Article 32][1)]

Only those parties which have received a licence thereto from [the Icelandic Medicines Agency][2)] are authorised to import ready-to-use medicinal products and medicinal product substances for wholesale distribution.

…[3)]

[1)] Act No. 89/2003, Article 3. [2)] Act No. 97/2008, Article 7. [3)] Act No. 59/2016, Article 3.

[Article 33][1)]

[To obtain a wholesale licence for medicinal products in Iceland a wholesaler must fulfil the following conditions:

1. It shall be under the professional direction of a pharmacist licensed to practice in Iceland, who does not hold a pharmacy licence, or an individual who, in the view of the Icelandic Medicines Agency, meets at least the equivalent educational requirements. He/she shall be professionally responsible for the wholesale enterprise.
2. It must have at its disposal premises, equipment and staff which, in the view of the Icelandic Medicines Agency, enable it to fulfil the requirements for storage and handling of medicinal products.

If the licence-holder does not fulfil the requirements made regarding equipment, staff or other factors relating to the handling of medicinal products or if the licence-holder violates the provisions of this Act, it shall be given written warning and allowed a reasonable period to rectify the situation. If the licence-holder fails to heed such warning, [the Icelandic Medicines Agency][2)] may withdraw the licence. If the violation is serious, [the Icelandic Medicines Agency][2)] may withdraw the licence without giving prior warning or a time limit within which to rectify the situation.

Wholesalers of medicinal products must keep adequate supplies of Essential Drug List regarded as essential by the health authorities, for which marketing authorisation has been granted in Iceland and which are distributed by the medicinal products wholesaler.

A medicinal products wholesaler may not break the seals of packaging of medicinal products or alter their appearance unless it also holds a licence to manufacture medicinal products. Alterations to the packaging of a medicinal product must be in accordance with the conditions of its marketing authorisation. With the consent of the marketing authorisation holder, the Icelandic Medicines Agency may authorise other alterations to packaging of a medicinal product if special circumstances make this advisable.

Medicinal product wholesalers may sell medicinal products to holders of pharmacy licences, [other medicinal product wholesalers,][3)] [those who have been granted a licence for dose dispensing of medicinal products],[4)] institutions with pharmacists on their staff which are operated on the basis of the Health Service Act or other special Acts, physicians and dentists for use in their own offices or on house calls, and laboratories conducting research on medicinal products. Costs incurred by physicians and dentists due to such purchases of medicinal products shall be considered as operational costs.

Furthermore, medicinal products wholesalers may sell veterinary medicinal products to veterinarians for use in their own offices or for house calls, and for sale from their offices. The Minister shall, in consultation with [the the Icelandic Food and Veterinary Authority],[5)] issue regulations providing for licences to sell veterinary medicinal products, which medicinal products veterinarians are authorised to sell, and which of them they themselves alone may administer to animals. Provision shall also be made for the information which accompany medicinal products administered to animals whose products are intended for human consumption, and for the records which must be kept of sales of veterinary medicinal products, *cf.* Article 24.

[[Medicinal products wholesalers may also carry out parallel importation of a medicinal product with the permission of the Icelandic Medicines Agency.][6)] [All intended parallel importation of a medicinal product shall be notified to the holder of the marketing authorisation of the product and to the Icelandic Medicines Agency. Further provision shall be made for the conditions for parallel imported medicinal products and the Icelandic Medicines Agency procedures in regulations[7)] on parallel importation of medicinal products, *cf.* paragraph 9 of Article 7.][6)] A parallel imported medicinal product shall mean a proprietary medicinal product for which a marketing authorisation has been granted in a country which is a member state of the European Economic Area Agreement, and which is imported from that country to Iceland, while the medicinal product in question has already been registered and a marketing authorisation issued in Iceland, [or is comparable enough to other medicinal product that has already been registered and also a marketing authorisation issued in Iceland].[8)]][3)]

Medicinal product wholesalers must maintain computerised records of sales in a form approved by the Icelandic Medicines Agency and, furthermore, provide the Agency with information on their activities and maintain records thereof.][9)]

[1)] Act No. 89/2003, Article 3. [2)] Act No. 97/2008, Article 7. [3)] Act No. 83/2004, Article 7. [4)] Act No. 63/2002, Article 4. [5)] Act No. 167/2007, Article 74. [6)] Act No. 58/2005, Article 6. [7)] Regulation No. 340/2016. [8)] Act No. 42/2014, Article 3. [9)] Act No. 108/2000, Article 24.

[SECTION XIII][1)]
Manufacture of medicinal products.

[1)] Act No. 89/2003, Article 3.

[Article 34][1)]

Only those parties which have received a licence for such from [the Icelandic Medicines Agency][2)] are authorised to manufacture medicinal products. [Manufacturing refers to all operations in purchase of materials and products, and also production processes, such as weighing, mixing, filling, packing, labelling, quality control, approval and storage, together with the appropriate monitoring. [The Icelandic Medicines Agency][2)] may issue temporary manufacturing licences, and restricted manufacturing licences, for specified categories of production, e.g. dose dispensing of medicinal products. Further provision shall be made for the conditions of such licences in regulations on manufacture of medicinal products.][3)]

… [4)]

[1)] Act No. 89/2003, Article 3. [2)] Act No. 97/2008, Article 7. [3)] Act No. 58/2005, Article 7. [4)] Act No. 59/2016, Article 4.

[Article 35][1)]

To obtain a licence to manufacture medicinal products, an enterprise must fulfil the following conditions:

1. It shall be under the professional direction of a pharmacist licensed to practice in Iceland, [who does not hold a pharmacy licence],[2)] or an individual who meets at least equivalent educational requirements; [that person shall be professionally responsible for the production].[2)]
2. It must have at its disposal premises, equipment and staff which enable it, in the view of [the Icelandic Medicines Agency,][2)] to fulfil the requirements for storage and handling of medicinal products.

If the licence-holder does not fulfil the requirements made regarding equipment, staff or other factors relating to the handling of medicinal products or if the licence-holder violates the provisions of this Act in one way or another, the licence may be withdrawn. A manufacturer of medicinal products must provide [the Icelandic Medicines Agency][2)] with information on its activities and keep records thereof.

[1)] Act No. 89/2003, Article 3. [2)] Act No. 108/2000, Article 25.

[Article 36][1)]

[1)] Act No. 89/2003, Article 3.

Pharmacies shall produce magistral formulae or obtain them as quickly as possible. Standardised formulae may be produced by pharmacies [and pharmaceutical manufacturing facilities][2)] if the specified requirements are fulfilled. Licence for their production may be restricted to certain pharmaceutical forms.

[1)] Act No. 89/2003, Article 3. [2)] Act No. 83/2004, Article 9.

[SECTION XIV][1)]
Medicinal product services in hospitals and other health care institutions.

[1)] Act No. 89/2003, Article 3.

[Article 37][1)]

Hospitals may operate special hospital pharmacies, which supervise and are responsible for procurement and storage of medicinal products and monitoring of their administration in individual wards. The operation of a hospital pharmacy shall be kept financially separate from other hospital operations.

The chief pharmacist shall be the director of the hospital pharmacy and shall be engaged by the Board of Directors of the hospital concerned.

The hospital directors may seek tenders for the operation of a hospital pharmacy to provide the services specified in this Section, provided such operations fulfil all other requirements of this Act on the activities and operations of pharmacies.
[1] Act No. 89/2003, Article 3.

[Article 38][1]

In hospitals and other institutions operated under the Health Service Act or other special Acts, where no pharmacy is operated, a pharmacist shall supervise and be responsible for procurement of medicinal products and monitoring of their administration.

If the institution does not have a pharmacist in its employ under paragraph 1, the directors of the institution shall reach an agreement with an external holder of a pharmacy licence [or hospital pharmacy][2] for medicinal product services, such as supervision of medicinal product procurement and monitoring of their administration. The agreement is subject to the approval of [the Icelandic Medicines Agency.][2]
[1] Act No. 89/2003, Article 3. [2] Act No. 108/2000, Article 26.

[Article 39][1]

A hospital pharmacy may dispense medicinal products to patients who are discharged from hospital and to outpatients. A hospital pharmacy may only dispense prescriptions bearing the hospital's name and issued by its physicians.

The general rules which apply to prescription forms and dispensing of medicinal products shall apply to dispensing of medicinal products as authorised under this Article.
[1] Act No. 89/2003, Article 3.

[Article 40][1]

[The medicinal products committee of a healthcare institution shall issue a list of the medicines to be used in the institution in question. Such a committee shall include at least one physician practising at the institution and one practising pharmacist serving the institution. Care shall be taken, when a choice exists between two or more medicinal products, that the less expensive be selected for use at the institution, taking into account effectiveness, quality and safety.][2]
[1] Act No. 89/2003, Article 3. [2] Act No. 97/2008, Article 9.

[Article 41][1]

The hospital Board of Directors must ensure that the premises and facilities of the hospital pharmacy or its medicinal product storage are fit for purpose and shall abide by the ruling of [the Icelandic Medicines Agency][2] in this respect.
[1] Act No. 89/2003, Article 3. [2] Act No. 108/2000, Article 27.

[SECTION XV][1]
Prices of medicinal products.

[1] Act No. 89/2003, Article 3.

[Article 42][1]

The pricing of all non-prescription medicinal products shall be without restriction. [[The Medicinal Product Pricing Committee][2] shall determine the pricing of non-prescription veterinary medicinal products, *cf.* [Article 43.][3]][4] [Vendors, i.e. medicinal product wholesalers and manufacturers and their agents ...,[5] which wish to sell prescription-only medicines at a lower price than the stated maximum price, shall notify the lower price to the Medicinal Products Pricing Committee, which publishes the price in the next issue of the Medicinal Products Price List. The vendor shall sell the medicinal product at the same price at all its sales outlets.][6]
[1] Act No. 89/2003, Article 3. [2] Act No. 83/2004, Article 10. [3] Act No. 89/2003, Article 4. [4] Act No. 131/1994, Article 4. [5] Act No. 177/2011, Article 1. [6] Act No. 97/2008, Article 10.

[Article 43][1)]

[The Minister appoints a five-person committee, the Medicinal Products Pricing Committee, for a four-year term. The committee shall comprise professionals in the fields of medicine, pharmacy and finance. Four of the committee members shall be appointed following nominations from [the Icelandic Health Insurance],[2)] [the Ministry in charge of procuring income of the state],[3)] the Director of Health and the Icelandic Medicines Agency respectively. The chair shall be appointed by the Minister without nomination. Alternates shall be appointed in the same manner. In taking decisions, the Medicinal Products Pricing Committee shall bear in mind the objective of this Act to keep the cost of medicinal products to a minimum.

Upon receiving an application, the Medicinal Product Pricing Committee shall decide:

1. The maximum wholesale and retail price of prescription medicinal products and of all veterinary medicinal products.
2. Whether public health insurance shall contribute under [Section III of the Health Insurance Act][2)] to the cost of medicinal products on the market in Iceland.
3. The contribution reference price, i.e. the price used as a basis for [health insurance][2)] contribution.
4. The contribution towards the price of medicinal products for which exemptions have been granted as provided in paragraph 7 of Article 7. The committee may refer applications concerning medicinal products for which exemptions have been granted under this provision to [the Icelandic Health Insurance][2)] for consideration.

[5. What medicinal products are subject to licence in collaboration with specialists from the University Hospital (Landspítali) and the Icelandic Health Insurance. By definition ‘medicinal products subject to licence’ are medicinal products that are or will be used exclusively in accordance with clinical instructions and that are generally expensive, and demand special care in their use.][4)]

The Medicinal Products Pricing Committee shall monitor the wholesale and retail pricing, and contribution reference price, of medicinal products in member states of the European Economic Area and take its observations into consideration in its decisions on prices under indents 1 and 3 of paragraph 2. The Minister may in regulations decide that the committee’s decisions on prices shall be based on specified states of the European Economic Area. In the case of parallel imported medicinal products, the Medicinal Products Pricing Committee shall, in determining a maximum price, take into consideration, for instance, the price for which an importer has made application, provided this is lower than the price for the same medicinal product in Iceland. In determining the price and contribution reference price of generic medicinal products (medicinal products containing the same active ingredient), the committee shall consider the price of the generic medicinal products in question in the European Economic Area.

The Medicinal Products Pricing Committee shall classify generic medicinal products and medicinal products with comparable therapeutic effects into reference categories to determine [the health insurance][2)] contribution. Decisions by the committee under idents 2, 3 and 4 of paragraph 2 shall be based, on the one hand, on an assessment of the efficacy of the medicinal product and, on the other hand, on the cost of contribution.

When maximum wholesale prices for medicinal products are on the agenda, a representative of the organisation of medicinal product wholesalers shall take a seat on the committee and when the maximum retail prices for medicinal products are on the agenda a representative of the retail pharmacy organisation shall take a seat on the committee. When the maximum retail price for veterinary medicinal products is on the agenda, a representative of the veterinarians’ organisation shall take a seat on the committee and the views of [the Icelandic Food and Veterinary Authority][5)] shall also be elicited. In the case of a tied vote on a decision by the committee, the chair shall cast the deciding vote.

The Medicinal Products Pricing Committee undertakes publication of a medicinal products price list, listing maximum prices and the contribution reference prices for prescription medicinal products and all veterinary medicinal products. The Medicinal Products Pricing Committee may collect a fee for the medicinal products price list as determined by the Minister, acting on a proposal by the Medicinal Products Pricing Committee. The fee shall cover the cost of preparing the list.

Pharmacy licence-holders, veterinarians, medicinal products wholesalers and medicinal product manufacturers must provide the Medicinal Products Pricing Committee with all reports and documentation concerning the pricing of medicinal products, and other information which the Committee deems necessary in order to carry out its tasks.

The cost of the committee's work, including remuneration to committee members and staff, shall be paid from the State Treasury.

If the committee does not agree to a requested price, price change or contribution, it must give grounds for its decision and inform the applicant of his/her right to refer the committee's decision to a court, under the general rules. Decisions by the committee are not subject to review by the Minister.

The Minister may in regulations[6)] make further provision for rules on the work of the Medicinal Products Pricing Committee. The Medicinal Products Pricing Committee may adopt its own rules of procedure.][7)]

[1)] Act No. 89/2003, Article 3. [2)] Act No. 112/2008, Article 62 [3)] Act No. 126/2011, Article 197. [4)] Act No. 45/2012, Article 5. [5)] Act No. 167/2007, Article 74. [6)] Regulation No. 353/2013, cf. No. 979/2014. [7)] Act No. 83/2004, Article 11.

[Article 44][1)]

[Importers and manufacturers of medicinal products and their representatives must make application to the Medicinal Products Pricing Committee concerning the maximum wholesale price, [health insurance][2)] contribution, and for all price changes to prescription medicinal products and veterinary medicinal products; applications must be accompanied by information on the wholesale price of the medicinal product in question in the countries specified in regulations, *cf.* paragraph 3 of Article 43.

A decision by the Medicinal Products Pricing Committee on the price of a medicinal product shall be available and made known to the applicant no later than 90 days after receipt of an application. If an applicant has not submitted the necessary information with an application, the Medicinal Products Pricing Committee shall notify the applicant without delay as to what information is missing. A reasoned decision by the Medicinal Products Pricing Committee shall be available and made known to the applicant no later than 90 days after receipt of the necessary additional information by the committee. If a decision is not available within this time limit the applicant may market the medicinal product at the price applied for.

If a decision is also requested on the health insurance contribution for those with health insurance, this shall be made known to the applicant no later than 180 days after receipt of an application concerning the price of a medicinal product. If an applicant has not submitted the necessary information with an application, the Medicinal Products Pricing Committee shall notify the applicant as to what information is missing. A decision by the Medicinal Products Pricing Committee shall in such case be available and made known to the applicant no later than 90 days after its receipt of the necessary additional information.

A decision by the Medicinal Products Pricing Committee on an increase in the price of a medicinal product shall be available and made known to the applicant no later than 90 days after receipt of an application. The applicant shall provide the committee with sufficient information, including detailed information on the factors which it considers to justify the increase to the previously determined price. If an applicant has not submitted the necessary information with an application, the Medicinal Products Pricing Committee shall notify the applicant as to what information is missing. A decision by the Medicinal Products Pricing Committee shall in such case be available and made known to the applicant no later than 90 days after its receipt of the necessary additional information. If the Committee has received an unusually large number of applications it may extend the processing period for one additional period of 60 days. The applicant shall be notified of such an extension before the end of the normal time that the Medicinal Products Pricing Committee has to process the application. If no decision has been made available within this time limit the applicant may raise the price in accordance with the application.][3)]

[1)] Act No. 89/2003, Article 3. [2)] Act No. 112/2008, Article 62. [3)] Act No. 83/2004, Article 12.

[Article 45

The Medicinal Products Pricing Committee is empowered to impose a price freeze. If a price freeze covers all medicinal products or medicinal products in a specific category the decision shall be reviewed at least once a year. Exemptions may be granted from a price freeze on the basis of an application under exceptional circumstances. Applicants requesting exemption shall provide sufficient information on the reasons for the request. A reasoned decision by the Medicinal Products Pricing Committee shall be made available and made known to the applicant within 90 days. If an applicant has not submitted the necessary information with an application, the Committee shall notify the applicant as to what information is missing. A decision by the Medicinal Products Pricing Committee shall in such a case be made available and made known to the applicant no later than 90 days after its receipt of the necessary additional information. If the committee has received an unusually large number of applications for exemptions it may extend the processing period for one additional period of 60 days. The applicant shall be notified of such an extension before the end of the normal time that the Committee has to process the application.][1)]

[1)] Act No. 83/2004, Article 13.

[Article 46

The Medicinal Products Pricing Committee shall re-evaluate the pricing basis of medicinal products in Iceland as compared to the same products in the European Economic Area on a regular basis and no less frequently than at two-year intervals, making proposals for changes if such evaluation so warrants.][1)]

[1)] Act No. 83/2004, Article 13.

[SECTION XVI
Importing and manufacture of medicated animal feeds.][1)]

[1)] Act No. 20/2013, Article 2.

[Article 47

Only those who hold a licence from the Icelandic Medicines Agency may import or manufacture medicated animal feeds. Licences referred to in sentence 1 shall confer the right to distribute medicated animal feeds. Regulations[1)] issued by the Minister shall contain further provisions on conditions for the issue of licences and the use, monitoring, delivery and distribution of medicated animal feeds.][2)]

[1)] Regulation No. 607/2013. Regulation No. 608/2013. [2)] Act No. 20/2013, Article 2.

[SECTION XVII][1)]
Surveillance, legal proceedings and penalties.

[1)] Act No. 20/2013, Article 2.

[Article 48][1)]

[Surveillance under this Act, regulations or other instructions shall be the responsibility of the Icelandic Medicines Agency. [In order to enforce a rectification or the implementation of a measure, or with respect to a violation of this Act, the Icelandic Medicines Agency may apply the following actions:][2)]

1. issue a reprimand;
2. issue a reprimand, allowing a suitable time limit for rectification;
[3. impose per diem fines];[3)]
[4.][3)] halt or limit the activities or use in question, including seizing products and ordering their destruction.

Halting activities and destruction of products may only be applied if the Icelandic Medicines Agency deems the danger of the operation or use in question to be so serious that action must be taken immediately, or if violations are repeated and the parties concerned fail to rectify the situation within the prescribed time limit. In the case of such a violation the Icelandic Medicines Agency may propose that the Minister revoke the licence for the operation in question.

In cases where a seal is used to halt activities, a special seal identifying the Icelandic Medicines Agency shall be used.][4)]

[If instructions from the Icelandic Medicines Agency are not heeded within the specified time limit, the Agency may levy per diem fines on parties subject to inspection under this Act. Such fines may amount to up to ISK 50,000 per 24-hour period. Their amount shall be determined by the nature of the violation and the financial capacity of the party subject to inspection. [The Minister][5] shall, in regulations,[6] provide for more detailed rules on the determination of per diem fines.

If a decision on a fine is referred to a court the per diem fines shall not commence until final judgement is pronounced. The fines shall accrue to the State Treasury and are enforceable by execution without a prior court judgement.][3]

[1] Act No. 20/2013, Article 2. [2] Act No. 58/2005, Article 8. [3] Act No. 63/2002, Article 5. [4] Act No. 108/2000, Article 30. [5] Act No. 162/2010, Article 64. [6] Regulation No. 412/2012.

[Article 49][1]

[...[2]

Violations against this Act or regulations issued on the basis of the Act shall be punishable by fines, unless more severe penalties are incurred under other legislation. In the case of repeated or major violations, punishment may consist of ...[3] imprisonment for up to two years. [The handling of gains resulting from a violation of this Act is punishable under Article 264 of the Criminal Code.][4]

An attempted violation or complicity in a violation of this Act is under Section III of the Criminal Code.

Medicinal products and substances for medicinal products which are manufactured, imported or sold illegally in Iceland shall be confiscated by court order, together with any profit from illegal sale of medicinal products. The value of the confiscated property shall accrue to the State Treasury.][5]

[1] Act No. 20/2013, Article 2. [2] Act No. 88/2008, Article 234. [3] Act No. 82/1998, Article 215. [4] Act No. 10/1997, Article 13. [5] Act No. 55/1995, Article 2.

[SECTION XVIII][1]
Final provisions.

[1] Act No. 20/2013, Article 2.

[Article 50][1]

[The Minister may issue regulations[2] on the implementation of this Act, e.g. on dispensing of medicinal products in dose packaging and on restrictions on and monitoring of the production and marketing of specific substances which can be used for illegal manufacture of narcotic drugs or psychotropic substances.

The Rules of the European Union on the European Medicines Evaluation Agency may be issued as Regulations.[3]

[The Rules of the European Union on Medicinal Products, as adapted for the European Economic Area Agreement and the European Free Trade Association Treaty, may be published as Regulations.[4]][5]

Decisions by the Icelandic Medicines Agency may be referred to the Minister under the provisions of the Public Administration Act.][6]

[1] Act No. 20/2013, Article 2. [2] Regulation No. 421/1988 (on prescription forms and prescription of medicinal products, etc.), as amended, cf. No. 539/2000, No. 91/2001, No. 105/2001, No. 111/2001 and No. 233/2001. Regulation No. 633/1994 (on the entry into force of EEA Acts on medicinal products). Regulation No. 650/1996 (on fees for medicinal product licences). Regulation No. 699/1996 (on the importation and wholesale distribution of medicinal products), cf. No. 484/2001 and No. 846/2002. Regulation No. 426/1997 (on licences for the sale of medicinal products and pharmacies), cf. No. 886/2013. Regulation No. 212/1998 (on importation by individuals of medicinal products for their own use), cf. No. 230/2001 and No. 609/2015. Regulation No. 421/1998 (on practical training of pharmacology students and pharmacy technicians). Regulation No. 539/2000 (on veterinarians' authorisations to prescribe medicinal products), cf. No. 912/2000, No. 14/2008, No. 1069/2008, No. 392/2012, No. 931/2012 and No. 661/2015. Regulation No. 967/2000 (on the importation, sale and distribution of homeopathic medicinal products). Regulation No. 850/2002 (on dosages of medicinal products). Regulation No. 241/2004 (on the selection, storage and handling of medicinal products in hospitals and other health care institutions), cf. No. 255/2016. Regulation No. 443/2004 (on clinical trials on humans), cf. No. 907/2004 and No. 1099/2010. Regulation No. 893/2004 (on manufacture of medicinal products), cf. No. 1100/2010. Advertisement No. 902/2004 (on adoption

of international conventions in the field of medicinal products). Regulation No. 441/2006 (on collection, handling, storage and distribution of blood), cf. No. 1024/2007, No. 411/2010, No. 625/2012 and No. 216/2016. Regulation No. 1077/2006 (on dentists' prescribing of medicinal products), cf. No. 874/2010 and No. 343/2016. Regulation No. 1065/2008 (on sale of medicinal products by mail order). Regulation No. 1188/2008 (on quality and safety in handling of human cells and tissues), cf. No. 453/2017. Regulation No. 141/2011 (on marketing authorisation of proprietary medicinal products, its labelling and attachments), cf. No. 1021/2011, No. 484/2012, No. 943/2012, No. 923/2014, No. 1006/2014, No. 118/2015, No. 654/2015, No. 891/2015, No. 1007/2015 and No. 993/2016. Regulation No. 142/2011 (on marketing authorisation of natural medicinal products and registration of traditional natural medicinal products). Regulation No. 1022/2011 (on colouring agents in medicinal products). Regulation No. 980/2016 (on advertising of medicinal products), cf. No. 1153/2016. Regulation No. 452/2017 (on the importation of tissues and cells from non-EEA states). 3) Regulation No. 181/2001. 4) Regulation No. 652/2001. Regulation No. 402/2002. Regulation No. 834/2004. Regulation No. 386/2006. Regulation No. 346/2007. Regulation No. 950/2008. Regulation No. 418/2010. Regulation No. 768/2010, cf. No. 896/2014. Regulation No. 794/2010. Regulation No. 788/2012. Regulation No. 1150/2013. Regulation No. 652/2015. Regulation No. 554/2016. Regulation No. 251/2017. Regulation No. 1264/2017. Regulation No. 1265/2017. 5) Act No. 76/2002, Article 28. 6) Act No. 108/2000, Article 31.

[Article 50 a.

This Act gives effect to Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use and Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products, reference to which is made in point 15q of Chapter XIII of Annex II to the EEA Agreement, as amended by Decision No. 158/2013 of the EEA Joint Committee of 8 October 2013.]1)

1) Act No. 52/2015, Article 3.

[Article 51]1)

This Act shall enter into force 1 July 1994.

...

1) Act No. 20/2013, Article 2.

Temporary provisions.

1. Regulations issued on the basis of the Medicinal Products Act, No. 108/1984, and the Medicinal Products Distribution Act, No. 76/1982, as amended,1) shall remain in force until new Regulations have entered into force, provided their content is not contrary to this Act.
2. Present pharmacy licence-holders shall retain their pharmacy licences following the entry into force of Section VII of this Act. Pharmacies operated by co-operatives in Akureyri and Selfoss, and the Pharmacy of the University of Iceland, shall have until [15 March 1996]2) to fulfil the requirements of this Act. Physicians and local authorities shall retain their pharmacy licences until [15 March 1996]2) and thereafter until a person fulfilling the requirements of this Act applies for a pharmacy licence. Notwithstanding the provisions of paragraph 2 of Article 6 of the Act on the Distribution of Medicinal Products, No. 76/1982, the Minister may extend pharmacy licences until the provisions of Section VII enter into force.
3. The provisions of Sections VII and [XV]3) shall not enter into force, however, until [15 March 1996].2) The same shall apply to the decision on remuneration for dispensing of medicinal products by veterinarians under [Article 33.]3)

[4. A Medicinal Products Pricing Committee shall be appointed under paragraph 1 of Article 43 of this Act not later than 1 September 2004. The Medicines Pricing Committee and Medicines Contribution Committee shall retain their authority until the Medicinal Products Pricing Committee has been appointed.]4)

[5. Marketing authorisations issued or renewed before 30 October 2005 shall be renewed once for a period of five years in accord with paragraph 2 of Article 7 of this Act.][5)]

[6. Licences to sell or import medicinal products, wholesale licences and manufacturing licences issued by the Minister of Health before 1 October 2008 remain in force, notwithstanding the provisions of Articles 20, 32 and 34 of this Act.][6)]

[1)] With respect to regulations for which provision was made in previous legislation, see Lagasafn 1990, cols. 1041–1050 and 1054–1062. [2)] Act No. 118/1995, Article 4. [3)] Act No. 89/2003, Article 4. [4)] Act No. 83/2004, Article 14. [5)] Act No. 58/2005, Article 9. [6)] Act No. 97/2008, Article 11.

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