Medicinal Products Bill

(Submitted to Alþingi (parliament) during the 147th legislative session, 2017–2018)

SECTION I

Objectives, scope and definitions

Art. 1

Objective

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 that apply in the European Economic Area or under the European Free Trade Association (EFTA) Treaty. Where trade in medicinal products is concerned, it shall 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 bodies in the health services towards fulfilling current health service objectives. It is also 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.

Art. 2

Scope

This Act applies to both medicinal products for humans and medicinal products for animals, unless otherwise stated.

This Act shall not apply to: medical devices, cf. Act on Medical Devices; chemicals and chemical mixtures, cf. the Chemicals Act; foodstuffs, cf. the Act on Foodstuffs; or tobacco cf. the Tobacco Control Act. In the case of a medicinal product, cf. art. 3, para. 1 no. 6, which contains radioactive material, the provisions of both this Act and the Radiation Protection Act apply.

In case of doubt regarding whether a particular chemical or compound is deemed a medicinal product, the Icelandic Medicines Agency decides. If, taking into consideration all its properties, a commodity falls under the definition of a medicinal product under art. 3, para. 1 no. 6, and also the definition of a commodity subject to other legislation, the provisions of this Act shall apply.

Art. 3

Definitions

For the purpose of this Act, the following definitions of words and concepts apply:

1. Magistral formula: All medicinal products prepared in a pharmacy in accordance with a prescription by a physician for an individual patient.

2. Manufacturing of medicinal products: All processes involved in manufacturing medicinal products, including the purchasing of chemicals and supplies as well as the manufacturing process, e.g. weighing, mixing, filling, packing, repacking, labelling, obtaining approval, storage and quality control.

3. Falsified medicinal products: Any medicinal product with incorrect information about:

a. its identity, including its wrapping and labelling, its name or its composition, and this on all of its components, including the excipients, and the dosage of these components

b. its source, relating to its manufacturer, its country of manufacturing, its country of origin or holder of the marketing authorisation; or

c. its history, including records and documents relative to the distribution channels used. This definition does not apply to inintended defects and is without prejudice to copyright infringement.

4. Wholesale distribution of medicinal products: All processes involved in the distribution of medicinal products at the wholesale level, including import, export, sourcing and distribution. This does not, however, include the distribution of medicinal products to the general public through retail sales.

5. Excipient: Any part of a medicinal product, other than the active ingredients and packaging material.

6. Herbal medicinal product: Any medicinal product that only contains active ingredients that are one or more herbal substances or one or more fully prepared herbal medicinal products, or a combination of one or more such herbal substances and one or more such fully prepared herbal medicinal products.

7. Medicinal product: Any substance or combination of substances that:

a. are presented as having properties for treating or preventing disease in human beings or animals, or

b. may be used for or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to confirming a medical diagnosis.

8. Medicinal product advertising: Any advertising or promotion of medicinal products, written or verbal, including pictures, providing samples of products, promotions and conferences, which are paid for directly or indirectly by a marketing authorisation holder for the purpose of encouraging prescription, dispensing, sale or use of medicinal products. Information provided to the public

by government authorities about medicinal products, for example regarding decisions about marketing authorisation, product pricing or whether Icelandic Health Insurance contributes to the cost of medicinal products for an insured person, are not deemed be medicinal product advertising.

9. Electronic prescription portal: A centralised message switcher that manages electronic prescriptions, mediating between prescription issuer and pharmacy.

10.Prescription: When a physician, dentist, veterinarian, midwife or nurse with the authority to prescribe issues a statement, a prescription, that the issuer of the prescription has personally prescribed the individual concerned, or the person responsible for an animal, a specified medicinal product in a specified amount and given instructions for dose and usage. A physician, dentist or veterinarian shall confirm a prescription that he/she issues, with his/her signature.

11. Pharmacological care: Collaboration between physician and pharmacist for improved pharmacotherapy. Pharmacological care can be of various types and includes a pharmacist reviewing the medicinal products used by an individual, with respect to dosage, price, potential interactions etc. It may also include instruction to ensure adherence and to encourage a patient to take responsibility for his/her own health.

12. Brokering of medicinal products: All activities connected to the sale or purchase of a medicinal product that are not considered part of wholesale distribution and do not involve the handling of the medicinal product or negotiations, either acting as an independent body or on behalf of another individual or legal entity.

13. Intermediate product: A mixture of active pharmaceutical ingredients with excipients, intended for further processing in the manufacture of a medicinal product.

14. Centralised prescription card: A centralised prescription “card” contains all the information about medicinal products prescribed to an individual, in electronic format.

15. Retail sales of medicinal products: Sales of medicinal products that take place in:

a. a special shop, a pharmacy, where the general public can purchase medicinal products, both prescription-only medicinal products and those available without prescription, or

b. a general shop where the public can purchase the smallest package and lowest strength of nicotine and fluoride medicinal products, and in exceptional cases certain over-the-counter medicinal products under the Icelandic Medicines Agency list, where the agency has granted an exemption for such sales.

16. Homeopathic medicinal product: Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States.

17. Officinal formula: Any medicinal product which is prepared in a pharmacy, or by the holder of a manufacturing licence, according to current medicinal product standards and dispensed in a pharmacy.

18. Active substance: Any substance or mixture of substances intended for use in the manufacture of a medicinal product and which will, if used in the product’s manufacture, be an active ingredient in a medicinal product that is intended to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to confirm a medical diagnosis.

SECTION II

Administration, the Icelandic Medicines Agency's role and responsibility

Art. 4

Administration

The Minister shall be ultimately responsible for administration of this Act.

A pharmaceutical manager works within the Ministry, administering pharmaceutical matters on behalf of the Minister. He/she shall be a qualified pharmacist and may not have any personal interests at stake in the manufacture, import or distribution of medicinal products.

Art. 5

Icelandic Medicines Agency

The Icelandic Medicines Agency is a governmental authority under the aegis of the Minister.

The Minister appoints 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, and have management experience The Director is responsible for administering the Agency, ensures that it operates in accordance with all currently applicable laws and regulations, and is responsible for its day-to-day operations.

Neither the Director nor any other Agency employee may have any personal interests at stake in the development, manufacture, marketing, importation, brokering or wholesale/retail sales of medicinal products.

Art. 6

Role of the Icelandic Medicines Agency

The role of the Icelandic Medicines Agency is to:

1. evaluate medicinal products in accordance with current rules in the European Economic Area and under the European Free Trade Association (EFTA) Treaty,

2. handle the issuing, amending, cancelling and revoking of marketing authorisaton for medicinal products, the issuing of licences for parallel importation of medicinal products and the registering of homeopathic medicinal products and traditional herbal medicinal products in accordance with rules that apply in the European Economic Area,

3. process applications for licences to import and sell for prescription medicinal products that do not have marketing authorisation in Iceland,

4. receive notifications of side-effects of medicinal products, from the public and healthcare workers, and record them in the database of the European Medicines Agency, and receive and record side-effects of medicinal products from veterinarians and people responsible for animals,

5. grant permission for manufacturing and wholesale marketing of medicinal products in Iceland, monitor such activities, including monitoring the availability of medicinal products in Iceland, and record in the European Medicines Agency database information about licences issued for the manufacturing and wholesale marketing of medicinal products,

6. grant pharmacy licences, operating licences, and exemptions from requirements for a pharmacy licence, and monitor such activities,

7. grant authorisations for clinical research on medicinal products and monitor the execution of such research,

8. manage and run a clinical medicinal products database,

9. monitor the handling of medicinal products in healthcare institutions and working premises of healthcare professionals,

10. monitor medicinal product advertising in accordance with this Act,

11. monitor habit-forming and addictive medicinal products and carry out the tasks entrusted to the Agency under the Narcotics Act,

12. monitor the collection, treatment, storage and distribution of blood, as well as its quality and the safe treatment of human cells and tissues,

13. make decisions about the price of medicinal products in Iceland, such decisions to be taken guided by the purpose of this Act, that the use of medicinal products in Iceland should be based on reasonable and economical principles, as well as deciding if Icelandic Health Insurance should participate in the cost of a medicinal product,

14. carry out tasks entrusted to the Agency under the Act on Medical Devices,

15. deal with other matters pertaining to the implementation of this Act, including collaboration with foreign organisations in the field of pharmacology.

The Minister may, in regulations, assign the Icelandic Medicines Agency to monitor other companies, other activities or products other than medicinal and related products if special circumstances recommend it and it is connected to the Agency's role according to this Act.

The Icelandic Medicines Agency may operate a research laboratory for the purpose of conducting research on its own behalf. The Icelandic Medicines Agency may also assign independent research laboratories in Iceland or abroad to conduct research on behalf of the Agency.

Art. 7

Working groups and specialists

The Icelandic Medicines Agency may appoint committees and working groups and summon experts to assist *inter alia* with assessing and classifying medicinal products, monitoring and auditing, and with deciding the price of

medicinal products and the degree of participation by Icelandic Health Insurance.

Neither the experts summoned to assist the Icelandic Medicines Agency nor those appointed to committees or working groups, cf. para. 1, may have any personal interests at stake in the developing, manufacturing, marketing, importation, brokering or wholesale/retail sales of medicinal products.

SECTION III

Pharmacopoeias

Art. 8

Pharmacopoeias valid in Iceland

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

Other requirements regarding the form, quality and purity of medicinal products, active ingredients and excipients, and also methods for the analysis and calibration of these substances are in accordance with legal advertisements regarding the validity of Nordic and other European standards in Iceland.

Art. 9

The Icelandic Medicines Agency registrar

The Icelandic Medicines Agency shall keep a medicinal product register. Information shall be entered on the register about those medicinal products that have marketing authorisation in Iceland. The register shall be based on generic names for medicinal products, but also include information about proprietary names and packaging available on the market. All information about medicinal products in the medicinal product register required for a computer system, such as active ingredients, interactions, contraindications and dose size, shall be available to the general public, companies and public bodies.

The Icelandic Medicines Agency is responsible for publishing the register of proprietary medicinal products. All medicinal products with marketing authorisation in Iceland shall be recorded in the register of proprietary medicinal products, arranged by class of product or another comparable manner. The register shall include indications, contraindications, dose size, principal side-effects and a maximum retail price for prescription-only medicinal products.

Art. 10

Other provisions valid in Iceland for medicinal products

The European Union guidelines for good practice in manufacturing medicinal products and good practice in medicinal product distribution, as well as other guidelines from the European Union in the field of pharmacology that have been adopted through the European Economic Area Agreement and the European Free Trade Association (EFTA) Treaty, shall be valid in Iceland. Current versions of the guidelines shall be valid in Iceland, and the Icelandic Medicines Agency shall publish a list of the relevant regulations on their website.

Payments for Iceland's participation in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme are made from the Treasury.

SECTION IV

Marketing authorisation for medicinal products

Art. 11

Marketing medicinal products

Only medicinal products with marketing authorisation from the Icelandic Medicines Agency may be marketed in Iceland.

Notwithstanding the provisions in para. 1, the following medicinal products may be sold in Iceland without a marketing authorisation:

a. magistral and officinal formulae. Magistral and officinal formulae may only be imported to Iceland and marketed, for patients' special needs, if a bilateral agreement for such trade exists between Iceland and the country concerned, and a mutual recognition of good manufacturing practice (GMP) between the countries.
b. deactivated immunological medicinal products for animals that are produced from pathogens and antibodies retrieved from an animal or animals from a particular farm and that are used to treat the animal

or animals from the same farm at the same place, with a licence from the Icelandic Medicines Agency, on the advice of the Icelandic Food and Veterinary Authority (MAST),

c. investigational medicinal products that are used in clinical research on medicinal products on humans,

d. medicated feed.

Notwithstanding the provisions of para. 1, the following medicinal products may also be sold in Iceland without a marketing authorisation:

a. traditional herbal medicinal products that have been registered with the Icelandic Medicines Agency, and

b. homeopathic medicinal products that have a marketing authorisation in another member state in the European Economic Area and have been registered with the Icelandic Medicines Agency.

Art. 12

Authorisation for compassionate use of medicinal products

On application, the Icelandic Medicines Agency may in special circumstances allow the sale or dispensing of medicinal products, in limited quantities, that do not have marketing authorisation or have not been marketed in Iceland.

The Icelandic Medicines Agency may make the use of medicinal products conditional upon compassionate use, and may recall the authorisation if the agency’s conditions are not met or if grave problems emerge regarding quality, safety or efficacy of the medicinal product, including grave side-effects.

The Icelandic Medicines Agency may establish procedures for the distribution of medicinal products subject to authorisation under para. 1.

Art. 13

Exemptions for medicinal products that do not have marketing authorisation in Iceland

The Icelandic Medicines Agency may, based on an application from a physician in his/her own name or that of a healthcare establishment, a dentist or a veterinarian, grant an exception to the provisions of art. 1l para. 1. Such an exception shall only be granted when the following conditions have been fulfilled:

a. sufficient grounds are provided to show that special circumstances recommend the use of a medicinal product that does not have a marketing authorisation in Iceland or that has a marketing authorisation but is not for sale in Iceland, and

b. the application includes information showing that the quantity for which an exemption is sought is limited to the needs of those who will use the medicinal product, and whether the use is intended for a particular individual or animal, or if it will take place in a healthcare establishment or a specified place.

When an application under para. 1 is approved, the applicant is responsible for informing the patient, or person responsible for an animal, that the prescribed medicinal product does not have a marketing authorisation in Iceland, and also making the patient, or person responsible for an animal, aware of potential side-effects and other information that may be necessary when using the product. If the medicinal product does not have a marketing authorisation in another member state within the European Economic Area, the physician, dentist or veterinarian is wholly responsible for prescribing the medicinal product in question.

Art. 14

Prescription-only medicinal products, dispensing permission and other restrictions

In connection with issuing, changing or renewing a marketing authorisation or granting a parallel import licence for a medicinal product, the Icelandic Medicines Agency shall decide the following:

a. whether a medicinal product should be prescription-only or not,

b. whether use of a medicinal product should only be permitted in a healthcare institution providing general or specialised healthcare services, cf. the Health Service Act,

c. whether the prescription of a medicinal product or a patient's first prescription of a medicinal product as part of a course of medication should only be permitted for specialists in specific fields of medicine.

The Icelandic Medicines Agency may allow that a specified quantity or form of a medicinal product that it has decided should only be available on prescription, cf. para. 1a, is exempted from being prescription-only.

When a decision is made based on para. 1a or para. 2, that a medicinal product may be sold without prescription, the Icelandic Medicines Agency shall also decide whether it is permitted to sell the product on the basis of a limited pharmacy licence.

The Icelandic Medicines Agency may, on its own initiative, change decisions that have been made under paras. 1–3. In doing so, the Icelandic Medicines Agency shall *inter alia* take into account the Council of Europe's resolution about the classification of medicinal products in connection with supply.

Art. 15

Duration and renewal of marketing authorisation

A marketing authorisation is valid for five years, with the exceptions stated in this article.

A marketing authorisation for a medicinal product may be renewed at the end of that period, on the basis of a reassessment, by the Icelandic Medicines Agency, of the risks and rewards. Before the reassessment is made, the

marketing authorisation holder shall, at least nine months before the expiry date of the authorisation, submit to the Icelandic Medicines Agency satisfactory and updated data about quality, safety and efficacy of the product, including data that are to be found in notifications of suspected side-effects and which are in safety reports that are regularly updated and provided in accordance with the provisions of Section XIII of this Act. When a marketing authorisation for a medicinal product has been renewed once it shall be valid indefinitely, unless the Icelandic Medicines Agency decides, with due diligence for pharmacovigilance, including the reason that an insufficient number of patients have used the medicinal product concerned, that it should only be renewed for five years.

A market licence expires if a medicinal product for which a marketing authorisation has been granted has not been placed on the market within three years of the granting of the licence, or if a medicinal product that has been granted a marketing authorisation and placed on the market has not in fact been on the market continuously for three years. The Icelandic Medicines Agency may make exceptions to these provisions in special circumstances and for reasons of public health. Such exceptions must be supported by substantial grounds.

Art. 16

Revocation, temporary withdrawal or amendment of marketing authorisation

The Icelandic Medicine Agency shall revoke, withdraw temporarily or amend a marketing authorisation if:

a. the medicinal product is believed to be harmful or lacking therapeutic efficacy,

b. the benefit-risk balance of the medicinal product is not believed to be favourable,

c. the qualitative and quantitative composition of the medicinal product is believed to be not as declared, or

d. mandatory information accompanying the application for a marketing authorisation proves to be incorrect.

The Icelandic Medicines Agency may revoke, withdraw temporarily or amend a marketing authorisation if:

a. the requirements under art. 46, of a marketing authorisation holder regarding pharmacovigilance for a medicinal product (obligations of a marketing authorisation holder) are not fulfilled,

b. the interval until animal produce utilisation may recommence after treatment with a medicinal product is no longer deemed sufficiently long to ensure that medicinal product traces in the animal product will be below levels that are harmful for human consumers,

c. manufacturing of the medicinal product is not in accord with information provided in the application for a marketing authorisation for a product,

d. quality control is not carried out in accordance with the requirements of current specifications as provided in rules.

A marketing authorisation holder may initiate a request that the Icelandic Medicines Agency withdraws a marketing authorisation.

Art. 17

Issue of special marketing authorisation for a medicinal product, on the initiative of the Icelandic Medicines Agency

The Icelandic Medicines Agency may, on the basis of a marketing authorisation in another European Economic Area (EEA) member state and the fulfilment of the conditions in this Act, issue a special marketing authorisation for a medicinal product that is deregistered or for a product for which an application has not previously been made, if the Agency deems it justifiable,

based on public health or safety, to have the medicinal product on the market. If the Icelandic Medicines Agency is considering applying this authority, it shall inform the marketing authorisation holder in the country where the medicinal product is registered of its intentions, and also request a copy of the appraisal report and a current marketing authorisation for the medicinal product, from the authorities in that country.

Art. 18

Permission for short-term distribution of a medicinal product that has not been granted a marketing authorisation

The Icelandic Medicines Agency may permit short-term distribution of a medicinal product that has not been granted a marketing authorisation, provided that it is intended for defence against a pathogen, toxin, chemical agent or ionising radiation that is suspected or confirmed to have spread or be about to spread.

Art. 19

Applications for marketing authorisation for a vaccine, serum or immunogen for animals

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

Art. 20

The duty of marketing authorisation holders and their agents to provide information

Marketing authorisation holders, their agents and applicants for parallel import licences have a duty to provide the Icelandic Medicines Agency, as soon

as possible, all new information regarding a medicinal product for which an application has been for a marketing authorisation or a parallel import licence and which is being considered by the Agency. The same applies to a medicinal product that has been granted a marketing authorisation or parallel import licence.

Art. 21

Regulations on registration, marketing authorisation and parallel import of medicinal products

The Minister shall make further provision in regulations for the granting of marketing authorisation for medicinal products, including the processing of applications, recognition of the European Medicines Agency centralised marketing authorisation, the duration of data-protection for pre-clinical and clinical trials, recognition on the basis of marketing authorisation from another member state of the European Economic Area Agreement, amendments to conditions of marketing authorisation, revocation and recall of marketing authorisation and exemptions for medicinal products that do not have marketing authorisation in Iceland.

The Minister shall make further provisions in regulations for granting marketing authorisation for homeopathic medicinal products or herbal medicinal products and their registration, including about the processing of applications, registration on the basis of marketing authorisation in other European Economic Area states, and the definition of traditional use.

The Minister may make further provisions in regulations for conditions for granting a parallel import licence for a medicinal product, including about the definition of parallel import of a medicinal product, the time limit for processing applications for a licence, requirements for supporting documents and labelling of inner/outer packaging and patient information leaflets for parallel import medicinal products.

SECTION V

Clinical medicinal product trials

Art. 22

Authorisation to conduct clinical medicinal product trials on humans

Clinical medicinal product trials on humans may only be carried out with authorisation. The Minister shall make further provisions in regulations for the granting of a licence to conduct clinical medicinal product trials on humans. The regulations shall designate the government body that grants permission to conduct clinical medicinal product trials on humans. The regulations shall also take account of European Economic Area legislation about clinical medicinal product trials on humans, the Helsinki Declaration and the Data Protection Act and the Patients' Rights Act.

SECTION VI

Manufacture of medicinal products

Art. 23

Manufacture of medicinal products

Medicinal products may only be manufactured on the basis of a manufacturing licence issued by the Icelandic Medicines Agency. The Minister shall make further provisions regarding conditions for granting a manufacturing licence, in regulations concerning the manufacture of medicinal products and active substances, including requirements made regarding professional qualifications of the lead licence holder, about instruments and equipment, premises and staff of the licence holder, and about good manufacturing practice in medicinal product manufacture.

The provisions of para. 1 do not, however, apply to the manufacture by hospitals or other healthcare institutions of medicinal products that are part of the relevant institution's treatment which takes place immediately after the

manufacture. Such manufacture should take account of European Council Resolutions regarding medicinal product manufacture that takes place in hospitals or other healthcare institutions.

A manufacturing licence for medicinal products includes permission for wholesale distribution of those medicinal products or types of medicinal products that are named in the manufacturing licence of the relevant licence holder.

Art. 24

Temporary or limited manufacturing licence

The Icelandic Medicines Agency may issue a temporary manufacturing licence or limit the licence to specific types of manufacturing, such as automated dose dispensing or the manufacture of formulae.

The Minister shall make further provisions in regulations about the conditions for granting a licence for automated dose dispensing.

Art. 25

Manufacture of active substances

Manufacture, import and export of active substances to be used in the manufacturing of medicinal products for holders of a marketing authorisation may only be carried out by those who have registered with the Icelandic Medicines Agency.

The Icelandic Medicines Agency shall maintain and publish on the Agency’s website a list of companies that are authorised to manufacture, import or export, cf. para. 1. The Icelandic Medicines Agency may remove a company from this list if it becomes clear that it has grossly or repeatedly violated the rules issued under para. 3.

The Minister shall make further provisions for the registration and activities of manufacturers, importers or exporters of active substances in regulations on

the manufacture of medicinal products and active substances, including requirements regarding specialised knowledge, organisation and staff, and good manufacturing practice.

Art. 26

Duty to notify falsified medicinal products or active substances

Anyone who has been granted a licence to manufacture medicinal products, cf. art. 22 para. 1, or has registered as a manufacturer, importer or exporter of active substances, cf. art. 24 para. 1, must notify the Icelandic Medicines Agency without delay if he/she purchases or is offered for purchase, active substances or intermediate products that are falsified or suspected of being falsified.

SECTION VII

Wholesale distribution of medicinal products

Art. 27

Wholesale licence for distribution of medicinal products

Wholesale distribution of medicinal products may only take place on the basis of a wholesale distribution licence issued by the Icelandic Medicines Agency. The Minister shall make further provision regarding the conditions for granting a wholesale distribution licence, in regulations about the import, wholesale distribution and brokering of medicinal products, including requirements regarding professional qualifications of the lead licence holder, about instruments and equipment, housing and employees of the licence holder, and about good practice in wholesale distribution of medicinal products.

Art. 28

Duties of a wholesale distribution licence holder

A wholesale distribution licence holder which sells medicinal products to pharmacies, healthcare institutions or the working premises of physicians, dentists or veterinarians, must have sufficient supplies of specific necessary medicinal products for humans that have been granted a marketing authorisation in Iceland and have been marketed in Iceland and that the wholesale distribution licence holder has distributed. In consultation with the Directorate of Health and a representative from the wholesale distribution licence holder, the Icelandic Medicines Agency shall publish on its website a list of the specific necessary medicinal products and the volume of stocks that are involved.

Wholesale distribution licence holders must electronically record information about their sales, by a method approved by the Icelandic Medicines Agency. On request they shall also provide the Icelandic Medicines Agency with information about their activities.

The Icelandic Medicines Agency may prohibit the wholesale distribution licence holder from selling and transporting stocks of medicinal products out of Iceland when it is foreseeable that such export could influence the availability of the medicinal product in Iceland in such a way as to threaten life and health of humans or animals.

Wholesale distribution licence holders that sell medicinal products to pharmacies, healthcare institutions or the working premises of physicians, dentists or veterinarians shall maintain and publish a waiting list for medicinal products, i.e. a list of medicinal products that have been granted a marketing authorisation in Iceland and that are marketed and distributed by a wholesale distribution licence holder, but which are unavailable at a given time.

Art. 29

Wholesale distribution licence holders' authority

Wholesale distribution licence holders may only sell to the following parties medicinal products at the wholesale level:

a. holders of a wholesale distribution licence,

b. holders of a pharmacy licence,

c. holders of a licence to sell veterinarian medicinal products,

d. holders of an exemption from the requirements of a pharmacy licence,

e. holders of a licence for automated dose dispensing,

f. healthcare institutions that have the services of a pharmacist,

g. physicians, dentists and veterinarians for use in their own work,

h. research laboratories and universities, cf. the Universities Act, that work in the field of pharmaceutical research and teach medicine and pharmacology.

Wholesale distribution licence holders may only purchase medicinal products from the following parties:

a. other holders of a wholesale distribution licence, and

b. those who have permission to sell medicinal products at the wholesale level but are exempted from the requirement of a wholesale distribution licence, cf. art. 22 para. 3.

Wholesale distribution licence holders may also sell the smallest package size and lowest available dose of nicotine medicinal products and fluoride medicinal products to anyone who so requests, cf. art. 31 para. 2.

Art. 30

Licence to broker medicinal products

The brokering of medicinal products is only permitted for those who have registered with the Icelandic Medicines Agency as medicinal product brokers.

The Icelandic Medicines Agency shall maintain and publish on its website a list of those who are authorised to broker medicinal products, cf. para. 1. The Icelandic Medicines Agency may remove a medicinal product broker from this list if it transpires that he/she has grossly or repeatedly violated the rules issued under para. 3.

The Minister shall make further provision for the registration and activities of those who broker medicinal products, in regulations about the import, wholesale distribution and brokering of medicinal products, including the requirements made of medicinal product brokers regarding specialised knowledge, organisation and staff, and about best practice in distribution of medicinal products.

SECTION VIII

Medicated feed

Art. 31

Licence to import and manufacture medicated feed

Medicated feed may only be imported and manufactured under a licence issued by the Icelandic Medicines Agency. A licence under clause 1 also confers permission to distribute medicated feed.

The Minister shall make further provisions about requirements for granting licences to import and manufacture medicated feed for animals, including use, monitoring, delivery and distribution.

SECTION IX

Medicinal product sales, pharmacies etc.

Art. 32

Retail sales of medicinal products

Medicinal products may only be sold to the general public on the basis of a pharmacy licence, or a licence to sell medicinal products intended for animals, which is granted by the Icelandic Medicines Agency, but with exceptions under this section.

Sale of the smallest package and lowest strength of nicotine medicinal products and fluoride medicinal products which do not require a prescription may be sold by anybody. The medicinal products listed in this paragraph may not be sold by self-service. The provisions in art. 8 paras. 1 and 7 of the Tobacco Control Act shall also apply to sales of these medicinal products. Monitoring, coercive measures and penalties are subject to the provisions of the Public Health and Pollution Control Act.

The Icelandic Medicines Agency may make exceptions from the provisions in para. 1, for the retail sale of specific over-the-counter medicinal products in general shops. The Icelandic Medicines Agency shall publish a list on its website of those medicinal products, strengths and package sizes that may be sold under the provision of this clause. Art. 37b also applies to those who have been granted such an exemption.

The Minister shall make further provisions for the operation of a pharmacy and conditions for granting a pharmacy licence in regulations on pharmacy licences and pharmacies, including requirements for the licence holder's premises and staff, granting of licences and exemptions from requirements for a pharmacy licence, running of branch pharmacies and their classification according to their nature and the extent of the services that they are permitted to provide, and about mail-order retailing of medicinal products and good working practice in pharmacies.

Art. 32

Pharmacy licences

The Icelandic Medicines Agency issues pharmacy licences. Pharmacy licences are only issued to individuals who meet the following conditions:

a. hold a valid licence to work as a pharmacist in Iceland, cf. Healthcare Professionals Act, and

b. have worked as a pharmacist for at least two years, of which twelve months must have been in a pharmacy in the European Economic Area.

The Icelandic Medicines Agency may evaluate work experience in pharmacies outside the European Economic Area as comparable to the work experience requirements under para. 1b. In addition the Icelandic Medicines Agency may grant a pharmacy licence to a pharmacist with a minimum of twelve months' work experience as a pharmacist, of which six months must have been in a pharmacy within the European Economic Area, if it has been demonstrated that no pharmacy will otherwise be operated in a specific municipality or a population centre within a municipality.

The Icelandic Medicines Agency may grant a pharmacy licence to the director of a primary healthcare centre if no pharmacy is operating in that municipality, or in a specific population centre within the municipality that is served by the healthcare centre. An agreement may be made with a pharmacy licence holder from elsewhere to provide a service of this kind, including the operation of a pharmacy.

Art. 34

Licences for veterinarians to sell medicinal products intended for animals

On application, the Icelandic Medicines Agency grants veterinarians a licence to sell medicinal products that are intended for animals, when the following requirements are met:

a. they have a valid licence to work as a veterinarian in Iceland, cf. the Veterinarian and Animal Healthcare Act, and

b. they have notified the Icelandic Food and Veterinary Authority (MAST) that they have commenced veterinarian work, and also the address from which the work takes place.

A veterinarian licence to sell medicinal products is limited to the sale and provision of the following:

a. over-the-counter medicinal products for animals, and

b. medicinal products that have been prescribed by a veterinarian, cf. Regulation on veterinarians' authority to prescribe medicinal products.

Art. 35

Operation of pharmacies

A pharmacy licence under art. 33 is restricted to the operation of one pharmacy, and the pharmacy licence holder is responsible for the operation of the pharmacy. Pharmacies shall be identified in a conspicuous manner.

A pharmacist may only be the holder of one pharmacy licence at a time. A pharmacy licence holder may apply to the Icelandic Medicines Agency for a licence to operate branch pharmacies from his/her pharmacy in a municipality, or a population centre within a municipality, where no pharmacy is operating.

Medicinal products may be sold by mail-order, on the basis of a pharmacy licence.

A pharmacy licence holder may give a discount from the maximum retail price of prescription medicinal products. If a pharmacy licence holder gives individuals covered by Icelandic Health Insurance a discount on the contribution reference price, Icelandic Health Insurance shall be notified of the discount and the institution calculates the insured individual's payment, based on the discount price and the individual's price level position, cf. art. 29 para. 1 no. 6 of the Health Insurance Act.

Art. 36

Preparation of formulae in pharmacies

Pharmacies may prepare magistral and officinal formulae on the basis of a medicinal product manufacturing licence, cf. art. 22. If magistral or officinal

formulae are not prepared in a pharmacy, the pharmacy licence holder shall ensure that they are procured as soon as possible after they are requested.

Art. 37

Operating licence

If an individual or legal entity other than the pharmacy licence holder is responsible for operating a pharmacy, the operator must apply to the Icelandic Medicines Agency for an operating licence for the operation.

The operating licence shall provide for the respective responsibilities of the holder of the operating licence and the holder of the pharmacy licence with regard to which party is responsible for ensuring compliance with specific articles of this Act as well as regulations laid down in the Act relating to the operation of pharmacies.

Art. 38

Obligations of pharmacy licence holders

A pharmacy licence holder must:

a. keep adequate stocks of medicinal products marketed in Iceland, obtain as promptly as possible medicinal products requested for sale that are not stocked and offer for sale, as far as possible, the main types of pharmaceutical, nursing and medical supplies,

b. provide the Icelandic Medicines Agency with information connected to the operation of the pharmacy at the request of the Agency,

c. be connected to the central payment system of Icelandic Health Insurance and comply with other rules under art. 29 of the Health Insurance Act, and also notify Icelandic Health Insurance of each occasion when the pharmacy licence holder grants a discount on the contribution reference price of a prescription-only medicinal product,

d. provide the general public and healthcare workers with information about medicinal products, their use and proper storage,

e. conduct pharmacological care,

f. record electronically all information about medicinal product prescriptions, in the format that the Directorate of Health decides and that complies with the rules of the Icelandic Data Protection Authority, cf. the Data Protection Act, and also provide to the Directorate of Health on request all information that appears in prescriptions of medicinal products about the dispensing of medicinal products, in the format that the Directorate requests; the Directorate of Health may require such information to be produced for a period of up to one year retrospectively,

g. employ a pharmacy technician who assists the pharmacy licence holder, or other pharmacists working on his/her behalf, in dispensing medicinal products.

Art. 39

Online sales of medicinal products

Holders of a pharmacy licence, cf. Art. 33, who intend selling medicinal products online on the basis of that licence, must notify the Icelandic Medicines Agency of their intention not later than the commencement of online sales.

The Icelandic Medicines Agency shall maintain and publish on its website a register of pharmacy licence holders who have notified the Agency of their intention to sell medicinal products online under para. 1. The Icelandic Medicines Agency shall also publish on its website information about online sales of medicinal products, including the potential risk that accompanies the purchase of medicinal products online from a party that does not have the necessary licence.

The Minister may make further provisions in regulations for the conditions and implementation of internet sales of medicinal products, including

information that must accompany the pharmacy licence holder's notification of intent to sell medicinal products online, about the form and content of such a notification, about formal and technical requirements for a website which includes an online sales outlet for medicinal products, and conditions for the publication of the common logo for legally operating online pharmacies/retailers in European Union member states.

SECTION X

Management of medicinal products in healthcare institutions and other workplaces of healthcare professionals

Art. 40

Hospital pharmacies

Hospitals and other institutions operating under the Health Service Act may operate a pharmacy in that institution. Such pharmacies are termed hospital pharmacies. The operation of a hospital pharmacy shall be financially separate from the healthcare institution's other operations.

If no hospital pharmacy is operated in a healthcare institution operating under the Health Services Act, a pharmacist shall be responsible for procurement of medicinal products and monitoring their administration.

If the healthcare institution does not employ a pharmacist under the provisions of para. 2, the institution shall reach an agreement with an external holder of a pharmacy licence, pharmacy operating licence holder, pharmacist or hospital pharmacy for a service that includes a responsibility to procure medicinal products and monitor their administration.

A healthcare institution may seek tenders for the operation of a hospital pharmacy which provides the services referred to in this section, provided that the operation fulfils all legal requirements pursuant to the operation and running of a pharmacy.

Art. 41

Authority and obligations of hospital pharmacies.

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

Premises, equipment and staffing of a hospital pharmacy or a pharmaceutical storage operated by a healthcare institution shall be in accordance with the provisions of this Act and regulations on pharmacy licences and pharmacies.

Art. 42

Medicinal products committees in healthcare institutions

At each healthcare institution where healthcare services are provided within the meaning of the Health Service Act, a medicinal products committee shall work to promote the safe and reasonable use of medicinal products. The medicinal products committees of healthcare institutions shall issue and make public a list of medicinal products that are to be used at the relevant institution. A medicinal products committee shall include at least one working physician from the institution and one pharmacist who works on behalf of the institution. Care shall always be taken to select the less expensive product for use in an institution when a choice exists between two or more medicinal products.

Healthcare institutions may have joint medicinal products committees and medicinal product lists.

Art. 43

Medicinal Therapeutic Committee

Icelandic Health Insurance, cf. art. 8 of the Health Insurance Act, appoints a Medicinal Therapeutic Committee that is a forum for collaboration between Icelandic Health Insurance and the medicinal products committees of the

University Hospital of Iceland and Akureyri Hospital. The committee shall include representatives from the Directorate of Health, regional healthcare organisations, primary healthcare facilities in the capital area and the Icelandic Medicines Agency, patients' organisations and an ethicist nominated by the University of Iceland.

The Medicinal Therapeutic Committee is a professional body that shall, *inter alia*, assess whether and how medicinal products benefit patients, prepare a prioritised list of medicinal products and work towards cost-effectiveness in the introduction of new medicinal products and the use of medicinal products in the health system. On recommendation from the Medicinal Therapeutic Committee, Icelandic Health Insurance may consult experts from outside the institution for assessment of individual factors under this article.

The Medicinal Therapeutic Committee shall:

1. consider applications and make proposals to Icelandic Health Insurance about medicinal products subject to licence (specialty-care high-cost medicines), i.e. medicinal products that are costly and demand special care in their use and are intended for treatment of certain types of disease that are further defined in regulations,
2. promote access to medicinal products subject to licence,
3. promote cost-effectiveness in the use of medicinal products, including by supervising making medicinal product lists for healthcare institutes and other instructions about reasonable use of medicinal products Iceland,
4. make proposals for prioritisation in the introduction of new medicinal products,
5. prepare instructions for the use of medicinal products subject to licence in Iceland. The instructions shall be prepared in collaboration with the medicinal products committees of the healthcare organisations,

6. carry out horizon-scanning in collaboration with the Icelandic Medicines Agency,
7. prioritise the introduction of new medicinal products, and
8. work closely with buyers and healthcare organisations.

The Minister may make further provision in regulations for the implementation of this article.

Art. 44

Regulations

The Minister shall in regulations make further provisions regarding the management of medicinal products in healthcare institutions and other workplaces of healthcare professionals, including selection, storage and usage of medicinal products in hospitals, other healthcare institutions and the workplaces of healthcare professionals where medicinal products are used.

SECTION XI

Prescriptions and dispensing of medicinal products in pharmacies

Art. 45

Authority to prescribe medicinal products

Only holders of a valid licence to work as a physician, dentist, midwife or nurse in the European Economic Area, cf. the Healthcare Practitioners Act, or a valid licence to work as a veterinarian in Iceland, cf. the Veterinarians and Animal Health Services Act, may prescribe medicinal products.

Art. 46

Prescription issuing and monitoring

Prescriptions may only be issued in the following manner:

a. by an electronic prescription that is prepared in an approved manner,
b. by a prescription that is written or printed on paper, or

c. by a prescription that is read aloud on the telephone and received by a pharmacist in a pharmacy.

The Directorate of Health supervises prescriptions issued by physicians and dentists, and the provision of medicinal products by a pharmacist in cases of emergency, cf. the Medical Director of Health and Public Health Act. The Icelandic Food and Veterinary Authority (MAST) supervises prescriptions issued by veterinarians, cf. the Veterinarians and Animal Health Services Act.

Art. 47

Electronic prescription portal

For the purposes of mediating electronic prescriptions, cf. art. 44 para. 1a, between a prescription issuer and a pharmacy, the Directorate of Health shall operate an electronic prescription service. Electronic prescriptions may be stored within the electronic prescription service while the prescription is valid. The Directorate of Health may establish procedures for access by prescription issuers and pharmacies to the electronic prescription service. The processing of personal data that passes through the electronic prescription service is governed by the Data Protection Act.

Art. 48

Dispensing of medicinal products by prescription

Medicinal products requiring a prescription may only be dispensed on presentation of a prescription at a pharmacy. For the purposes of this article, presentation of a prescription includes the accessing, by a pharmacy employee, of an electronic prescription from the electronic prescription service.

Only a holder of a valid licence to work in Iceland as a pharmacist, cf. the Healthcare Practioners Act, may dispense prescriptions in a pharmacy or branch pharmacy, and that person is responsible for correct processing according to the prescription.

In emergencies a pharmacist in a pharmacy may dispense prescription-only medicinal products in the smallest package that is available on the Icelandic market, without a prescription being presented.

A pharmacy licence holder shall keep a register of the dispensing of medicinal products under para. 3. The register shall be available to the Icelandic Medicines Agency on request.

Art. 49

Interchangeability of medicinal products

When dispensing medicinal products in a pharmacy, a pharmacist may change a physician's prescription to another generic medicinal product in similar quantity to that stated in the prescription, but only when the medicinal product is to be found on the Icelandic Medicines Agency's list of interchangeable medicinal products, cf. para. 3.

A physician who prescribes a medicinal product, cf. art. 43, may restrict the rights of a pharmacist under para. 1, partially or wholly.

The Icelandic Medicines Agency shall keep and publish on its website a list of interchangeable medicinal products in which generic medicinal products, biosimilars and medicinal products with equivalent therapeutic effects are grouped together.

Art. 50

Regulations

The Minister shall make further provisions in regulations for physicians' prescriptions and the dispensing of medicinal products in pharmacies, including the form of prescriptions, prescription of medicinal products, prescription of habit-forming and addictive medicinal products, the Icelandic Medicines Agency's list of interchangeable medicinal products, dispensing of prescription-only medicinal products in emergencies by a pharmacist without the provision

of a prescription, period of validity for prescriptions and labelling of medicinal products in pharmacies, and about approved ways of preparing electronic prescriptions.

The Minister shall make further provisions in regulations for licences for dentists to prescribe medicinal products.

The Minister shall make further provisions in regulations for licences for veterinarians to prescribe medicinal products.

SECTION XII

Medicinal product advertisements

Art. 51

Authority to advertise medicinal products

Advertising of medicinal products in Iceland is permitted, with the restrictions referred to in this Section.

Art. 52

Information in medicinal product advertisements

A medicinal product advertisement shall always be presented objectively and supply adequate information about correct usage of the product. An advertisement may not exaggerate or mislead about the medicinal product’s properties. Information in an advertisement shall always be in accordance with the approved summary of the medicinal product’s properties.

Art. 51

Prohibited medicinal product advertisements

Advertising the following is prohibited:

a. medicinal products that do not have a marketing authorisation or a parallel import licence in Iceland,

b. medicinal products that have a marketing authorisation or a parallel import licence in Iceland but that have not been placed on the market,

c. magistral formulae, and

d. officinal formulae.

Advertising the following to the general public is prohibited:

a. prescription-only medicinal products,

b. medicinal products containing substances that fall within the scope of the Narcotics Act.

The general public refers to all others than those who are licensed to work as a physician, dentist, pharmacist or nurse, cf. the Healthcare Practitioners Act, or have been granted a licence as a veterinarian under the provisions of the Veterinarians and Animal Health Services Act.

The Icelandic Medicines Agency may grant exemptions in order that a medicinal product can be advertised in professional journals for healthcare workers other than those listed in para. 2.

The Icelandic Medicines Agency may grant an exemption from para. 1 if the objective is to inform the general public about measures for disease prevention and control that the Minister has approved for action, cf. Section IV of the Health Security and Communicable Diseases Act.

Art. 54

Samples of medicinal products

A medicinal product sample in the smallest package size may be delivered personally to a physician, dentist, veterinarian, midwife or nurse without charge, provided that it is a newly registered medicinal product being introduced on the market and it is not classed as an addictive and habit-forming medicinal product. Such delivery is only authorised if the physician has signed and dated a request

to this effect. Only one sample of a newly registered medicinal product may be delivered each year, for five years after the registration date.

Art. 55

Duties of marketing authorisation holders

Marketing authorisation holders or their agents in Iceland shall keep a list of all their medicinal product advertisements published in Iceland. The records shall be retained for two years and the Icelandic Medicines Agency shall be granted access to the records on request.

The Minister, having received recommendations from the Icelandic Medicines Agency, shall in regulations make provisions for the form and content of information that shall appear in the list of advertisements kept by marketing authorisation holders or their agents, cf. para. 1, including target group, content, form of publication and distribution method.

Art. 56

Monitoring of medicinal product advertising

The Icelandic Medicines Agency monitors medicinal product advertising under this Act.

The Icelandic Medicines Agency can order the publication of a medicinal product advertisement which contravenes the articles in this section or regulations about medicinal product advertising to be halted.

The Icelandic Medicines Agency can order marketing authorisation holders or their agents in Iceland, who have published advertisements that contravene the articles of this section, publish corrections or additional clarification with respect to unlawful medicinal product advertisements.

The Icelandic Medicines Agency may provide for the form, content, type of publication and publication place of such corrections and clarifications, by a decision.

Art. 57

Regulations

The Minister shall make further provision in regulations about medicinal product advertising, including advertising of over-the-counter medicinal products, advertising of prescription-only medicinal products and necessary information to be included in the advertisements. These regulations shall be consistent with the rules of the European Economic Area regarding the advertising of medicinal products.

SECTION XIII

Pharmacovigilance

Art. 58

The Icelandic Medicines Agency pharmacovigilance system

The Icelandic Medicines Agency shall operate a pharmacovigilance system in order to monitor the safety of medicinal products, and the agency shall keep a record of all side-effects that are notified to the Agency. The Icelandic Medicines Agency pharmacovigilance system shall be based on good practice in pharmacovigilance. The Icelandic Medicines Agency may provide the Directorate of Health, patient organisations operating in Iceland, the European Medicines Agency, the European Commission, competent authorities in the field of pharmaceuticals in European Economic Area states and marketing authorisation holders information about side-effect notifications.

Art. 59

Duties of marketing authorisation holders

Marketing authorisation holders must:

a. operate a pharmacovigilance system in order to monitor the safety of medicinal products, assess possibilities to minimise and prevent risks and

undertake appropriate measures if necessary. A marketing authorisation holder's pharmacovigilance system shall be based on good practice in pharmacovigilance,

b. have a detailed description of their pharmacovigilance system in their pharmacovigilance system master file (PSMF) of side-effects of medicinal products other than medicinal products for animals, and provide the Icelandic Medicines Agency with access to the description on request,

c. keep a record of side-effects suspected of being connected to medicinal products, and have the record accessible to the Icelandic Medicines Agency,

d. report side-effects suspected of being connected to medicinal products to the Icelandic Medicines Agency or the European Medicines Agency,

e. compile and submit to the Icelandic Medicines Agency a summary of a medicinal product's safety, and

f. have in their service a person responsible for pharmacovigilance, who shall reside and work inside the European Economic Area.

The Icelandic Medicines Agency can require a marketing authorisation holder for a medicinal product for humans to designate a contact person in Iceland, who acts on behalf of the person responsible for pharmacovigilance under para. 1f.

The Icelandic Medicines Agency monitors marketing authorisation holders' fulfilment of duties under para. 1. A marketing authorisation holder must supply the Icelandic Medicines Agency with data and information that the Agency considers necessary to perform its monitoring role. Marketing authorisation holders are further required to grant the Icelandic Medicines Agency access to their premises for the same purpose, if deemed necessary by the Agency.

The Icelandic Medicines Agency shall notify the European Medicines Agency, the European Commission, competent authorities in the field of pharmaceuticals in other European Economic Area states and the marketing authorisation holder if the findings of monitoring are that a marketing

authorisation holder does not fulfil the conditions of the pharmacovigilance system as described in the pharmacovigilance system master file, cf. para. 1b.

Art. 60

Duties of healthcare professionals

If, during their work, healthcare professionals become aware of a suspicion that side-effects are connected to some medicinal product, they are must notify it to the Icelandic Medicines Agency.

The Icelandic Medicines Agency shall provide on its website special online forms on which healthcare professionals must notify such side-effects.

Art. 61

Dissemination of information on medicinal product safety

A marketing authorisation holder for a medicinal product for humans may not publish information about the product's safety based on information in the pharmacovigilance system without first, or simultaneously, notifying the Icelandic Medicines Agency, the European Medicines Agency and the European Commission of the publication.

A marketing authorisation holder for a medicinal product for animals may not publish information about the product's safety based on information in the pharmacovigilance system without first, or simultaneously, notifying the Icelandic Medicines Agency of the publication.

A marketing authorisation holder shall ensure that information under provisions in paras. 1 and 2 is presented objectively and is not misleading.

The Icelandic Medicines Agency can order a marketing authorisation holder for a medicinal product for humans to publish information about the medicinal product with respect to patient safety, including information about side-effects

suspected of being connected to the medicinal product, or to distribute such information to a specified group of healthcare professionals.

Art. 62

Regulations

The Minister may make further provisions in regulations for requirements for marketing authorisation holders in connection with pharmacovigilance, in accordance with the relevant rules of the European Economic Area.

The Minister may make provision in regulations for the obligations of healthcare professionals to notify the Icelandic Medicines Agency of side-effects suspected of being connected to a medicinal product, including information from medical records and death registers.

The Minister may provide in regulations for the rights of patients, their next of kin and people responsible for an animal to notify the Icelandic Medicines Agency of side-effects suspected of being connected to a medicinal product.

SECTION XIV

Medicinal product price and contributions

Art. 63

Pricing of medicinal products and contributions from Icelandic Health Insurance

The Icelandic Medicines Agency decides the price of prescription-only medicinal products in Iceland and whether Icelandic Health Insurance contributes towards paying for a medicinal product, cf. the Health Insurance Act. Pricing of over-the-counter medicinal products and all veterinarian mediincal products is unregulated.

Decisions of the Icelandic Medicines Agency under this section are final at the administrative level and cannot be appealed to the Minister. Should the Icelandic Medicines Agency not accept a requested price, price change or contribution level according to provisions in this section, the Agency shall state the grounds for its decisions and inform the applicant of his/her authority to submit the Agency's decision to the courts.

Pharmacists, veterinarians, wholesalers of medicinal products and marketing authorisation holders are obliged to provide the Medicines Agency with all information relating to pricing of medicinal products and provide other information that the Agency considers necessary to carry out its role under this section.

Costs incurred by the Icelandic Medicines Agency with regard to pricing medicinal products and contributions by Icelandic Health Insurance are paid from the Treasury.

The Minister shall make further provision in regulations for the pricing of medicinal products and contributions by Icelandic Health Insurance to the cost of medicinal products, including that the price decisions of Icelandic Health

Insurance shall be based on pricing in specified states in the European Economic Area.

The Icelandic Medicines Agency may introduce procedural rules regarding decisions on medicinal product pricing and contributions by Icelandic Health Insurance under this section.

Art. 64

Decisions on pricing of medicinal products and reimbursement from Icelandic Health Insurance

The Icelandic Medicines Agency shall appoint a six-person committee, cf. para. 7, for a term of five years. The committee shall comprise professionals in the fields of medicine, pharmacy and finance. Three committee members shall be appointed following nominations from Icelandic Health Insurance, the Directorate of Health, and the ministry in charge of government revenues at any time. Two committee members shall be appointed, one following a joint nomination by marketing authorisation holders in Iceland and the other following a joint nomination by the Organisation of the Disabled in Iceland and the Consumers' Association. The chair shall be appointed by the Icelandic Medicines Agency without nomination. Alternates shall be appointed in the same manner. In taking decisions, the Icelandic Medicines Agency shall bear in mind the objective of this Act, to keep the cost of medicinal products to a minimum.

The Icelandic Medicines Agency shall decide the following, after consideration and in accord with the opinion reached by the committee, cf. para. 1:

Maximum wholesale and retail prices for prescription medicinal products for humans.

Whether Icelandic Health Insurance contributes under section III of the Health Insurance Act to the cost of medicinal products for humans marketed in Iceland.

The contribution reference price, i.e. the price used by Icelandic Health Insurance, taking into account discounts granted by marketing authorisation holders on dispensing of the medicinal products.

Contributions to the cost of medicinal products for which exemptions have been granted under para. 11. The Icelandic Medicines Agency may refer applications concerning medicinal products for which exemptions have been granted under this provision to Icelandic Health Insurance.

When maximum pricing of prescription-only medicinal products at wholesale level is under consideration, the representative from the wholesale licence holders takes a seat on the committee, cf. para. 1, and when maximum pricing at retail level is under consideration the representative from the pharmacy licence holders takes a seat on the committee. If voting is evenly divided on a decision, cf. para. 1, the chair has the casting vote.

If the Icelandic Medicines Agency makes a decision, on the basis of para. 2 nos. 1–5, which is contrary to the opinion of the committee, cf. para. 1, the Agency shall explain the grounds of such a decision, detailing all points of view that lie behind the decision. Such grounds shall always be made public, including on the Icelandic Medicines Agency website.

Vendors, i.e. medicinal product wholesalers, marketing authorisation holders and their agents, who wish to sell prescription medicinal products at a lower price than the maximum price indicates, shall notify that price to the Icelandic Medicines Agency, which publishes the reduced price in the next issue of the medicinal products price list. Retailers shall sell the medicinal product at the same price at all their points of sale.

Art. 65

Criteria for deciding medicinal product price

The Icelandic Medicine Agency shall monitor the pricing of medicinal products for humans at wholesale and retail level, and also the contribution reference price in states in the European Economic Area, and take them into account in its pricing determinations under para. 2 nos. 1 and 3. In the case of parallel import of a medicinal product, the Icelandic Medicines Agency shall, in deciding the maximum price, consider the price that the importer applies for, provided it is lower than the price for the same medicinal product in Iceland. In deciding the price and contribution reference price for generic medicinal products i.e. medicinal products containing the same active ingredient(s), and biosimilars, the Agency shall consider the price of the relevant medicinal products in the European Economic Area.

Art. 66

Medicinal products price list and reference price list

The Icelandic Medicines Agency is responsible for issuing and publishing a medicinal products price list in which maximum prices and contribution reference prices for prescription-only medicinal products for humans are published.

The Icelandic Medicines Agency is responsible for issuing and publishing a reference price list in which generic medicinal products and medicinal products with equivalent therapeutic effects are arranged in reference price groups for determining the contribution by Icelandic Health Insurance. Decisions by the Icelandic Medicines Agency, according to provisions under art. 62, para. 2 nos. 2–5, shall be based on an assessment of a medicinal product’s efficacy and also on the cost of contributing.

Art. 67

Pricing application procedure

Medicinal product importers, brokers, marketing authorisation holders and their agents shall apply to the Icelandic Medicines Agency for maximum wholesale prices, contributions from Icelandic Health Insurance and for all price changes to prescription medicinal products for humans, and their applications shall be accompanied by information on the wholesale price of the relevant medicinal product in those countries specified in regulations, cf. art. 61 para. 5.

A decision by the Icelandic Medicines Agency on the price of a medicinal product shall have been reached and made known to an applicant no later than 90 days after receipt of an application. If an applicant has not submitted the necessary information with an application, the Agency shall notify the applicant without delay as to what information is missing. In that case a reasoned decision by the Icelandic Medicines Agency shall have been reached and made known to the applicant no later than 90 days after receipt of the necessary additional information by the Agency. If a decision is not reached within this time limit, the applicant may market the medicinal product at the price applied for.

If a decision on the health insurance contribution for those covered by Icelandic Health Insurance has also been requested, 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, he/she shall be notified as to what information is missing. A reasoned decision by the Icelandic Medicines Agency shall in that case reached and made known to the applicant no later than 90 days after receipt of the necessary additional information

A decision by the Icelandic Medicines Agency on an increase in the price of a medicinal product shall be reached and made known to the applicant no later than 90 days after receipt of an application. The applicant shall provide the Agency with sufficient information, including detailed information on the factors which he/she deems to justify the increase from a previously determined

price. If an applicant has not submitted the necessary information with an application, the Icelandic Medicines Agency shall notify the applicant as to what information is missing. A decision by the Icelandic Medicines Agency shall in such case be reached and made known to the applicant no later than 90 days after receipt of the necessary additional information. If the Icelandic Medicines Agency 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 Agency's normal processing period. If no decision has been made within this time limit the applicant may increase the price in accordance with the application.

Art. 68

Price freeze

The Icelandic Medicines Agency is empowered to impose a price freeze. If a price freeze is imposed on all medicinal products or on 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 in special circumstances. Applicants requesting exemption shall provide sufficient information on the reasons for the request. A reasoned decision by the Icelandic Medicines Agency shall be reached and made known to the applicant within 90 days. If an applicant has not submitted the necessary information with an application, the Agency shall notify the applicant as to what information is missing. A decision by the Icelandic Medicines Agency shall in such a case be reached and made known to the applicant no later than 90 days after receipt of the necessary additional information. If the Agency 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 Agency's normal processing period.

Art. 69

Review of pricing basis

The Icelandic Medicines Agency shall review the pricing basis of medicinal products in Iceland as compared to the same products in the European Economic Area regularly and no less frequently than at two-year intervals, making proposals for changes if such review so warrants.

SECTION XV

Medicinal product statistics and database

Art. 70

Medicinal product statistics

Companies that manufacture medicinal products, import or export them, hold stocks of, deal or resell, distribute, deliver, pack or repack medicinal products, and associates or companies connected to them must supply the Minister, or institutions or legal entities that the Minister nominates, with information about turnover and quantity of sold or delivered medicinal products. The information shall be in the form requested by the Minister or the institution or legal entity nominated by the Minister.

The Minister or the institution or legal entity nominated by the Minister may supply other bodies with the information. Publication of numerical information about turnover and quantity of all medicinal products and medicinal packages is deemed to be supplying information.

The companies and/or their associations named in para. 1 shall further supply the Icelandic Medicines Agency with information about turnover and quantity of sold medicinal products in electronic format if so requested.

The Minister shall make provisions in regulations about the supplying and handling of information about medicinal products under para. 1, including supplying and handling confidential information, authority for supplying information under para. 2, supplying information to the Minister under para. 3 and supplying information to the Icelandic Medicines Agency under para. 3.

The Icelandic Medicines Agency, the Directorate of Health or Icelandic Health Insurance must inform other bodies nominated by the Minister about information and data on medicinal product sales and deliveries, for presentation and publication of statistical information about quantity and turnover of medicinal products.

Art. 71

Medicinal products database

For the purpose of ensuring quality of the healthcare service and the safety of patients, general monitoring of medicinal product prescribing by physicians, monitoring of habit-forming and addictive medicinal products, dissemination of information about personal prescriptions, *inter alia* to improve safety in physicians' prescribing, and for monitoring the cost of medicinal products and the implementation of a quality development programme in healthcare services and scientific research, the Directorate of Health, or another party nominated by the Minister to conduct the work, operates a medicinal products database of prescriptions and dispensing of medicinal products that holds information from pharmacies, cf. art. 37, para. 1f.

The Minister may entrust outside parties with operating the medicinal products database pursuant to a contract thereon.

Patient personal identity shall be specially encrypted in the medicinal products database. The Directorate of Health, or the body entrusted with operating the medicinal products database, is responsible for encrypting personal identities and has sole custody of the key to it, for both encryption and decryption.

The Icelandic Data Protection Authority, in accordance with the institution's role under the Data Protection Act, monitors the security of personal information in the medicinal products database and its operation in other respects.

Art.72

Access to information in the medicinal products database

The Directorate of Health has access to the medicinal products database in accordance with the monitoring role of that office according to the Health Service Act, the Medical Director of Health and Public Health Act and this Act, when any of the following conditions are met:

there is reason to believe that a patient has been prescribed a larger quantity of habit-forming and addictive medicinal products than can be deemed normal, from more than one physician.

there is reason to believe that a patient has been prescribed more habit-forming and addictive medicinal products than can be deemed normal in a specific period.

there is reason to believe that a physician has self-prescribed habit-forming and addictive medicinal products.

The Directorate of Health shall also have access to the medicinal products database for purposes of general monitoring of medicinal product prescription and to monitor and promote reasonable use of medicinal products in Iceland.

A patient shall have access to his/her own medicinal products information in the database.

Physicians, nurses, midwives, pharmacists and dentists involved in a patient's care and in need of the patient's history of medicinal product use for treatment purposes shall have access to the patient's medicinal products information for the last three years in the database. The duties of these healthcare professionals, such as confidentiality and non-disclosure of sensitive personal information gained in the execution of their work, including medicinal products information, are subject to provisions of the Healthcare Practitioners Act, Patients' Rights Act and other legislation as applicable.

The Icelandic Medicines Agency has access to the medicinal products database in accordance with the monitoring role of the Agency under this Act when any of the following conditions are met:

there is reasoned suspicion of falsification of a prescription or if it is suspected of having been made in some other illegal manner, or

there is reasoned suspicion of incorrect dispensing of a prescription or if the dispensing has been done in an illegal manner.

The Icelandic Medicines Agency also has access to the medicinal products database for purposes of general monitoring of quality, efficacy and safety of medicinal products that are used in Iceland, including monitoring of pharmacovigilance.

Icelandic Health Insurance has access to the medicinal products database in accordance with the institution's monitoring role under the Health Insurance Act when any of the following conditions are met:

when it is necessary to verify information about a patient's history of medicinal product use for the purpose of monitoring health insurance cost, or

to check physicians' prescriptions and prescribing habits for purposes of monitoring medicinal product cost.

The Icelandic Food and Veterinary Authority has access to the medicinal products database in accordance with its monitoring role under the Veterinarians and Animal Health Services Act when any of the following conditions are met:

there is reason to believe that a person responsible for an animal has had prescribed a larger quantity of habit-forming and addictive medicinal products than can be deemed normal, from more than one veterinarian.

there is reason to believe that a person responsible for an animal has had prescribed more habit-forming and addictive medicinal products than can be deemed normal in a specific period .

there is reason to believe that a veterinarian has self-prescribed habit-forming and addictive medicinal products.

The Icelandic Food and Veterinary Authority shall also have access to the medicinal products database for the purpose of monitoring prescribing by veterinarians and to monitor and promote the reasonable use of medicinal products for animals in Iceland.

Information from the medicinal products database may be used for scientific research. Access to personally identifiable information from the medicinal products database for scientific research is subject to the Patients' Rights Act, the Act on Scientific Research in the Health Sector, and the Data Protection Act.

The Directorate of Health, or the body that has been entrusted with operating the medicinal products database, shall conduct active monitoring of access to the medicinal products database under this article. The Directorate of Health is responsible for the centralised prescription cards and establishes procedural rules for access to the medicinal products database. The procedures shall include rules on controlling and tracking access. If an individual requests information about who has accessed information about him/her from the medicinal products database, the Directorate of Health, or the body entrusted with operating the medicinal products database, must provide him/her with the information.

The Ministry shall also have access to non-personally identifiable information from the medicinal products database for the purpose of decision taking and policy making with regard to medicinal products.

Access to the personal identity of individual patients shall not be accessible otherwise than as stated in this article unless it is unequivocally necessary for specific monitoring measures.

Art. 73

Statistics based on information from the medicinal products database

Statistics may be processed from the medicinal products database. In statistical processing it shall be ensured that the personal identity of patients cannot be accessed. The Directorate of Health supervises the granting of access

to statistics from the medicinal products database. Access to statistics from the medicinal products database may be granted only for the following purposes:

a. education or research,

b. official monitoring of medicinal product costs,

c. processing of medicinal product statistics under art. 66.

SECTION XVI

Monitoring

Art. 74

Monitoring and implementation of inspections

The Icelandic Medicines Agency monitors compliance with the requirements established in this Act and regulations pursuant to it. In order to monitor compliance and to accommodate requests from another member state of the European Economic Area agreement or the European Free Trade Association (EFTA) Treaty, the Icelandic Medicines Agency may go to any site that operates on the basis of the following licences, registrations or exemptions:

a. manufacturing licence, cf. art. 22.

b. registration as an importer, exporter or manufacturer of an active substance, cf. art. 24.

c. wholesale licence, cf. art 26.

d. registration as a medicinal products broker, cf. art. 29.

e. exemption for retail sales of medicinal products in a general shop, cf. art.31 para. 3.

f. pharmacy licence, art. 32.

g. licence to sell medicinal products intended for animals, cf. art. 33.

Monitoring includes permission to take samples and photographs and to have samples of medicinal products, active substances, intermediate products or

excipients delivered for closer examination, and also permission to examine and photocopy data. It is not permitted to enter residential premises or similar place for this purpose without consent of the owner or person in charge of the building, except with a court order.

Art. 75

The Icelandic Medicines Agency's authority and duty to inform

During inspection and monitoring, including audits, cf. art. 72, anyone subject to monitoring shall without charge provide all necessary assistance to the monitoring, e.g. assistance from staff and access to buildings and equipment. The Icelandic Medicines Agency must also be provided with all requested information, and all data must be submitted that the Agency deems relevant to the monitoring. Other official bodies which hold information that may be relevant to the monitoring shall, at the request of the Icelandic Medicines Agency, provide that information, including personally identifiable information.

The Icelandic Medicines Agency may call on independent external experts for advice if this is important for the monitoring in the view of the Agency.

Art. 76

Implementation of monitoring

In carrying out monitoring under art. 70, the Icelandic Medicines Agency may demand free of charge samples of medicinal products, including packaging materials and accompanying information leaflets, active substances, intermediate products or excipients. Furthermore, the Icelandic Medicines Agency may require all information and data relevant to the monitoring.

The party monitored under para. 1 shall be given the opportunity to provide the Icelandic Medicines Agency with information about the medicinal product, active substance, intermediate product, or excipient before the investigation

begins. The Icelandic Medicines Agency shall allow a reasonable period of grace for this.

The Icelandic Medicines Agency shall compile a report containing the results of the audit after its completion.

Art. 77

Requirement for changed practice

The Icelandic Medicines Agency may require licence holders, cf. arts. 22, 26, 32 and 33, parties of whom registration is required, cf. arts. 24 and 29, and exemption holders, cf. art. 31 para. 3,to change their practices to comply with the provisions of this Act and regulations issued under it. The Icelandic Medicines Agency shall allow a reasonable period of grace in which to meet these demands.

Art. 78

Information from customs authorities

The Icelandic Medicines Agency may request information from customs authorities about quantities of medicinal products, active substances, intermediate products and excipients, as well as quantities from individual manufacturers and importers, concerning the manufacturing and importing of medicinal products, active substances, intermediaries and excipients subject to this Act. Article 188 of the Customs Act shall not prevent the Directorate of Customs from providing the Icelandic Medicines Agency with information under this article.

Art. 79

Special authority for monitoring of advertisements for medicinal products

The Icelandic Medicines Agency may require an individual or legal entity to provide written information about alleged violations of arts. 47–51, and it shall be provided within a reasonable time period, as determined by the Agency. The

Icelandic Medicines Agency may, in investigating alleged violations against arts. 47–51, make necessary checks on workplaces or a site where data are stored, if there are sound reasons to believe that a violation of the provisions has occurred. In carrying out the procedure, search and seizure of property shall comply with the provisions of the Criminal Procedures Act. The Icelandic Medicines Agency may provide the authorities of other European Economic Area states with information and data deemed necessary for the implementation of arts. 47–51, in accord with Iceland's commitments under the European Economic Area agreement and the European Free Trade Association (EFTA) Treaty.

When supplying information and data, the following conditions shall be made:

1. recipients shall treat the information and data as confidential,

2. the information and data shall only be used for the purpose stated in the agreement with the European Economic Area or the European Free Trade Association Treaty, and in accordance with the request for information,

3. the information and data will only be delivered to others with the consent of the Icelandic Medicines Agency and for the purposes for which consent has been given.

SECTION XVII

Fees

Art. 80

Fees according to tariff

The Icelandic Medicines Agency may charge for:

issuing marketing authorisation for medicinal products, herbal medicinal products, homeopathic medicinal products and licences for the parallel import of medicinal products.

changes to marketing authorisation and licences for the parallel import of medicinal products.

the cost of keeping the pharmacopoeias required by law, pharmacovigilance, information provision for medicinal products with marketing authorisation in Iceland, and the international collaboration necessitated by those medicinal products.

product classification.

scientific advice to applicants for a marketing authorisation in the European Economic Area.

granting exemptions for the use of medicinal products without marketing autorisation in Iceland.

granting permission to perform clinical trials of medicinal products on humans.

granting permission and exemptions under the Narcotics Act.

issuing certificates at the request of pharmaceutical companies.

issuing licences under this Act, other than marketing authorisation and licences for the parallel import of medicinal products, including the cost incurred in issuing licences, e.g. travel costs for Agency staff in Iceland and abroad, and the cost of bringing experts to Iceland to assist the Agency.

publishing the medicinal products price list.

providing access to the medicinal products register.

The Minister, after receiving recommendations from the Icelandic Medicines Agency, issues a tariff for services rendered, monitoring which does not fall under article 70 and tasks assigned to the Agency or undertaken by the Agency under this Act. Fees 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 is based. The fee must not exceed the cost. The tariff shall be published

in Section B of *Stjórnartíðindi* [Government Gazette]. Fees are legally enforceable by seizure of assets.

Art. 81

Monitoring fees

The following parties shall pay a monitoring fee to cover the cost of regular monitoring by the Icelandic Medicines Agency:

manufacturers of medicinal products, including blood banks and hospital blood department.

medicinal product wholesalers.

medicinal product brokers.

holders of pharmacy licences.

holders of licences to sell medicinal products intended for animals.

holders of exemptions to sell medicinal products in general shops.

healthcare institutes and workplaces of healthcare professionals.

Veterinarians.

importers and manufacturers of medicated feed.

The inspection fee shall be determined in the following manner:

Concerning the activities of holders of pharmacy licences, 0.3% of the total amount of payments from Icelandic Health Insurance to these 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 Icelandic Health Insurance. The amount of the inspection fee shall, however, never be lower than ISK 188,500 per year,

Concerning the activities of manufacturers of medicinal products, including blood banks and hospital blood department, medicinal product wholesalers, medicinal product brokers, holders of a veterinarian licence to sell medicinal products, and holders of a special licence to sell medicinal products, 0.3% of

the total sales 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 87,800 per year,

Concerning the activities of veterinarians and healthcare institutes and workplaces of healthcare professionals, 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 18,700 per year, and

Concerning the activities of importers and manufacturers of medicated animal feed, 0.3% of the total amount of purchases of medicinal products for use in feeds. The inspection fee shall, however, never be lower than ISK 87,800 per year.

The amounts provided for in para. 2 nos. 1–4 are at December 2015 price levels. They shall be adjusted annually on 15 January, indexed in such a way that 70% of the fee reflects changes in the wage index and 30% the consumer price index, in the updating of wages and prices under each year's Budget. Of the total cost given in para. 2 nos. 1–4, 70% shall be regarded as the cost for wages and 30% for other costs, and this shall be taken into account in reassessment of fees payable. The Icelandic health insurance institution and parties listed in para. 1 must provide the Icelandic Medicines Agency with all the information necessary for calculating monitoring fees.

Should the parties listed in para. 1 fail to provide the necessary information, the Icelandic Medicines Agency may estimate their inspection fees. The income base for this purpose shall be estimated sufficiently 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 assessment base changes

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 determination and calculation of penalty interest is governed by the Act on Interest and Price Indexation. The Icelandic Medicines Agency collects the fees under this article and the fees are legally enforceable by seizure of assets.

SECTION XVIII

Coercive measures

Art. 82

Reprimands

In order to enforce the implementation of a measure under this Act, the Icelandic Medicines Agency may reprimand a relevant party. An appropriate period of grace shall also be provided for rectification if necessary.

Art. 83

Daily fines

When a party fails to comply with instructions within a specified time period, the Icelandic Medicines Agency can levy daily fines until the situation is remedied.

Such fines may amount to up to ISK 500,000 per day. The amount of the daily fines shall be determined by the scope and gravity of the violation, how long it has continued and whether it is a repeated violation.

Decisions by the Icelandic Medicines Agency to impose daily fines are legally enforceable by seizure of assets. If a fine under this article is not paid within 30 days of the Icelandic Medicines Agency’s decision, the fine shall accrue interest. The determination and calculation of penalty interest is governed by the Act on Interest and Price Indexation. Uncollected daily fines, imposed up to the final day, are not dismissed even though the party settles the fine, unless the Icelandic Medicines Agency specifically decides to do so. Fines under this article are paid to the Treasury, minus the collection cost.

Art. 84

Temporary halting of marketing of medicinal products

The Icelandic Medicines Agency may restrict the marketing of medicinal products, active substances, intermediate products or excipients that do not fulfil the requirements of this Act or regulations issued under it. This includes *inter alia* that the Icelandic Medicines Agency may remove from sale or distribution or recall a particular medicinal product, active substance, intermediate products or excipient until any shortcomings have been rectified.

Art. 85

Halting of marketing of medicinal products

The Icelandic Medicines Agency may halt marketing of a medicinal product that does not fulfil the requirements of this Act or regulations established under it. This includes *inter alia* that the Icelandic Medicines Agency may remove from or distribution or recall a particular medicinal product, active substance, intermediate products or excipient, and may seize such products. The Agency may also order a particular medicinal product, active substance, intermediate product or excipient to be safely disposed of and/or recalled or stored until the shortcomings have been rectified or danger avoided by satisfactory means.

Art. 88

Temporary halting of activities

If the Icelandic Medicines Agency deems the danger from a particular operation or the usage of a medicinal product, active substance, intermediate product or excipient to be so grave that action must be taken immediately, it may temporarily halt operations or usage immediately, with the assistance of the police if deemed necessary.

Art. 87

Police assistance

The Icelandic Medicines Agency may seek assistance from the police, if deemed necessary to implement coercive measures.

SECTION XIX

Penalties

Art. 88

Seizure

The Icelandic Medicines Agency may seize medicinal products, active substances, intermediate products or excipients that do not fulfil the requirements of this Act or regulations established under it and dispose of them at the cost of their holder.

Art. 89

Civil penalties (non-criminal fines)

The Icelandic Medicines Agency may impose civil penalties on individuals or legal entities that contravene:

provisions for marketing medicinal products, cf. art.11.

provisions for a duty to provide information by marketing authorisation holders/their agents, cf. art. 19.

provisions for authorisation to conduct clinical trials on humans, cf. art. 21.

provisions for medicinal product manufacturing, cf. art. 22.

provisions for the manufacturing of active substances that are to be used in the manufacture of medicinal products for humans and that have marketing authorisation, cf. art. 24.

provisions for the duty to report falsified medicinal products or active substances, cf. art. 25.

provisions for the wholesale distribution of medicinal products, cf. arts. 26 and 27.

provisions for mandatory registration for medicinal product brokers, cf. art. 29.

provisions for the import and export of medicated feed, cf. art. 30.

provisions for the retailing of medicinal products, cf. arts. 32–34.

provisions for the prescribing of medicinal products, cf. art. 44.

provisions for the dispensing of medicinal products on prescription, cf. art. 46.

provisions for medicinal product advertisements, cf. arts. 50–53.

provisions for the duties of marketing authorisation holders with respect to pharmacovigilance, cf. arts. 57 and 59.

The Minister shall in regulations determine the monetary amount of civil penalties for violations of the individual provisions of this Act within the framework provided in para. 4.

If the monetary amount of a penalty has not been determined in regulations, provisions for the fine shall *inter alia* take account of the gravity of a violation, how long it has continued, the willingness of the offending party to cooperate, and whether it is a repeated violation. Account shall also be taken of whether the violation may be deemed to have been perpetrated to the advantage of the company and whether the infringement could have been prevented by management and monitoring. The Icelandic Medicines Agency may decide on higher fines if a party has benefited from the violation. The amount of the civil penalty shall then be decided as up to double the profit that the party made by violating this Act or regulations set according to it, but within the frame provided for in para. 4.

Penalties for individuals can be from ISK 10,000 to ISK 10,000,000. Penalties for legal entities can be from ISK 25,000 to ISK 25,000,000.

The due date of civil penalties is 30 days after the decision on the fine was made. If a civil penalty has not been paid within 15 days of the due day, interest shall be calculated on the fine, commencing from the due date. The decisions of the Icelandic Medicines Agency on civil penalties are legally enforceable by seizure of assets, the fines going to the Treasury, minus the cost of charging and collecting. The determination and calculation of penalty interest is governed by the Act on Interest and Price Indexation.

Civil penalties shall be applied irrespective of whether the infringement was deliberate or the result of negligence.

A party to a case may only appeal a civil penalty to the courts. The time period in which to lodge an appeal is three months from when the penalty decision was made. An appeal postpones enforcement.

Art. 90

Right to avoid self-incrimination

In a case against an individual which could lead to the imposition of a civil penalty or criminal proceedings, a person suspected of having committed an infringement against the law has the right to refuse to answer questions or deliver data or property unless it can be ruled out that this could be significant for decisions on his/her case. The Icelandic Medicines Agency shall advise the suspect regarding this right.

Art. 91

Time limits on a civil penalty

The Icelandic Medicines Agency’s authority to impose a civil penalty under this Act shall expire when five years have passed since the conduct ceased.

The time period provided for in para. 1 is interrupted when the Icelandic Medicines Agency notifies a party of the start of an investigation of a suspected

violation. The interruption of the time limit has a legal effect on all parties to the offence.

Art. 92

Fines or imprisonment

Penalties of fines or up to two years' imprisonment apply, unless more severe penalties for an offence are provided in other legislation, for violations of:

provisions for marketing medicinal products, cf. art.11,

provisions for authorisation to conduct clinical trials on humans, cf. art. 21,

provisions for the manufacturing of medicinal products, cf. art. 22,

provisions for the manufacturing of active substances that are to be used in the manufacture of medicinal products for humans and that have marketing authorisation, cf. art. 24,

provisions for the duty to report falsified medicinal products or active substances, cf. art. 25,

provisions for the wholesale distribution of medicinal products, cf. art. 26 and 27,

provisions for mandatory registration for medicinal product brokers, cf. art. 29,

provisions for the retailing of medicinal products, cf. arts. 32–34,

provisions for prescribing medicinal products, cf. art. 44,

provisions for the dispensing of medicinal products on prescription, cf. art. 46.

Fines may be imposed on a legal entity even if guilt is not proved for a legal representative or employees or other individuals working on behalf of the entity, provided that the infringement was, or could have been, to the financial advantage of the legal entity. However, the legal entity shall not be punished in the case of an unintentional violation. Also, with the same proviso, a legal entity

may be fined if representatives or employees or other individuals working on behalf of the legal entity are guilty of an infringement or if it arises from inadequate equipment or supervision.

Art. 93

Culpability, confiscation of property, attempted violations and complicity

Infringements against this Act result in fines or imprisonment, whether they are deliberate or due to negligence.

Direct or indirect profit arising from infringements of this Act which entail fines or imprisonment may be confiscated by court order.

An attempted violation or complicity in a violation of this Act is a criminal offence as provided in the General Penal Code.

Art. 94

Complaint to the police

The Icelandic Medicines Agency may report an offence to the police.

Where an alleged infringement of this Act entails both civil or criminal penalties, the Icelandic Medicines Agency assesses whether to report it to the police, or to conclude the case by an administrative decision by the Agency. In the case of gross offences, the Icelandic Medicines Agency must refer them to the police. An offence is deemed gross where an act was committed in a particularly reprehensible manner or in a situation that greatly increases the criminality of the offence. In addition, the Icelandic Medicines Agency may at any stage refer a case of an offence against this Act to a public investigation. Consistency shall be maintained in the resolution of similar cases.

A complaint lodged by the Icelandic Medicines Agency shall be accompanied by copies of all data regarding the suspected offence. Provisions in Sections IV–VII of the Administrative Procedures Act do not apply to decisions by the Icelandic Medicines Agency to lodge a complaint with the police.

The Icelandic Medicines Agency may provide the police and public prosecutor's office with information and data that the Agency has gathered, connected to those offences specified in para. 2. The Icelandic Medicines Agency may participate in police actions relating to the investigation of offences specified in para. 2

The police and public prosecutor's office may provide the Icelandic Medicines Agency with information or data that they have gathered relating to offences specified in para. 2. The police may take part in actions by the Icelandic Medicines Agency relating to the investigation of offences specified in para. 2.

If the prosecutor concludes that there is insufficient evidence to proceed with a case of alleged criminal acts, which also involves administrative penalties, he/she can refer or redirect the case to the Icelandic Medicines Agency for consideration and decision.

Art. 95

Authority to appeal

Unless otherwise provided in this Act, administrative authority decisions taken under it may be appealed to the Minister. The right to appeal and procedure are governed by the Administrative Procedures Act.

SECTION XX

Miscellaneous provisions

Art. 96

Ownership of physicians, dentists and veterinarians in medicinal product companies

Practising physicians and dentists may not own such a large share of a company that operates on the basis of a medicinal product manufacturing licence, a licence for wholesale distribution of medicinal products, a licence to

broker medicinal products or a pharmacy licence, that it has a significant impact on their financial livelihood. The same applies to their spouses and their children under the age of 18.

Practising veterinarians may not own such a large share of a company that operates on the basis of a medicinal product manufacturing licence, a licence to distribute medicinal products at wholesale level or a licence to broker medicinal products that it has a significant impact on their financial livelihood. The same applies to their spouses and their children under the age of 18.

SECTION XXI

Regulations

Art. 97

Regulatory provisions

The Minister makes further provisions in regulations about the implementation of this Act with regard to:

1. quality and safety in handling human cell and tissue samples, cf. art. 6 no. 11,
2. the collection, treatment, storage and distribution of blood, cf. art. 6 no. 11,
3. granting marketing authorisation for medicinal products, cf. art. 20 para 1,
4. granting marketing authorisation for homeopathic medicinal products and herbal medicinal products, and their registration, art. 20 para 2,
5. clinical medicinal product trials on humans, cf. art. 21,
6. manufacture of medicinal products and active substances, cf. art. 22,
7. automated dose dispensing of medicinal products, art. 23,
8. import, distribution at the wholesale level and brokering of medicinal products, cf. arts. 26 and 29,
9. medicated feed, cf. art. 30,
10. pharmacy licences and pharmacies, cf. art. 31,
11. administration of medicinal products in healthcare institutions, cf. art. 42,

12. prescription and dispensing of medicinal products, cf. art. 48 para 1,
13. licensing dentists to prescribe medicinal products, cf. art. 48 para. 2,
14. licensing veterinarians to prescribe medicinal products, cf. art. 48 para 3, and
15. advertising medicinal products, cf. art. 55.

The Minister may also make further provisions in regulations about the implementation of this Act including:

authorising parallel import of medicinal products, cf. art. 19 para. 3,

pharmacological care, cf. art. 37,

conditions and execution of internet sales of medicinal products, cf. art. 38,

requirements of marketing authorisation holders in connection with pharmacovigilance cf. art. 60 para. 1,

obligations of healthcare professionals to notify the Icelandic Medicines Agency of side-effects suspected of being connected to medicinal products, cf. art. 60 para. 2,

rights of patients, their next of kin and people responsible for an animal to report to the Icelandic Medicines Agency about side-effects, cf. art. 60 para. 3,

the treatment and handling of information about medicinal products that companies manufacture, import or export, hold stocks of, deal or resell, distribute, deliver, pack or repack, delivered to the Minister or an institution nominated by the Minister, cf. art 68.

SECTION XXII

Adoption and entry into force

Art. 98

Adoption

This Act is enacted in order to adopt the following instruments:

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community Code relating to medicinal products for human use.

Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.

Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products.
Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products
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.
Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.
Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance.

Art. 99

Entry into force

This Act shall enter into force immediately. At the same time, the Medicinal Products Act no. 93/1994 and the Pharmacy Act no. 30/1963 are repealed.

Regulations made pursuant to Act no. 93/1994 shall remain in force in so far as they are consistent with this Act.

Art. 98

Amendments to other legislation

When this Act takes effect the following amendments are made to other legislation:

Veterinarian and Animal Healthcare Act no. 66/1998:

The word “*lyfseðilsskyldum*” [prescription-only] in art. 8 is replaced by: *lyfjaávísunarskyldum* [prescription-only].

The words “art. 11 para. 4.” in art. 11 para. 2. are replaced by: art. 44 para. 2

Media Act no. 38/2011: The word “*lyfseðilsskyld*” [prescription-only] in art. 36 para. 4 is replaced by: *lyfjaávísunarskyld* [prescription-only].

Health Insurance Act no. 112/2008: The words “Section XV” in art. 29 para. 1 no. 6 are replaced by: Section XIV

Health Security and Communicable Diseases Act no. 19/1997: The words “under art. 27” in art. 3 para. 4 are replaced by: under art. 71

Environment Agency Act no. 90/2002: The words “Medicinal Products Act no. 93/1994 with subsequent amendments” in art. 1 para. 2a are removed.

Temporary provisions

I.

All posts at the Medicinal Products Pricing Committee are abolished when this Act takes force. All staff of the Medicinal Products Pricing Committee shall be offered employment at the Icelandic Medicines Agency from that same time. The provisions of art. 7 of Act no. 70/1996 do not apply to appointments to posts under this provision.

From the entry into force of this Act, the Icelandic Medicines Agency takes over the assets of the Medicinal Products Pricing Committee, together with its rights and responsibilities with regard to the implementation of legislation on matters under its aegis at that time.

II.

Licences for manufacturing and import and export of medicinal products and pharmacy licences issued on the basis of the Medicinal Products Act no. 93/1994 remain valid. Companies which produce active ingredients for use in manufacture of medicinal products for humans, and hold a marketing

authorisation, and companies and individuals which/who are brokers of medicinal products, shall register with the Icelandic Medicines Agency, cf. the provisions of arts. 24 and 29, before #*DATE#*.