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Bill on a Medicinal Products Act

Proposed by the Minister of Health.

SECTION I
Objectives, scope and definitions.

Article 1
Objectives

The objective of this Act is to ensure that the people of Iceland have a sufficient supply of necessary medicinal products, with patient safety as the guiding principle and employing the most efficient means of distribution on the basis of normal competition and in accordance with the rules which apply in the European Economic Area or under the Convention Establishing the European Free Trade Association. It is, furthermore, the objective of this Act to ensure as far as possible the quality and safety of medicinal products and services, increase public awareness regarding the use of medicinal products, counter their excessive use and keep medicinal product costs to a minimum.

Article 2
Scope

Unless otherwise specifically stated, this Act shall apply both to medicinal products for humans and veterinary medicinal products.

This Act does not cover medical equipment (*cf.* the Medical Equipment Act), chemicals and chemical mixtures (*cf.* the Chemicals Act), foodstuffs (*cf.* the Foodstuffs Act), tobacco (*cf.* the Tobacco Act) or e-cigarettes (*cf.* the Electronic Cigarettes and Refill Containers Act). This Act, together with the Radioactive Substances Act, shall apply to medicinal products falling under item 8 of the first paragraph of Article 3 which contain radioactive substances.

In cases of doubt as to whether individual substances or compounds are to be regarded as medicinal products, the Icelandic Medicines Agency shall resolve the issue. If, when all of a product's properties are taken into account, it is found to come under the definition of a medicinal product as determined by the Icelandic Medicines Agency (*cf.* item 8 of the first paragraph of Article 3) and also the definition of a product under other legislation, the provisions of this Act shall apply.

Article 3
Definitions.

In this Act, the following terms and expressions are used as defined below.

1. *Magistral formula products:* Medicinal products that are manufactured in a pharmacy in accordance with a prescription by a physician.

2. *Manufacture of medicinal products:* All measures aimed at the manufacture of medicinal products, including the purchasing of substances and products and also the production process, such as weighing, mixture, filling of containers, packaging, repackaging, labelling, approval, storage and quality monitoring.
3. *Falsified medicinal products:* Any medicinal product with a false representation of:
    a. its identity, including its packaging and labelling, its name or its composition as regards its ingredients, including excipients and the strength of those ingredients;
    b. its origin, including the manufacturer, country of manufacture, country of origin or marketing authorisation holder; or
    c. its history, including the records and documents relating to the distribution channels used.
4. *Wholesale distribution of medicinal products*: All measures aimed at distributing medicinal products at the wholesale level, including importing, exporting, acquisition and distribution.
5. *Excipients:* Any part of a medicinal product other than the active ingredient and the packaging material.
6. *Herbal medicinal product:* Any medicinal product in which the active ingredients consist solely of one or more herbal substances or one or more fully-processed herbal preparations or a combination of one or more such herbal substances and one or more such herbal medicinal products.
7. *Medicinal products subject to licence* : 'Medicinal products subject to licence' refers to medicinal products that are normally expensive, qualify for full cost participation by Icelandic Health Insurance, require great care in their use, are used solely in accordance with clinical instructions in the treatment of illnesses that must be diagnosed in a hospital and require some sort of expert knowledge and the involvement of healthcare workers, whether this is in connection with their administration or the monitoring of the patient or the medicinal product.
8. *Medicinal product:* All types of substance or combination of substances which:
    a. are said to have properties that are of use in the treatment of illnesses in humans or animals or in the prevention of illness, or
    b. which may be administered to humans or animals, or given to them, in order to restore, correct or modify physiological functions by means of pharmacophysiological or immunological action or through action on metabolism, or in order to confirm a diagnosis.
9. *Medicinal product advertising:* Any type of advertising or publicity activity, written or oral, involving images, the handing over of medicinal product samples, promotions of medicinal products and meetings for the purpose of encouraging the prescription, handing over, sale or use of medicinal products. Information provided by government authorities to the public regarding medicinal products, e.g. regarding decisions to grant marketing authorisations, medicinal product pricing or whether Icelandic Health Insurance participates in the cost of medicinal products for persons who are health-insured, shall not be considered to be advertising.
10. *Medicinal product prescription portal*: A central message exchange handling the passage of electronic medicinal product prescriptions between their issuers and pharmacies.

11. *Medicinal product prescription:* When a physician, dentist, veterinarian, nurse or midwife issues a declaration, i.e. a medicinal product prescription, stating that the issuer of the prescription has personally prescribed the specific medicinal product in the specified quantity and given instructions on its dosage and use. The issuer shall certify the prescription by means of his or her signature.
12. *Marketing*: When a medicinal product is made accessible for use, following the issue of marketing authorisation by the Icelandic Medicines Agency or of other comparable authorisation from the agency and the medicinal product meets all the licence requirements. In the case of a prescription product, the agreed maximum price of the medicinal product shall also be published in the medicinal product price list.
13. *Brokering of medicinal products:* All activities in connection with the purchase or sale of medicinal products, with the exception of wholesale distribution, that do not involve handling of the products and consist of negotiating business deals independently and on behalf of another legal or natural person.
14. *Intermediate product:* A mixture of active ingredients and excipients intended for further processing in the manufacture of medicinal products.
15. *Centralised medicinal product card:* A card which grants healthcare professionals and the patient access to electronic information on the treatment of the patient by means of medicinal products at any given time.
16. *S-labelled medicinal products*: Medicinal products that are used in healthcare institutions or physicians' surgeries, or medicinal products which in some way call for specialised knowledge and require the involvement of healthcare professionals, whether in connection with their administration or with monitoring of the patient or of the medicinal product. In exceptional cases, use of the medicinal product may take place outside a healthcare institution or physician's surgery as determined by a healthcare professional.
17. *Retailing of medicinal products:* Retailing of medicinal products which takes place:
    a. in a pharmacy, where the public is able to purchase medicinal products (both prescription medicinal products and over-the-counter medicinal products), or
    b. in a shop where the public is able to purchase minimum packages and minimum strengths of nicotine and fluoride medicines.
18. *Homeopathic medicinal product:* Any type of medicinal product that is processed from substances referred to as homeopathic stocks, in accordance with the method of production of homeopathic medicinal products described in the European Pharmacopoeia or, if not there, then in the pharmacopoeias in force in the member states of the European Economic Area.
19. *Officinal formula products:* Medicinal products manufactured in a pharmacy in accordance with a formula in a pharmacopoeia, and which the pharmacy in question hands over to the patient directly.
20. *Active substance:* Any substance or mixture of substances that is intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.

SECTION II

Supervision, and the role and responsibilities of the Icelandic Medicine Agency.

Article 4

Supervision

The minister shall exercise supervision of matters covered by this Act.

Article 5

The Icelandic Medicines Agency

An Icelandic Medicines Agency shall be operated under the supervision of the minister.

The minister shall appoint the director of the Icelandic Medicines Agency for terms of five years at a time.

The director shall hold a university degree and have knowledge in the agency's field of operations, and shall have acquired administrative experience. The director shall direct the agency, ensure that it functions in accordance with the acts of law and regulations valid at any given time and be responsible for its day-to-day operations.

Neither the director nor other staff of the Icelandic Medicines Agency may have special and substantial interests at stake in the development, production, marketing, importation, wholesaling or retailing of medicinal products.

Article 6

Role of the Icelandic Medicines Agency.

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

1. To evaluate medicinal products in accordance with this Act and the rules applying in the European Economic Area and according to the Convention Establishing the European Free Trade Association.
2. To handle the issuing, amendment, temporary suspension and revocation of authorisations for the marketing of medicinal products, together with monitoring the holders of authorisations for the marketing of medicinal products, issuing authorisations for parallel importation of medicinal products and the registration of traditional homeopathic medicinal products and herbal medicinal products in accordance with this Act and the rules applying in the European Economic Area.
3. To process applications for authorisation to import and sell, according to prescription, medicinal products that do not have marketing authorisation in Iceland.
4. To receive and register notifications of side-effects of medicinal products from the public, healthcare professionals, veterinarians, keepers of animals and the Directorate of Public Health in the medicinal product prescription portal of the Icelandic Medicines Agency and in the databases of the European Medicines Agency.
5. To grant licences for the manufacture and wholesaling of medicinal products in Iceland, monitor such activities (including the supply of medicinal products in Iceland) and to record details of licences granted for the manufacture and wholesaling of medicinal products in the database of the European Medicines Agency.
6. To grant licences for the sale of medicinal products, and operating licences, and to monitor such activities.
7. To monitor the handling of medicinal products in healthcare institutions, the workplaces of healthcare professionals and the workplaces of veterinarians.
8. To grant licences for clinical studies of medicinal products for human use and to monitor the conduct of such studies.
9. To operate and supervise the medicinal products reference register.

10. To monitor the importation of medicinal products, pharmaceutical substances and raw materials for the manufacture of medicinal products, or any other products subject to the agency's authority.
11. To monitor the advertising of medicinal products.
12. To monitor narcotic drugs and psychotropic substances under this Act and to carry out the tasks assigned to the agency under the Narcotic Drugs and Psychotropic Substances Act and regulations.
13. To monitor the collection, handling, storage and distribution of blood and the quality and safety of the handling of human cells and tissues.
14. To take decisions on medicinal product pricing, with the objective of this Act, that the use of medicinal products in Iceland be based on a rational and efficient basis, as the guiding principle, and to decide on whether medicinal products qualify for cost participation, as appropriate, under this Act.
15. To attend to the tasks entrusted to the agency under the Medical Equipment Act.
16. To attend to other tasks relevant to the application of this Act, including collaboration with overseas institutions in the field of medicinal products.
17. To monitor the supply of medicinal products in such a way that medicinal product shortages will have the minimum impact on patient safety.
18. To grant licences for the manufacture and importation of medicated animal feeds.
19. To grant licences for the sale of medicinal products for veterinary use in accordance with point 4 of the first paragraph of Article 11.

The minister may issue regulations entrusting the Icelandic Medicines Agency with the monitoring of other undertakings, other activities or other products apart from medicinal products and related products if particular circumstances favour this and such functions are related to its role under this Act.

The Icelandic Medicines Agency may operate a laboratory to carry out tests and research for the agency. The Icelandic Medicines Agency may furthermore commission independent laboratories in Iceland or abroad to carry out tests or research on behalf of the agency.

Article 7

Task forces and specialists.

The Icelandic Medicines Agency may appoint committees and task forces, and call in specialists to advise it, for example in evaluating and classifying medicinal products, conducting supervision and investigations and in taking decisions on medicinal product pricing and participation in the cost of medicinal products.

Specialists called in to assist the Icelandic Medicines Agency, and persons appointed to committees or task forces (*cf.* the first paragraph) may not have special and substantial interests at stake in the development, production, marketing, importation, wholesaling or retailing of medicinal products. The Icelandic Medicines Agency may decide to waive these demands if such a decision is supported by relevant considerations.

SECTION III

Pharmacopoeia

Article 8

Pharmacopoeia valid in Iceland.

Iceland is a signatory state of the European Pharmacopoeia and of its protocols. The current English edition of the pharmacopoeia applies in Iceland.

Other demands regarding medicinal product forms, quality and purity, active substances and excipients, and also methods of analysing and standardising these substances shall be in accordance with a regulation which the minister may set, or with advertisements on the validity of Nordic and other European standards in Iceland.

Article 9

Medicinal product registers issued by the Icelandic Medicines Agency.

The Icelandic Medicines Agency shall maintain a medicinal products reference register. Information shall be recorded in the Medicinal Products Reference Register on the medicinal products that are marketed in Iceland and the medicinal products for which cost participation has been granted under point 2 of the first paragraph of Article 6. The Medicinal Products Reference Register shall be based on the common names of medicinal products, but shall also contain information on the names of proprietary medicinal products and packagings on the market. All the information on medicinal products that is necessary for computer systems, e.g. regarding their active substances, interactions, indications, contraindications and dosages, shall be accessible to the public, undertakings and public institutions.

The Icelandic Medicines Agency shall supervise the publication of a proprietary medicinal product register. Medicinal products that are placed on the market shall be entered into the Proprietary Medicinal Product Register, grouped by category or in another comparable manner. Information published in the register shall include an approved summary of the properties of the medicinal product and the package leaflet, together with the maximum price of prescription medicinal products.

Article 10

Other instructions on medicinal products that are in force in Iceland.

European Union guidelines on good manufacturing practice (GMP) in medicinal product manufacture and on good distribution practice (GDP) regarding medicinal products, and other EU guidelines relating to medicinal products that have been adopted in the Agreement on the European Economic Area and the Convention Establishing the European Free Trade Association, shall be valid in Iceland. The editions of such guidelines current at any given time shall be valid in Iceland.

Payments covering Iceland’s membership of the Pharmaceutical Inspection Convention and the Pharmaceutical Co-operation Scheme shall be borne by the Treasury.

SECTION IV

Marketing authorisation for medicinal products.

Article 11

Marketing of medicinal products.

Only medicinal products for which the Icelandic Medicines Agency has granted marketing authorisation may be marketed in Iceland. In the case of prescription medicinal products for human use, the Icelandic Medicines Agency must also have approved a maximum wholesale and retail price, and information on the product must be published in the medicinal product price list.

Without prejudice to the first paragraph, the following medicinal products may be sold in Iceland without a marketing authorisation:

1. Inactivated immunological veterinary medicinal products that are manufactured from pathogens and antigens obtained from an animal, or animals from the same farm, and

which are used to treat the animal, or the animals from that farm, in the same place, by permission from the Icelandic Medicines Agency after receiving the comments of the Icelandic Food and Veterinary Authority. In exceptional cases, such immunological veterinary medicinal products may be used in the immediate vicinity of the original farm after permission has been obtained from the Icelandic Medicines Agency.

2. Investigational medicinal products that are used in clinical trials of medicinal products on humans.
3. Medicated animal feeds.
4. Veterinary medicinal products intended solely for tropical fish, caged birds, carrier pigeons, terrestrial animals that are kept in cages, small rodents that are kept in cages, ferrets and rabbits that are kept solely as pets, providing that these products do not contain substances the use of which requires supervision by a veterinarian and that all available measures have been taken to prevent their being given without permission to other animals.

Without prejudice to the first paragraph, the following medicinal products may also be sold in Iceland without a marketing authorisation:

1. Traditional herbal medicinal products which have been registered by the Icelandic Medicines Agency.
2. Homeopathic medicinal products which have received marketing authorisation in another member state of the European Economic Area and been registered by the Icelandic Medicines Agency.

Article 12

Exemptions.

The Icelandic Medicines Agency may, in accordance with an application by a physician, in its own name or in the name of a healthcare institution, dentist or veterinarian, grant an exemption from the provisions of the first paragraph of Article 11. Such an exemption shall only be granted if the following conditions are met:

a. That reasoning stating that special circumstances obtain which call for the use of a medicinal product for which no Icelandic marketing authorisation has been granted, or which has received Icelandic marketing authorisation but has not been marketed in Iceland, be considered satisfactory.
b. That it be stated in the application that the quantity for which the exemption is sought is limited to the requirements of those who are to use the medicinal product, and whether the use is intended for a specific individual or animal and whether it will take place in a healthcare institution or another specific location.

When an application according to the first paragraph is granted, the applicant shall be responsible for informing the patient or the animal's keeper that the medicinal product being prescribed has not receive Icelandic marketing authorisation, and at the same time for informing the patient or keeper of possible side-effects and of other matters which may be necessary to know when using the medicinal product. If no marketing authorisation has been granted for the medicinal product in another member state of the European Economic Area, then the physician, dentist or veterinarian shall be entirely responsible for the prescription and effects of the medicinal product involved.

Article 13

Permits for the compassionate use of medicinal products.

Without prejudice to the provisions of Article 11, the Icelandic Medicines Agency may, for compassionate reasons, authorise the use of limited quantities of medicinal products for humans for which no marketing authorisation has been granted in Iceland.

Use under the first paragraph may be permitted if a marketing authorisation application has been made, but has not been processed, or if the medicinal product in question is the subject of a clinical study and the relevant patient group does not have access to the medicinal product in that study and access to the medicinal product in question is based on the scheduled availability of the medicinal product.

Under this provision, a medicinal product may be made accessible to a group of patients with a disease that causes chronic or serious disability or a disease that is considered fatal and that cannot be treated in a satisfactory manner with a medicinal product for which marketing authorisation has been granted.

If no information is available on the scheduled availability of the medicinal product in question from the European Medicines Agency or a comparable body in a member state of the European Economic Area, the Icelandic Medicines Agency may, in consultation with the manufacturer or the applicant for marketing authorisation, draw up a schedule on the availability of the medicinal product in question, including guidelines on the use of the product for compassionate reasons and its distribution.

In the event of serious problems arising regarding the quality, safety or effects of the medicinal product, including serious side-effects, the Icelandic Medicines Agency may immediately halt all use of the product.

The manufacturer or the applicant for marketing authorisation shall be obliged to ensure that those patients who participate in a schedule regarding the availability of the medicinal product in question in accordance with this provision shall have access to the medicinal product in question during the period that may elapse between the granting of a marketing authorisation and the marketing of the product.

Even if a schedule on the availability of a medicinal product has been drawn up, this shall not affect the liability of the manufacturer or applicant for marketing authorisation in private law or criminal law actions.

The Icelandic Medicines Agency shall inform the European Medicines Agency of all schedules under this provision.

Article 14

Prescription requirement for medicinal products, authorisation for dispensing and other restrictions.

In connection with the granting of a marketing authorisation or the granting of a licence for the parallel importation of a medicinal product, the Icelandic Medicines Agency shall decide the following:

a. whether or not a medicinal product is to be subject to prescription,
b. whether the use of a medicinal product is permitted solely in healthcare institutions which provide general or specialised health services (*cf.* the Health Services Act),
c. whether the prescription of a medicinal product, a particular dosage size of a medicinal product, a particular length of duration of the administration of a medicinal product or the first prescription of a medicinal product to a patient at the commencement of treatment is to be restricted solely to specialists in specific medical disciplines,

d. whether a medicinal product is to be administered to animals only and whether a medicinal product is solely to be administered to animals when this is done in person by a veterinarian.

The Icelandic Medicines Agency may permit the exemption from prescription of a particular quantity or form of a medicinal product which has been decided as being subject to prescription as per indent a of the first paragraph.

After receiving an application from the marketing authorisation holder or holder of a licence for the parallel importation of a medicinal product, or at its own initiative, the Icelandic Medicines Agency may change decisions that have been taken under the first or second paragraphs. When taking such decisions, the Icelandic Medicines Agency shall, amongst other things, take account of the conclusions reached by the European Medicines Agency regarding the categorisation of medicinal products in connection with their supply.

Article 15

Validity and renewal of marketing authorisations.

The ordinary period of validity of marketing authorisations shall be five years. The Icelandic Medicines Agency may limit the period of validity of marketing authorisations if particular circumstances obtain.

A marketing authorisation for a medicinal product may be renewed on the basis of a re-evaluation by the Icelandic Medicines Agency showing that the benefit of using a medicinal product outweighs the risks involved. When the marketing authorisation for a medicinal product has been renewed once, it shall remain in force permanently unless the Icelandic Medicines Agency decides, with valid reasons based on pharmacovigilance, that it is to be renewed for five years only.

Marketing authorisation shall lapse if the medicinal product for which it was granted has not in fact been placed on the market within three years of the granting of the authorisation or if the medicinal product for which it was granted has not in fact been on the market for an unbroken period of three years. The Icelandic Medicines Agency may grant exemptions from this provision under special circumstances and for reasons concerning public health. Reasons for such exemptions shall be stated.

Article 16

Revocation, suspension or amendment of marketing authorisations.

The Icelandic Medicines Agency shall revoke, suspend or amend a marketing authorisation if:

a. it is considered that the medicinal product is harmful or that it does not have a medicinal effect,
b. it is considered that the benefits of using the medicinal product do not sufficiently outweigh the risks,
c. the qualitative and quantitative composition of the medicinal product are not regarded as being what they were stated to be when the application for marketing authorisation was made,
d. the required information submitted with the application for marketing authorisation proves to be incorrect.

The Icelandic Medicines Agency may revoke, suspend or amend marketing authorisations if:

a. the demands made of the marketing authorisation holder regarding pharmacovigilance under Article 61 are not met,

b. the time until the utilization of animal products may be resumed following the administration of medicinal products is no longer considered sufficiently long so as to ensure that no medicinal product residues that are harmful to consumers will be present in the animal products,
c. the manufacture of the medicinal product no longer conforms with the information submitted with the marketing authorisation application for the product,
d. no quality control is carried out in accordance with the requirements of the valid quality description as provided for in the rules.

A marketing authorisation holder may request at his own initiative that the Icelandic Medicines Agency cancel his marketing authorisation. When assessing requests from market authorisation holders for the cancellation of their authorisations, the Icelandic Medicines Agency shall take into consideration the impact this would have on the supply of the medicinal product in Iceland.

Article 17

Granting of special authorisation for the marketing of medicinal products for human use.

The Icelandic Medicines Agency may, on the basis of a marketing authorisation issued in another member state of the European Economic Area, issue a special licence for the marketing of a medicinal product that has been deregistered, or for which no marketing authorisation has been sought, if the Icelandic Medicines Agency considers it justifiable, in terms of public health considerations or the general public interest, to have the medicinal product in question on the market. If the Icelandic Medicines Agency intends to avail itself of this authorisation, it shall inform the holder of the marketing licence in the country in which the medicinal product is registered of its intention, and also request a copy of the evaluation report and valid marketing authorisation for the medicinal product from the authorities in that country.

Article 18

Permission for the temporary distribution of a medicinal product for which no marketing authorisation has been granted.

The Icelandic Medicines Agency may permit the temporary distribution of a medicinal product for which no marketing authorisation has been granted, providing that it is intended for protection against pathogens, toxic substances, chemical agents or ionizing radiation which are believed, or known, to have spread, or to be capable of having done so.

Article 19

Applications for marketing authorisation for veterinary vaccines, serum or antigens.

The Icelandic Medicines Agency may, following consultation with the Icelandic Food and Veterinary Authority, reject an application for marketing authorisation for a veterinary vaccine, serum or antigen if its use would be in violation of the law or if it is intended as a protection against a disease that is unknown in animals in Iceland.

Article 20

Obligation of applicants and licensees to provide information.

Applicants for marketing authorisation. or other types of authorisation, shall be obliged to provide the Icelandic Medicines Agency with all new information regarding the medicinal products for which authorisation is sought, and which are under discussion by the agency, at

the first opportunity. The same shall apply in the case of medicinal products for which marketing authorisation, or authorisation of another type, has been granted.

Article 21

Regulations on marketing authorisation and other types of authorisation relating to medicinal products.

The minister shall issue a regulation containing further provisions on the granting of marketing authorisation for medicinal products, including the processing of applications, the recognition of centralised marketing authorisations granted by the European Medicines Agency (EMA), the retention times applying to materials in pre-clinical and clinical trials, recognition on the basis of marketing authorisation from another member state of the EEA Agreement, changes to the conditions for marketing authorisation, the revocation and cancellation of marketing authorisation and exemptions granted for medicinal products for which marketing authorisation has not been granted in Iceland.

The minister shall issue a regulation containing further provisions on the registration of homeopathic medicinal products and herbal medicinal products, including as regards the processing of applications, registration on the basis of marketing authorisation from another member state in the European Economic Area and definition of traditional use.

The minister may issue a regulation containing further provisions on the conditions for granting authorisation for the parallel importation of medicinal products, including a definition of parallel importation of medicinal products, time limits for the processing of applications for authorisation, demands regarding materials to be submitted with applications and the labelling of external and immediate packaging and package leaflets accompanying imported medicinal products.

The minister may issue a regulation containing further provisions on the conditions for the compassionate use of medicinal products.

The minister may issue a regulation containing further provisions on the granting of authorisations, restrictions and monitoring of the sale of veterinary medicinal products (*cf.* point 4 of the first paragraph of Article 11) and the granting of exemptions from the demand for marketing authorisation in the case of veterinary medicinal products that are intended solely for tropical fish, birds and terrestrial animals that are kept in cages, carrier pigeons and small rodents that are kept in cages, providing that these products do not contain substances the use of which requires supervision by a veterinarian and that all available measures have been taken to prevent their being given without permission to other animals.

SECTION V

Clinical trials of medicinal products on humans.

Article 22

Licences for clinical trials of medicinal products on humans.

Clinical trials of medicinal products on humans may only be carried out on the basis of a licence. The minister shall issue a regulation setting out further provisions on the conditions for granting licences for clinical trials of medicinal products on humans. The regulation shall specify the government authority that is to issue licences for such trials and the role of the authority in evaluating such trials and granting licences. The regulation shall also address how participants in trials are to be insured, informed consent and the future preservation of materials in clinical trials. The regulation shall furthermore take account of the rules of the

European Economic Area applying to such trials, the Helsinki Convention and the Data Protection Act.

SECTION VI
Manufacture of medicinal products.

Article 23
Manufacture of medicinal products.

Medicinal products may only be manufactured on the basis of a manufacturing authorisation granted by the Icelandic Medicines Agency.

A manufacturing authorisation for medicinal products shall include authorisation for the wholesale distribution of the medicinal products or types of medicinal products that are specified in the manufacturing authorisation granted to the authorisation holder in question and which it manufactures.

The provisions of the second paragraph shall not apply to manufacturing by a hospital or other healthcare institution of medicinal products that are used in treatment administered by the institution involved following manufacture. In the case of such manufacture, the Council of Europe's resolutions regarding the manufacture of medicinal products in hospitals or other healthcare institutions shall be taken into account.

Article 24
Temporary and restricted manufacturing licences.

The Icelandic Medicines Agency may issue temporary manufacturing authorisations and restrict authorisations to a specific type of manufacture.

Article 25
Manufacturing of active substances.

Importers, manufacturers and distributors of active substances in Iceland shall register with the Icelandic Medicines Agency.

The Icelandic Medicines Agency shall maintain and publish on its website a list of undertakings covered by the first paragraph. The Icelandic Medicines Agency may strike undertakings off the list if it is found that they have grossly or repeatedly violated the regulations issued under the first paragraph of Article 27.

Article 26
Notification obligation concerning falsified medicinal products or active substances.

All those who have been granted authorisations for the manufacture of medicinal products (*cf.* the first paragraph of Article 23) or have registered as manufacturers, importers or exporters of active substances (*cf.* the first paragraph of Article 25) shall be obliged to inform the Icelandic Medicines Agency immediately if the party concerned purchases, or offers to purchase, active substances or intermediate substances that are falsified, or are suspected of being falsified.

Article 27
Regulations.

The minister shall issue a regulation on the manufacture of medicinal products and active substances containing further provisions on the activities of manufacturers, importers or exporters of active substances, including as regards the requirements made concerning

specialised knowledge, their organisation, activities and staff, and good working practice in medicinal product manufacture. Furthermore, provisions shall be laid down regarding the requirements made of the authorisation holder's professional director, its premises, equipment and good manufacturing practice in medicinal product manufacture.

The minister shall set out provisions in a regulation on the conditions for granting manufacturing authorisations for the dose dispensing of medicinal products.

SECTION VII
Wholesale distribution of medicinal products.

Article 28
Authorisations for the wholesale distribution of medicinal products.

Medicinal products may only be distributed on a wholesale basis in accordance with a wholesale authorisation granted by the Icelandic Medicines Agency. The minister shall set out further conditions for the granting of wholesale authorisations in a regulation on the importation, wholesale distribution and brokering of medicinal products, including the requirement that the authorisation holder have a professional director, requirements regarding the authorisation holder's premises, equipment and staff and the maintenance of good working methods in medicinal product distribution.

Article 29
Obligations of wholesale authorisation holders.

Wholesale authorisation holders who sell medicinal products to pharmacies, healthcare institutions and the workplaces of physicians, dentists and veterinarians shall be obliged to maintain sufficient stocks of specific necessary medicinal products for which marketing authorisation has been granted in Iceland and which have been placed on the market, and of which the wholesale authorisation holder handles the distribution. Following consultation with the Directorate of Public Health, Landspitali or the Food and Veterinary Authority, as appropriate, and a representative of the wholesale authorisation holder, the Icelandic Medicines Agency shall publish on its website a list of the specific necessary medicinal products and stock quantities in question.

Wholesale authorisation holders shall be obliged to record sales information electronically and in a manner approved by the Icelandic Medicines Agency. They shall also provide the Icelandic Medicines Agency and the Directorate of Public Health with information about their activities if requested to do so.

The Icelandic Medicines Agency may prohibit wholesale authorisation holders from selling and exporting specific stocks of a medicinal product from Iceland if it is foreseeable that such exportation could impact the availability of the medicinal product in the country and that this could jeopardize human or animal health.

Wholesale authorisation holders who sell medicinal products to pharmacies, healthcare institutions and the workplaces of physicians, dentists and veterinarians shall maintain and publish medicinal product waiting lists, i.e. lists of medicinal products for which marketing authorisation has been granted in Iceland and which have been marketed, and of which they handle the distribution, but are not available at any given time.

Wholesale authorisation holders shall be obliged to inform the Icelandic Medicines Agency of impending stock shortages of medicinal products.

Article 30

Authorisations of wholesale authorisation holders.

Wholesale authorisation holders may only sell medicinal products to the following:

a. Wholesale authorisation holders.
b. Pharmacy licence holders.
c. Holders of authorisations for the sale of veterinary medicinal products (*cf.* Article 35).
d. Holders of authorisations for the dose dispensing of medicinal products.
e. Healthcare institutions that have a pharmacist in their service.
f. Physicians, dentists and veterinarians for use in their own work.
g. Experimental laboratories and universities which come under the Higher Education Act and which work at medicinal product research and testing and teaching in medicine and pharmacology.

Wholesale authorisation holders may only purchase medicinal products from the following:

a. other wholesale authorisation holders,
b. those who are licenced to sell medicinal products wholesale but are exempt from the requirement to hold wholesale licences (*cf.* Article 23).

Wholesale authorisation holders may also sell minimum packages and minimum strengths of nicotine and fluoride medicines (*cf.* the second paragraph of Article 33.

Article 31

Authorisation for the brokering of medicinal products.

Medicinal products may only be brokered by those who have registered as medicinal product brokers with the Icelandic Medicines Agency.

The Icelandic Medicines Agency shall maintain and publish on its website a list of those who are licensed to broker medicinal products (*cf.* the first paragraph). The Icelandic Medicines Agency may strike medicinal product brokers off this list if it comes to light that they have grossly and repeatedly violated the rules set under the third paragraph.

The minister shall set out further provisions on the registration and activities of those who broker medicinal products in a regulation on the importation, wholesale distribution and brokering of medicinal products, including as regards the demands made of brokers' specialist knowledge, the organisation of their activities and their staff, and regarding good working practice in medicinal product distribution.

SECTION VIII
Medicated animal feeds.

Article 32

Authorisation for the importing and manufacture of medicated animal feeds.

Medicated animal feeds may only be imported and manufactured on the basis of a licence granted by the Icelandic Medicines Agency. Licences according to the first sentence shall furthermore confer authorisation for the distribution of medicated animal feeds.

The minister shall set out further provisions on the conditions for granting licences for the importation and manufacture of medicated animal feeds, including as regards prescription, monitoring, delivery and distribution.

SECTION IX
Retailing of medicinal products, pharmacies, etc.

Article 33

Retailing of medicinal products.

Medicinal products may only be sold to the public under a pharmacy licence issued by the Icelandic Medicines Agency; exemptions are, however, permitted as described in this Section.

Minimum packages and minimum strengths of nicotine and fluoride medicinal preparations that are not subject to prescription requirements may be sold in places other than pharmacies. Medicinal preparations sold under this paragraph may not be offered in self-service dispensers. The sale of these medicinal products shall furthermore be subject to the first and seventh paragraphs of Article 8 of the Tobacco Act. The provisions of the Hygiene and Anti-Pollution Measures Act shall apply as regards monitoring, coercive measures and sanctions.

The Icelandic Medicines Agency may also grant exemptions from the provisions of the first paragraph for the sale of specific medicinal products directly from wholesale authorisation holders to the public. The Icelandic Medicines Agency shall publish on its website a list of the medicinal products that may be sold according to this provisions of this paragraph.

The minister shall set out further provisions on the activities of pharmacies and the conditions for granting pharmacy licences in a regulation on pharmacy licences and pharmacies, including the demands made regarding licensees' premises, equipment and staff, the operation of pharmacy branches and their classification according to the nature and scope of the services they are permitted to provide, mail-order and internet sales of medicinal products and good working practices in pharmacies.

Article 34

Pharmacy licences.

The Icelandic Medicines Agency shall grant pharmacy licences. Pharmacy licences may only be granted to those who meet the following conditions:

a. they must hold valid operating licences as pharmacists in Iceland (*cf.* the Healthcare Practitioners Act),
b. they must have worked as pharmacists for at least two years, of which at least 12 months shall have been in a pharmacy in the European Economic Area.

The Icelandic Medicines Agency may assess working experience in a pharmacy outside the European Economic Area as being comparable in validity to meet the working experience requirement of indent b of the first paragraph. Furthermore, the Icelandic Medicines Agency may grant a pharmacist's licence to a pharmacist with a minimum of 12 months' working experience as a pharmacist, of which 6 months shall have been in a pharmacy in the European Economic Area if it is considered demonstrated that otherwise there would be no functioning pharmacy in a particular local government area or in a particular urban area within a local government area.

The Icelandic Medicines Agency shall send applications for new pharmacy licences to the relevant local authority for comment. When assessing applications, factors such as the number of persons to be served by the pharmacy and the distance between it and the nearest pharmacy shall be taken into consideration. If the party giving the opinion is opposed to the granting of a new licence, the Icelandic Medicines Agency may reject the application. Applications for pharmacy branches shall be sent to the local authority for comment in the same way.

Article 35

Licences for veterinarians to sell veterinary medicinal products.

In response to applications, the Icelandic Medicines Agency shall grant veterinarians licences to sell veterinary medicinal products if they meet the following conditions:

a. they must hold valid operating licences as veterinarians in Iceland (*cf.* the Veterinarians and Animal Health Services Act),

b. they must have informed Icelandic Food and Veterinary Authority that the person concerned has begun operating as a veterinarian and also where their activities take place.

Veterinarians' licences for the sale of veterinary medicinal products shall be limited to the sale and supply of the following veterinary medicinal products for animals which the veterinarian is treating:

a. retail veterinary medicinal products,

b. medicinal products prescribed by a veterinarian (*cf.* the Regulation on veterinarians' authorisation to prescribe medicinal products).

Article 36

Pharmacy licences for health centres.

The Icelandic Medicines Agency may grant pharmacy licences to the manager of a health centre while no pharmacy is being operated in the local government area, or in a specific urban centre within the local government area, which the health centre serves. Agreements may be concluded with external pharmacy licence holders covering services of this type, including the operation of a pharmacy.

Article 37

Operation of pharmacies.

Pharmacy licences as provided for in Article 34 shall be restricted to the operation of one pharmacy and the licence holder shall be responsible for the operation of the pharmacy. Pharmacies shall be marked in a conspicuous manner.

Pharmacists may hold only one pharmacy licence at any given time. A pharmacy licence holder may apply to the Icelandic Medicines Agency for a licence to operate a branch from his or her pharmacy within the local government area, or in a specific urban area within the local government area, where no pharmacy is operated.

Mail-order and internet sales of medicinal products may be made on the basis of a pharmacy licence.

Pharmacies may grant discounts on the maximum retail price of prescription medicinal products. If a pharmacy grants a person covered by health insurance a discount on the price on which cost participation by Icelandic Health Insurance is calculated, Icelandic Health Insurance shall be informed of the discount and shall calculate the price to be paid by the insured person based on the discount price and person's position on the cost steps (*cf.* item 6 of the first paragraph of Article 29 of the Health Insurance Act).

During normal dispensing hours in pharmacies, and during busy periods outside normal dispensing hours, not fewer than two pharmacists shall normally be on duty, processing prescriptions and giving advice and guidance on the correct use of medicinal products and their handling. The Icelandic Medicines Agency may, in response to an application on this point, permit only one pharmacist to be on duty in a pharmacy, providing that the scope of its operations is small and trained staff assist the pharmacist. The Icelandic Medicines Agency may also, in response to an application on this point, grant a temporary permit for having only one pharmacist on duty in a pharmacy if there is a danger that the operation of the pharmacy in the area in question would otherwise have to be terminated.

Article 38

Manufacture of magistral formula medicinal products in pharmacies.

Pharmacies may manufacture physicians' magistral formula medicinal products and standardised magistral formula medicinal products on the basis of a medicinal product manufacturing authorisation (*cf.* Article 23).

The Icelandic Medicines Agency may grant exemption from the provision of the first paragraph and magistral formula medicinal products may thus be manufactured in places other than in pharmacies. An application for exemption shall be made for the manufacture of each specific medicinal product. Exemptions may only be granted for medicinal products that are considered necessary and impossible or expensive to have supplied to Iceland via other channels. Authorisation may not be granted for manufacture if marketing authorisation has been granted for a comparable medicinal product and this has been placed on the market in Iceland.

Article 39

Operating licences.

If a natural or legal person other than the pharmacy licence holder is the operator of a pharmacy, that person shall be obliged to apply to the Icelandic Medicines Agency for an operating licence.

The operating licence shall contain provisions on the division of roles between the operating licence holder and the pharmacy licence holder as regards which party shall be responsible for compliance with specific provisions of this Act and of regulations issued hereunder and applying to the operation of pharmacies.

Article 40

Obligations of pharmacy licence holders.

Pharmacy licence holders shall be obliged to:

a. Maintain suitable stocks of medicinal products that are on the market in Iceland, obtain, as quickly as possible, medicinal products that are in demand but not in stock and offer for sale the principal types of medical equipment to the extent possible.
b. Provide the Icelandic Medicines Agency with information, as requested by the agency, relating to the activities of the pharmacy.
c. Connect to the central payment database of the Health Insurance Administration and comply with other rules set under Article 29 a of the Health Insurance Act, and also to inform the Health Insurance Administration of all instances when the pharmacy grants a discount on the cost participation price of medicinal products that are subject to prescription.
d. Provide the public and healthcare institutions and veterinarians with information about medicinal products, their use and how they are to be stored..
e. Carry out pharmacological supervision.
f. Record, electronically, all information about medical product prescriptions in the form decided upon by the Directorate of Public Health and in accordance with the Data Protection Act, and also to supply the Directorate of Public Health, at its request, with all information contained in a medicinal product prescription concerning the dispensing of the medicinal product in the form desired by the directorate; the Directorate of Public Health may demand this information going back for up to one year in time.

g. Have in their service, as necessary, pharmacy technicians to assist the pharmacy licence holder or other pharmacists working for him or her with the dispensing of prescriptions.

Article 41

On-line sales of medicinal products.

Pharmacy licence holders (*cf.* Article 34) who propose to engage in on-line selling of medicinal products on the basis of such licences shall be obliged to notify the Icelandic Medicines Agency of this not later than at the time when on-line sales commence.

The Icelandic Medicines Agency shall maintain and publish on its website a list of pharmacy licence holders who have informed the agency of their intention to engage in on-line selling of medicinal products as provided for in the first paragraph. The Icelandic Medicines Agency shall also publish on its website information on on-line sales of medicinal products, including as regards the potential danger involved in purchasing medicinal products on-line from parties that do not hold the required authorisations.

The minister may issue a regulation setting more detailed provisions on the conditions for, and the practice of, on-line sales of medicinal products, including as regards the information to be submitted with announcements by pharmacy licence holders of their intention to make on-line sales, the form and content of such announcements, the form of, and technical demands made regarding, web pages housing on-line shops for medicinal products and conditions for the publication of the common logo of the EU for on-line pharmacies.

SECTION X

Medicinal product services in healthcare institutions.

Article 42

Hospital pharmacies.

Healthcare institutions operated on the basis of the Health Services Act may operate pharmacies in the healthcare institutions in question. Such pharmacies are referred to as hospital pharmacies. Operations of hospital pharmacies shall be financially separate from the other operations of the healthcare institution.

If no hospital pharmacy is operated in a healthcare institution that is operated under the Health Services Act, a pharmacist shall be responsible for, amongst other things, the procurement of medicinal products, their storage, the maintenance of mandatory registers and monitoring of the use of the medicinal products.

If the healthcare institution does not have a pharmacist in its service as provided for in the second paragraph, the institution shall enter into an agreement with and external pharmacy licence holder, pharmacist or hospital pharmacy covering services that shall involve responsibility for the procurement of medicinal products and the monitoring of their use.

A healthcare institution may invite tenders for the operation of a hospital pharmacy to provide the services covered in this Section, providing that the operations meet all the requirements of this Act on the activities and operations of pharmacies.

Article 43

Authorisations and obligations of hospital pharmacies.

The director of the healthcare institution in which a hospital pharmacy is operated shall engage a pharmacist to head the hospital pharmacy; this person shall be responsible for the activities of the hospital pharmacy.

The hospital pharmacy shall, amongst other things, be responsible for the procurement of medicinal products, their storage, the maintenance of mandatory registers and monitoring of the use of the medicinal products.

A hospital pharmacy may dispense medicinal products to patients who are discharged from the hospital and also to out-patients. A hospital pharmacy may only dispense medicinal product prescriptions issued by physicians who work there.

The dispensing of medicinal products under the authorisation of this article shall be subject to the ordinary rules applying to medicinal product prescriptions and the dispensing of medicinal products.

The premises, equipment and appointment of the staff of hospital pharmacies or medicinal product services in healthcare institutions shall be in accordance with the provisions of this Act and of regulations issued hereunder.

Article 44

Landspitali's medicinal products committee.

A medicinal products committee shall function in Landspítali to promote the safe and rational use of medicinal products at Landspítali and other public hospitals, the aim being to ensure that professional and financial responsibility be combined in the choice and use of medicinal products.

The director of Landspítali shall appoint Landspítali's medicinal products committee for terms of five years; care shall be taken to ensure that the committee include persons with an extensive knowledge of clinical medicine, clinical pharmacology, nursing, ethics and finances in the health services. Alternate members of the committee shall be appointed in the same manner. The director of Landspítali shall set the committee rules of procedure, including as regards what is to be considered as a substantial cost (*cf.* the seventh paragraph). These procedural rules shall be published on Landspítali's website.

Landspítali's medicinal products committee shall, amongst other things, take decisions on the use of medicinal products subject to licence and S-marked medicinal products in the health services, assess whether, and how, medicinal products are of benefit to patients and prepare guidelines for, and priority lists of, medicinal products, taking account of financial allocations for the adoption of medicinal products subject to licence and S-marked medicinal products and their use in the health services. It shall also be the responsibility of the committee to prepare and monitor medicinal product lists for public hospitals.

Landspítali's medicinal products committee shall submit comments to the Icelandic Medicines Agency regarding applications for participation in the cost of medicinal products that are subject to licence (*cf.* Article 66). Comments shall be written and backed by reasoning. Comments submitted to the Icelandic Medicines Agency shall be accompanied by all the necessary documentation.

Landspítali's medicinal products committee shall take decisions on the bearing of the full cost of medicinal products by Landspítali, including as regards medicinal products that are covered by point 5 of the first paragraph of Article 66. Applications regarding individuals' participation in the cost of medicinal products shall be submitted to Landspítali's medicinal products committee.

Members of the medicinal products committee may not have special and substantial interests in the development, manufacture, marketing, importing, exporting, brokering, wholesaling or retailing of medicinal products.

Decisions and comments by Landspítali's medicinal products committee which entail substantial costs shall be referred to the director of Landspítali.

Landspítali's medicinal products committee shall collaborate closely with the medicinal products committee of the Healthcare Development Centre (*cf.* Article 45) and overseas partners. The committee may also consult other healthcare professions and individual patients' organisations as is deemed necessary.

Decisions of Landspítali's medicinal products committee are final at their administrative level and no appeals may be lodged against them with the minister.

Article 45

The Healthcare Development Centre's medicinal products committee.

A medicinal products committee shall function in the Healthcare Development Centre to promote the safe and rational use of medicinal products that are prescribed or used in health centres (primary clinics) and in nursing and residential homes.

The director of the Healthcare Development Centre shall appoint the medicinal products committee of the Healthcare Development Centre, taking care to ensure that the committee include persons with an extensive knowledge of clinical medicine, clinical pharmacology, nursing and finances in the health services. Alternate members of the committee shall be appointed in the same manner.

The committee's role shall include assessing whether, and how, medicinal products are of benefit to patients and preparing guidelines on the use of medicinal products in the health centres, nursing homes and residential homes.

Members of the medicinal products committee may not have special and substantial interests in the development, manufacture, marketing, importing, brokering, wholesaling or retailing of medicinal products.

The medicinal products committee of the Healthcare Development Centre shall collaborate closely with Landspítali's medicinal products committee (*cf.* Article 44). The committee may also consult other healthcare professions, the University of Iceland's Centre for Ethics and individual patients' organisations as is deemed necessary.

Article 46

Regulations.

The minister shall issue a regulation setting out further provisions on medicinal product services in healthcare institutions and the workplaces of healthcare practitioners, including as regards the selection, storage and handling, use and safety of medicinal products and medicinal product treatment programmes in hospitals, other healthcare institutions and the workplaces of healthcare practitioners where medicinal products are prescribed or used.

The minister shall issue a regulation on the structure, role and activities of Landspítali's medicinal products committee and the medicinal products committee of the Healthcare Development Centre.

SECTION XI

Safety features on the packaging of medicinal products for human use.

Article 47

Safety features on the packaging of medicinal products for human use.

It shall be possible to verify, in the medicinal product supply chain, that individual packages of medicinal products for humans are authentic for the entire time the medicinal

product stays on the market and the additional time necessary for returning and disposing of the pack after it has expired.

The minister shall issue a regulation on safety features on the packaging of medicinal products for human use.

SECTION XII
Medicinal product prescriptions and the dispensing of medicinal products in pharmacies.

Article 48
Authorisation to prescribe medicinal products.

Only holders of valid operating licences as physicians or dentists in the European Economic Area (*cf.* the Medical Practitioners Act), or valid operating licences as veterinarians (*cf.* the Veterinarians and Animal Health Services Act) may prescribe medicinal products.

Nurses and midwives who have received special licences from the Directorate of Public Health and work where healthcare, gynaecological or obstetric services are delivered, may prescribe hormone medicinal preparations for contraceptive purposes.

Prescriptions issued by those who are licenced to prescribe medicinal products shall be recorded in the medicinal product database.

Persons licenced to prescribe medicinal products shall promote the responsible use of antibiotics when prescribing medicinal products for patients.

Article 49
Issuing of medical product prescriptions; monitoring.

Medical product prescriptions may only be issued as follows:

a. by electronic prescription prepared in accordance with the Regulation on medicinal product prescriptions and the dispensing of medicinal products,
b. by a medicinal product prescription written or printed on paper,
c. by a medicinal product prescription that is read over the telephone and received by a pharmacist in a pharmacy.

The Directorate of Public Health shall monitor medicinal product prescriptions by physicians, dentists, midwives and nurses and dispensing by pharmacists in emergency cases (*cf.* the Directorate of Public Health Act and Article 75 of the present Act). The Icelandic Food and Veterinary Authority shall monitor prescriptions of medicinal products by veterinarians (*cf.* the Veterinarians and Animal Health Services Act and Article 78 of the present Act).

Article 50
The medicinal product prescription portal.

For the transmission of electronic medicinal product prescriptions (*cf.* indent a of the first paragraph of Article 48) between the issuers of medicinal product prescriptions and pharmacies, the Directorate of Public Health shall operate a medicinal product prescription portal. Electronic medicinal product prescriptions may be kept in the portal while they are valid. The Data Protection Act shall apply regarding the processing of personal data sent via the medicinal product prescription portal.

Article 51

Dispensing and supply of medicinal products by prescription.

Medicinal products subject to prescription may only be dispensed by submission of a prescription in a pharmacy.

Only those who hold valid pharmacists' licences (*cf.* the Medical Practitioners Act) may dispense medical product prescriptions in a pharmacy or pharmacy branch, and the person in question is responsible for the correct dispensing according to the prescription.

In cases of emergency, pharmacists in pharmacies may supply medicinal products that are subject to prescription in the smallest available packages without a prescription being submitted.

Pharmacy licence holders shall keep registers of medicinal products supplied under the authorisation of the third paragraph. Such registers shall be accessible by the Icelandic Medicines Agency and the Directorate of Public Health if this is requested.

Article 52

Substitution of medicinal products.

When dispensing a medicinal product prescription in a pharmacy, pharmacists may change the physician's prescription to another medicinal product of comparable quantity as that prescribed; however, this may only be done if the medicinal product is to be found on the Icelandic Medicines Agency's substitute list (*cf.* the fourth paragraph).

In special cases, when there is a shortage of a medicinal product that has been placed on the market, the Icelandic Medicines Agency may change a prescription to one for a medicinal product that is permitted by exemption, providing that authorisation of this type is granted following an assessment by the agency of the safety of making such a change.

A physician may, when prescribing a medicinal product (*cf.* Article 48), may restrict, in part or entirely, the right of a pharmacist as laid down in the first paragraph.

The Icelandic Medicines Agency shall maintain and publish on its website a substitute list in which synonym preparations, biosimilars and medicinal products with comparable efficacy in treatment are grouped together listed.

Article 53

Regulations.

The minister shall issue a regulation setting out further provisions on medicinal product prescriptions and the dispensing of medicinal products in pharmacies, including the structure of prescriptions, the prescription of medicinal products, the prescription of medicinal products containing narcotics and psychotropic substances, the Icelandic Medicines Agency's substitute list, dispensing by a pharmacist of a medicinal product in an emergency without submission of a prescription, the period of validity of prescriptions and the labelling of medicinal products in pharmacies and recognised methods of issuing electronic prescriptions.

The minister may issue a regulation setting out more detailed rules on the prohibition or restriction of the use of antibiotics.

The minister shall issue a regulation containing more detailed provisions on dentists' authorisations to prescribe medicinal products.

The minister shall issue a regulation setting out further provisions on veterinarians' authorisations to prescribe medicinal products.

The minister shall issue a regulation setting out further provisions on the conditions for authorisations for nurses and midwives to prescribe medicinal products, including as regards

additional study qualifications and the medicinal products, or medicinal product categories, to which nurses' and midwives' authorisations extend.

The minister may issue a regulation on the medicinal product prescription portal.

SECTION XIII
Medicinal product advertising.

Article 54
Authorisation to advertise medicinal products.

Medicinal products may be advertised in Iceland, subject to the restrictions set out in this Section.

Landspítali may gather information on, and accept informative materials about, medicinal products for which no marketing authorisation or authorisation for parallel importation has been granted, or which have been granted marketing authorisation but have not been placed on the market.

Article 55
Information in medicinal product advertisements.

Medicinal product advertisements shall at all times be presented in a neutral manner and give satisfactory information about the correct use of the medicinal product. The properties of the medicinal product may not be exaggerated and misleading information may not be given about them in advertisements. The information in a medicinal product advertisement shall at all times be in accordance with the approved summary of the product's properties. If a product that has not been granted marketing authorisation as a medicinal product is advertised in such a way as to imply that it is a medicinal product, the provisions of this Section shall apply (*cf.* point e of the first paragraph of Article 56).

Article 56
Prohibited advertising of medicinal products.

The following may not be advertised:

a. Medicinal products for which marketing authorisation, or authorisation for parallel importing in Iceland, has not been granted.
b. Medicinal products for which marketing authorisation, or authorisation for parallel importing in Iceland has been granted, but which have not been placed on the market.
c. Physicians' magistral formula medicinal products.
d. Standardised magistral formula medicinal products.
e. Any product that has not been granted marketing authorisation or approval as a medicinal product but is advertised as preventing, curing or assuaging diseases, symptoms of a disease or pain, or altering organ function.

In special cases, the Icelandic Medicines Agency may grant exemption from the first paragraph.

The following may not be advertised to the public:

a. Medicinal products that are subject to prescription,
b. Medicinal products that contain substances which are covered by the current Narcotics and Psychotropic Substances Act.

'The public' here refers to all persons other than those who have received operating licences as physicians, dentists, pharmacists, midwives and nurses (*cf.* the Healthcare

Practitioners Act) or have received operating licences as veterinarians (*cf.* the Veterinarians and Animal Health Services Act).

The Icelandic Medicines Agency may grant exemptions to make it possible to advertise medicinal products in professional journals of healthcare practitioners other than those listed in the third paragraph.

The Icelandic Medicines Agency may grant exemptions from the provisions of the first paragraph in cases where information is given to the public regarding general measures against infection which the minister has decided are to be taken (*cf.* Section IV of the Health Security and Communicable Diseases Act).

Article 57

Medicinal product samples.

Medicinal product samples may be supplied to physicians, dentists or veterinarians in the smallest package sizes, in person and without payment, providing that they are newly-registered medicinal products for introduction on the Icelandic market and that they are not regarded as medicinal products containing narcotics or psychotropic substances.

Any other form of supply or sending by post of medicinal product samples is not permitted.

Article 58

Obligations of marketing authorisation holders.

Holders of marketing authorisations shall maintain registers of all their medicinal product advertisements in Iceland. This register shall be preserved for two years and the Icelandic Medicines Agency shall be granted access to it if this is requested.

Article 59

Monitoring of medicinal product advertisements.

The Icelandic Medicines Agency shall monitor medicinal product advertisements under this Act. The Icelandic Medicines Agency shall also monitor advertisements in which a product for which no marketing authorisation has been granted as a medicinal product is advertised in a manner designed to imply that it is a medicinal product (*cf.* indent e of the first paragraph of Article 56).

The Icelandic Medicines Agency may demand that the publication of an advertisement that violates the provisions of this Section, or of a regulation on medicinal product advertising, be stopped.

The Icelandic Medicines Agency may demand that holders of marketing authorisations who have published medicinal product advertisements that violate the provisions of this Section publish corrections or supplementary explanations relating to the unlawful advertisements.

The Icelandic Medicines Agency may take a decision laying down requirements regarding the form, content, method of publication and place of publication of such corrections or supplementary explanations.

Article 60

Regulations.

The minister shall issue a regulation setting out further provisions on medicinal product advertisements, including advertisements for over-the-counter medicinal products and the supply of medicinal product samples, the provision of information and educational guidance

on medicinal products for which no marketing authorisation or authorisation for parallel importation has been granted, or which have been granted marketing authorisation but have not been placed on the market, the advertising of medicinal products subject to prescription, the advertising of medicinal products to the public and the necessary information that is to appear in medicinal product advertisements.

The minister shall set rules, after receiving proposals from the Icelandic Medicines Agency, in which provision shall be made for the form and substance of the information to be stated in marketing authorisation holders' registers of medicinal product advertisements, including as regards the target group, contents, use, method of publication and distribution channel.

SECTION XIV
Pharmacovigilance.

Article 61
Pharmacovigilance by the Icelandic Medicines Agency.

The Icelandic Medicines Agency shall operate a pharmacovigilance system to monitor the safety of medicinal products and shall keep a list of side-effects reported to the agency. The Icelandic Medicines Agency may release information on reported side-effects to the Directorate of Public Health, patients' organizations operating in Iceland, the European Medicine Agency, the European Commission, the competent authorities in the medical product field in member states of the European Economic Area and marketing authorisation holders.

Article 62
Obligations of the marketing authorisation holders.

Marketing authorisation holders shall be obliged to operate pharmacovigilance systems in order to monitor medical product safety, assess the possibility of minimizing and preventing risks and taking the appropriate measures when necessary.

The Icelandic Medicines Agency may demand that the holder of a marketing authorisation for a medical product for human use nominate a contact person in Iceland who will represent the person responsible for pharmacovigilance.

Marketing authorisation holders shall be obliged to inform the Icelandic Medicines Agency and the Icelandic Food and Veterinary Authority if a changes occurs in the product expiry date of a veterinary medicinal product.

The Icelandic Medicines Agency shall monitor to ensure compliance by marketing authorisation holders with their obligations under the first paragraph. Marketing authorisation holders shall be obliged to provide the Icelandic Medicines Agency with such materials and information as the agency considers necessary for it to be able to carry out its monitoring functions. Marketing authorisation holders shall furthermore be obliged to grant the Icelandic Medicines Agency access to their premises for the same purpose, should this be necessary in the opinion of the agency.

The Icelandic Medicines Agency shall inform the European Medicines Agency, the European Commission, the competent authorities of other member states of the European Economic Area in the field of medicinal products and the marketing authorisation holder if the outcome of monitoring is that the marketing authorisation does not meet the requirements of the pharmacovigilance system as described in the pharmacovigilance system master file.

Article 63

Obligations of healthcare practitioners.

If a healthcare practitioner acquires a suspicion regarding a side-effect of the use of a medicinal product in the course of his work, he shall be obliged to report this to the Icelandic Medicines Agency via a special form on the agency's website.

If a veterinarian acquires a suspicion regarding a side-effect of the use of a medicinal product in the course of his work, he shall be obliged to report this to the Icelandic Medicines Agency and the Icelandic Food and Veterinary Authority.

Medical practitioners shall be obliged to enable the Icelandic Medicines Agency, the Directorate of Public Health and market authorisation holders to send them information on medical product safety, danger warnings and other information based on data from the pharmacovigilance system.

Article 64

Publication of information on medicinal product safety.

Marketing authorisation holders for human medical products may not publish information on medicinal product safety that is based on pharmacovigilance data without announcing the publication, previously or simultaneously, to the Icelandic Medicines Agency, the European Medicines Agency and the European Commission.

Marketing authorisation holders for veterinary medical products may not publish information on the safety of veterinary medicinal products that is based on pharmacovigilance data without announcing the publication, previously or simultaneously, to the Icelandic Medicines Agency.

The marketing authorisation holder shall ensure that information under the first or second paragraph is presented impartially and that it is not misleading.

The Icelandic Medicines Agency may demand that marketing authorisation holders for medicinal products for humans publish medicinal product information relating to patient safety, including information on side-effects which are suspected of being related to medicinal products, or disseminate such information to a specified group of healthcare practitioners.

Article 65

Regulations.

The minister shall issue a regulation setting out further provisions on demands made of marketing authorisation holders in connection with pharmacovigilance.

The minister may, in a regulation, set out provisions on the obligation of healthcare practitioners to report to the Icelandic Medicines Agency suspicions of side-effects of the use of a medicinal product, including information from medical records and registers of the causes of death.

The minister may, in a regulation, set out provisions on the right of patients, their families and the keepers of animals to inform the Icelandic Medicines Agency of side-effects which are suspected of being related to medicinal products.

The minister may issue a regulation on further implementation of the Icelandic Medicines Agency's pharmacovigilance system, including as regards healthcare practitioners' obligation under the third paragraph of Article 63.

SECTION XV

Medicinal product prices and cost participation.

Article 66

Medicinal product pricing, determination of medicinal product prices and cost participation.

The pricing of over-the-counter medicinal products is unrestricted.

The Icelandic Medicines Agency shall determine the following in response to an application:

1. The maximum wholesale and retail prices of medicinal products that are subject to prescription and all veterinary medicinal products, irrespective of whether or not they are subject to prescription. When the Icelandic Medicines Agency takes ordinary decisions on the maximum wholesale prices of medicinal products that are subject to prescription, the agency shall consult representatives of wholesale authorisation holders, and when taking ordinary decisions on maximum retail prices and retail pricing, the agency shall consult representatives of pharmacy licence holders.
2. Whether a medicinal product qualifies for cost participation (*cf.* Section III of the Health Insurance Act on participation by Icelandic Health Insurance in the cost of medicinal products for humans on the market in Iceland) and the cost participation price, i.e., the price on which Icelandic Health Insurance is to base its participation, taking into account any discount granted by the pharmacy licence holder when dispensing a prescription.
3. Whether a medicinal product is regarded as S-labelled and whether it qualifies for cost participation, following prior comment from Landspítali's medicinal products committee. The Icelandic Medicines Agency shall send its application, as soon as possible, to Landspítali's medicinal products committee. Before a decision is taken, the contract or tender price quoted by the party in charge of negotiating contracts on behalf of the state shall be obtained.
4. Whether a medicinal product is regarded as being subject to authorisation and, as such, covered by the national health insurance system, following prior comment from Landspítali's medicinal products committee. The Icelandic Medicines Agency shall send its application, as soon as possible, to Landspítali's medicinal products committee. Before a decision is taken, the contract or tender price quoted by the party in charge of negotiating contracts on behalf of the state shall be obtained.
5. Participation in the cost of medicinal products for which exemptions have been granted under Article 12. The Icelandic Medicines Agency may refer the processing of applications in connection with medicinal products for which exemptions have been granted under that provision to Icelandic Health Insurance. Landspítali shall take decisions on participation in the cost of medicinal products under this point (*cf.* the fourth paragraph of Article 44).

Sellers, i.e. medicinal product wholesalers and market authorisation holders, who wish to sell medicinal products subject to prescription at a price below the stated maximum price shall inform the Icelandic Medicines Agency of that price, which shall publish the reduced price in the next edition of the medicinal products price list. The seller shall sell the medicinal product at the same price at all its points of sale.

If the Icelandic Medicines Agency does not agree to a requested official price, a change of price or cost participation under the provisions of this Section, the agency shall give reasons for its decision and inform the applicant of his right to refer the agency's decision to the courts.

Pharmacies, medical product wholesalers and market authorisation holders shall be obliged to supply the Icelandic Medicines Agency with all information regarding medicinal product

pricing, and other information, which the agency considers it needs in order to discharge its role under this Section.

Expenses arising from the work of the Icelandic Medicines Agency in connection with the determination of medicinal product prices, decisions on licensing requirements, S-labelling and cost participation shall be paid by the Treasury.

Decisions taken by the Icelandic Medicines Agency under this Section are final at the administrative level and no appeals may be lodged against them with the minister.

The minister shall issue a regulation setting out further provisions on medicinal product pricing and participation in the cost of medicinal products, including the requirement that decisions by the Icelandic Medicines Agency are to be based on pricing and cost participation in states, to be specified, in the European Economic Area.

Article 67

Landspítali's procurement of medicinal products.

Notwithstanding decisions on pricing by the Icelandic Medicines Agency under this Section, those who attend to the procurement of medicinal products for government authorities may enter into negotiations on procurement prices for S-labelled medicinal products and medicinal products that are subject to licence.

Article 68

Criteria when determining medicinal product prices and cost participation.

The Icelandic Medicines Agency shall, when deciding medicinal product prices, aim at keeping medicinal product costs to a minimum. Consideration shall also be given to the special nature of the Icelandic market for medicinal products and security in medicinal product supply.

The Icelandic Medicines Agency shall take account of medicinal product prices and cost participation in the Nordic countries and also in other countries in the European Economic Area when taking its decisions under points 1 and 3 of the first paragraph of Article 66.

The Icelandic Medicines Agency shall, when determining the maximum price of medicinal products in parallel importation, take account of factors including the price applied for by the importer if it is lower than the price of the same medicinal product in Iceland.

The Icelandic Medicines Agency shall, when deciding the price of synonym preparations, i.e. medicinal products with the same active substance, and biosimilars, take account of the price of the medicinal products in question in the European Economic Area.

Article 69

The medicinal product price list and substitute list.

The Icelandic Medicines Agency shall see to the issue and publication of a medicinal product price list where information shall be published on, amongst other things, the maximum prices and participation in the cost of medicinal products for humans that are subject to prescription and the maximum prices of all veterinary medicinal products.

The Icelandic Medicines Agency shall see to the issue and publication of a substitute list in which all synonym preparations, biosimilars and medicinal products with comparable efficacy in treatment are grouped together in guideline price categories to make it possible to determine participation in costs.

The minister may issue a regulation on the medicinal products price list and the substitute list.

Article 70

Processing of applications regarding prices and cost participation.

Marketing authorisation holders, medicinal product wholesalers and medicinal product brokers shall apply for maximum wholesale prices, cost participation by Icelandic Health Insurance and all changes in the price of medicinal products that are subject to prescription to the Icelandic Medicines Agency, and applications shall be accompanied by information on the wholesale price of the medicinal product in question in the countries specified in the current regulation. The Icelandic Medicines Agency's decision on the medicinal product price shall be available, and shall have been made known to the applicant, not more than 90 days after the application was received. If the applicant fails to provide the necessary information with the application, the agency shall inform the applicant of what information is lacking immediately. The Icelandic Medicines Agency's decision, with reasons, shall then be available, and shall have been made known to the applicant, not more than 90 days after the necessary additional information is received by the agency. If no decision is available by these deadlines, the applicant may place the medicinal product on the market at the price applied for.

If a decision was also sought on participation by Icelandic Health Insurance in the cost of medicinal products for insured persons, such a decision shall be made known within 180 days of receipt of the application regarding the price of the medicinal product. If the applicant has not provided sufficient information with the application, he shall be informed what information is lacking. A decision, with reasons, shall then be available, and shall have been made known to the applicant, not more than 90 days after the necessary additional information is received by the agency. If an application for cost participation is received before the Icelandic Medicines Agency has taken a decision on the medicinal product price, the processing time for the application regarding cost participation shall be extended by a further 90 days.

The Icelandic Medicines Agency's decision on a higher price of a medicinal product shall be available, and shall have been made known to the applicant, not more than 90 days after the application was received. Applicants shall provide the agency with satisfactory information, including detailed information on the points that they consider to justify raising a price that has previously been decided. If the applicant fails to provide the necessary information with the application, the Icelandic Medicines Agency shall immediately inform the applicant of what information is lacking. The Icelandic Medicines Agency's decision shall then be available, and shall have been made known to the applicant, not more than 90 days after the necessary additional information is received by the agency. If an abnormally large number of applications have been received by the Icelandic Medicines Agency, it may additionally extend the deadline once by 60 days. Such an extension shall be announced to the applicant before the time permitted to the Icelandic Medicinal Agency to take its decision has elapsed. If no decision has been taken by these deadlines, the applicant may raise the price in accordance with the application.

Article 71

Price freezes.

The Icelandic Medicines Agency may apply price freezes. If a price freeze is applied to all medicinal products, or to medicinal products in a particular category, then the decision shall be reviewed at least once a year. Exemptions from price freezes may be granted in response

to applications in special cases. If the applicant seeks an exemption, he shall provide satisfactory information on the reasons for this request. The Icelandic Medicines Agency's decision, backed with reasons, shall be available, and shall have been made known to the applicant, within 90 days. If the applicant fails to provide the necessary information with the application, the Icelandic Medicines Agency shall inform the applicant of what information is lacking. The Icelandic Medicines Agency's decision shall then be available, and shall have been made known to the applicant, not more than 90 days after the necessary additional information is received by the agency. If an abnormally large number of applications for exemption have been received by the Icelandic Medicines Agency, it may additionally extend the deadline once by 60 days. Such an extension shall be announced to the applicant before the time permitted to the Icelandic Medicinal Agency to take its decision has elapsed.

Article 72

Reassessment of the premises for medicinal product pricing.

The Icelandic Medicines Agency shall reassess the premises for medicinal product pricing in Iceland, comparing pricing with that of the same medicinal products in the European Economic Area regularly and at least every two years, and make proposals regarding amendments if its reassessment gives occasion to do so.

SECTION XVI

Medicinal product statistics and the medicinal product database.

Article 73

Medicinal product statistics.

Undertakings which manufacture medicinal products, import them or export them, maintain stocks, negotiate agreements on them resell, distribute, supply, package or repackage them, and companies and firms related to them, shall provide the minister, or an institution nominated by the minister, information on the turnover and quantities of medicinal products sold or supplied. This information shall be in the form requested by the minister or the institution nominated by the minister. Publication of numerical information on turnover and quantities of all medicinal products shall be regarded as provision of this information.

The minister, or the institution that he or she nominates, may release statistical data of a general nature to other entities.

The undertakings mentioned in the first paragraph and/or their associations, shall furthermore provide the Icelandic Medicines Agency with information on the turnover and quantities of medicinal products sold in electronic format if this is requested.

The minister may issue regulations on the provision and handling of the information on medicinal products under the first paragraph, including the release and handling of confidential information, the authorisation for the release of data under the second paragraph, the provision of information to the minister under the third paragraph and the provision of information to the Icelandic Medicines Agency under the third paragraph.

The Icelandic Medicines Agency, the Directorate of Public Health or Icelandic Health Insurance shall be obliged to supply the entity nominated by the minister with information and materials on medicinal product sales and releases for presentation and publication of statistical information on medicinal product quantities and turnover.

Article 74

The medicinal product database.

In order to ensure the quality of the health services and patient safety, maintain general supervision of medicinal product prescriptions, monitor medicinal products containing narcotic and psychotropic substances and the sharing of information on medicinal product prescriptions to individuals for purposes including the enhancement of safety in medicinal product prescription by physicians and in the interest of monitoring medicinal product costs and preparing projections on quality development in the health services and scientific research, the Directorate of Public Health operates a medicinal product database covering medicinal product prescriptions and the dispensing of medicinal products and containing information from pharmacists (*cf.* point f of Article 40). Veterinarians' medicinal product prescriptions shall also be preserved in the database.

The Directorate of Public Health is the entity responsible for the maintenance of the medicinal product database, and each and every entity referred to in this Section shall be responsible for its accessions to the database.

Patient's personally identifiable features shall be specially encrypted in the medical products database. Encrypted patients' personally identifiable features that are more than 30 years old shall be deleted from the database. The Directorate of Public Health shall be responsible for the encryption of personally identifiable features and it alone shall keep the key to it, both for encryption and de-encryption.

The Data Protection Authority shall, in accordance with its role under the Data Protection Act, monitor the safety of personal data in the medicinal product database and other aspects of the operation of the database.

The minister may specify, in a regulation, the types of data that may be recorded and how it is to be handled.

Article 75

Access by the Directorate of Public Health to the medicinal product database.

The Directorate of Public Health shall have access to the medicinal product database for the purpose of maintaining general supervision of medicinal product prescriptions and promoting the rational use of medicinal products in Iceland.

The Directorate of Public Health shall have access to the medicinal product database in accordance with the directorate's supervisory function under the Health Services Act, the Healthcare Practitioners Act and the Directorate of Health and Public Health Act, and the present Act, when there is reason to believe:

a. that a patient has been prescribed a greater quantity of medicinal products containing narcotic or psychotropic substances than can be regarded as normal, by one or more physicians;
b. that a patient has been prescribed a greater quantity of medicinal products containing narcotic or psychotropic substances than can be regarded as normal during a particular period;
c. that a physician has prescribed himself or herself medicinal products containing narcotic or psychotropic substances, or
d. that a physician has prescribed a greater quantity of medicinal products containing narcotic or psychotropic substances than can be regarded a normal for one or more patients, or if there is reason to believe that a physician has prescribed medicinal products containing narcotic or psychotropic substances for more patients than can be regarded as normal.

Article 76

Access by the Icelandic Medicines Agency to the medicinal product database.

The Icelandic Medicines Agency shall have access to the medicinal product database for the purpose of maintaining general supervision of the quality, efficacy and safety of the medicinal products that are used in Iceland, including pharmacovigilance monitoring.

The Icelandic Medicines Agency shall have access to the medicinal product database in accordance with the agency's supervisory role under the present Act when there is a reasonable suspicion concerning:

a. falsification of a medicinal products prescription, or that a prescription has been made in some other unlawful manner, or
b. the incorrect dispensing of a medicinal products prescription, or that a prescription has been dispensed in an unlawful manner.

Article 77

Access by the Icelandic Health Insurance to the medicinal product database.

Icelandic Health Insurance shall have access to the medicinal product database in accordance with the agency's supervisory function under the Health Insurance Act:

a. when it is necessary to verify information about a patient's medicinal product history in connection with cost monitoring by Icelandic Health Insurance, or
b. in order to examine medicinal product prescriptions and physicians' medicinal product prescription habits in connection with the monitoring of medicinal product expenses.

Article 78

Access by the Food and Veterinary Authority to the medicinal product database.

The Icelandic Food and Veterinary Authority shall have access to the medicinal product database in order to monitor prescriptions by veterinarians and to monitor and promote the rational use of veterinary medicinal products in Iceland.

The Icelandic Food and Veterinary Authority shall have access to the medicinal product database in accordance with the authority's supervisory function under the Veterinarians and Animal Health Services Act when there is reason to believe:

a. that the keeper of an animal has been prescribed a greater quantity of medicinal products containing narcotic or psychotropic substances than can be considered normal, from more than one veterinarian,
b. that the keeper of an animal has been prescribed a greater quantity of medicinal products containing narcotics or psychotropic substances than can be considered normal during a specific period, or
c. that a veterinarian has prescribed himself or herself medicinal products containing narcotics or psychotropic substances.

Article 79

Access by physicians, nurses, midwives, pharmacists and dentists to the medicinal product database.

Physicians, nurses, midwives, pharmacists and dentists who are involved in the treatment of a patient and need to examine his or her medicinal product record in connection with the treatment shall have access to information about the patient's use of medicinal products over the previous five years in the medicinal product database. The Healthcare Practitioners Act, the Patients' Rights Act and other acts of law, as appropriate, shall apply regarding the

obligations of these healthcare practitioners and their non-disclosure obligations regarding personal data of a sensitive nature of which they become aware in the course of their work, including information on the use of medicinal products.

Article 80

Monitoring and special access to the medicinal product database.

If, in the course of monitoring by the Directorate of Public Health, Icelandic Health Insurance, the Icelandic Medicines Agency or the Food and Veterinary Authority, suspicion is aroused concerning something which falls under the monitoring function of one of the other institutions, that institution shall be informed of this immediately in order to be able to make the appropriate response.

Information from the medicinal product database may be used for scientific research. The Health Services Research Act and the Data Protection Act shall apply as regards access to personally identifiable information from the medicinal product database.

Furthermore, the ministry may access non-personally identifiable data from the medicinal product database in connection with the taking of decisions and the formulation of policy on medicinal product issues.

The Directorate of Public Health shall maintain active monitoring of access to the medicinal product database under this Section. The Director of Public Health shall set procedural rules regarding access to the medicinal product database. These shall include rules on access control and traceability. If a patient requests information on who has obtained data about him or her from the medicinal product database, the Director of Public Health shall be obliged to provide this information.

Personally identifiable data on individual patients shall not be accessible otherwise than as provided for in this Article unless it is unequivocally necessary in connection with individual monitoring actions or with access by a healthcare practitioner in accordance with Article 79.

Article 81

Centralised medicinal product cards.

The Directorate of Public Health shall be responsible for the operation of centralised medicinal product cards.

The Directorate of Public Health shall ensure that patients have access to their medicinal product histories via their centralised medicinal product cards.

Those who are involved in treatment using medicinal products, and in the dispensing of medicinal products, shall have access to patients' centralised medicinal product cards with their consent.

The Data Protection Act shall apply regarding the processing of personal data via centralised medicinal product cards.

The minister may issue a regulation on centralised medicinal product cards, including as regards access to centralised medicinal product cards and what information may be recorded on centralised medical product cards and how this information is to be handled.

Article 82

Statistics based on data from the medicinal product database.

Statistics may be processed from the medicinal product database. When statistical processing is carried out, measures shall be taken to ensure that patients' personal identification features are not accessible. The Directorate of Public Health shall supervise the

granting of access to statistical data from the medicinal product database. Access to statistical data from the medicinal product database may only be granted for the following purposes:

a. for educational and research purposes,

b. in connection with monitoring of medicinal product costs by public institutions,

c. in connection with the processing of medicinal product statistics under Article 73.

SECTION XVII
Monitoring.

Article 83
Monitoring and its implementation.

The Icelandic Medicines Agency shall monitor compliance with the provisions of this Act and of regulations issued hereunder, unless otherwise specified. In order to carry out this monitoring or to respond to a request from another member state of the Agreement on the European Economic Area or the Convention Establishing the European Free Trade Association, the Icelandic Medicines Agency may visit any place where activities are pursued on the basis of the following authorisations and licences, registrations or exemptions:

a. A manufacturing authorisation (*cf.* Article 23).

b. Registration as the importer, exporter or manufacturer of an active substance (*cf.* Article 25).

c. A wholesale distribution authorisation (*cf.* Article 28).

d. Registration as a medicinal product broker (*cf.* Article 31).

e. A pharmacy licence (*cf.* Article 34).

f. An authorisation for the importing and manufacture of medicated animal feeds (*cf.* Article 32).

g. A licence to sell veterinary medicinal products (*cf.* Article 35).

Entry into residential premises or other similar places for this purpose without the consent of the owner or other person in charge of the premises shall only be permitted under a court order.

Monitoring shall include authorisation to take specimens and photographs, to be given samples of medicinal products without payment, including packaging materials and package leaflets, active substances, intermediate products or excipients for further examination, and also authorisation to examine and copy materials. Furthermore, the Icelandic Medicines Agency may demand all information and materials that are relevant for monitoring.

A person who is subject to monitoring as provided for in the first paragraph shall have the opportunity of providing 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 suitable period of time for this purpose.

The Icelandic Medicines Agency shall compile a report setting out the findings of the investigation when it is complete.

Article 84
Authorisations of the Icelandic Medicines Agency; obligations to provide information.

In connection with examinations and monitoring, including investigations (*cf.* Article 83), all parties under monitoring shall render all assistance necessary for the monitoring without recompense, such as assistance by staff and access to premises and equipment. Furthermore, the Icelandic Medicines Agency shall be provided with all the information it requests, and materials considered by the agency to be relevant to the investigation shall be provided. Other

public entities that have information that may be of significance for monitoring shall provide such information at the request of the Icelandic Medicines Agency. If it is considered necessary to obtain access to data that may be identified as relating to particular persons, the Data Protection Authority shall be informed before the data is provided.

The Icelandic Medicines Agency may call in external specialists for consultation if, in the agency's opinion, this is of significance for monitoring purposes.

Article 85

Demands regarding changed working procedures.

The Icelandic Medicines Agency may demand that licensees and holders of authorisations under Articles 23, 28, 34, 35 and 36, and parties subject to registration requirements under Articles 25 and 31 change their working procedures to conform with the provisions of this Act and of regulations issued hereunder. The Icelandic Medicines Agency shall allow a suitable period for them to comply with demands of this type from the agency.

Article 86

Information from the customs authorities.

The Icelandic Medicines Agency may request information from the customs authorities regarding quantities of medicinal products, active substances, intermediate products and excipients, and also quantities from individual manufacturers and importers in connection with the manufacture and importing of medicinal products, active substances, intermediate products and excipients that come under this Act. The provisions of Article 188 of the Customs Act shall not prevent the Directorate of Customs from providing the Icelandic Medicines Agency with information under this Article.

Article 87

Special authorisations covering monitoring of medicinal product advertisements.

The Icelandic Medicines Agency may demand that natural and legal persons provide it with written information relating to suspected violations of the provisions of Articles 55-59; this shall be submitted within a suitable period of time decided by the agency. When investigating alleged violations of the provisions of Articles 54-58, the Icelandic Medicines Agency may make the necessary examinations of the workplace or place where materials are kept, providing there is good reason to believe that a violation of the provisions has taken place. Provisions of the Code of Criminal Procedure covering searches and the seizure of items shall be observed when measures are taken.

The Icelandic Medicines Agency may release to the government authorities of other member states of the European Economic Area information and materials considered necessary to apply the provisions of Articles 55-59 in accordance with Iceland's obligations under the Agreement on the European Economic Area and the Convention Establishing the European Free Trade Association.

The following conditions shall be set for the release of information and materials:

1. that the recipient treat the information and materials in confidence;

2. that the information and materials will only be used for a purpose specified in the Agreement on the European Economic Area or the Convention Establishing the European Free Trade Association and in accordance with the request for information, and

3. that the information and materials will only be release to other parties with the consent of the Icelandic Medicines Agency and for the purpose specified in its statement of consent.

SECTION XVIII

Fees.

Article 88

Fees according to a tariff of charges.

The Icelandic Medicines Agency may charge fees for:

1. The issue of marketing authorisations and authorisations for the parallel importing of medicinal products.
2. Amendments to marketing authorisations and authorisations for the parallel importing of medicinal products.
3. Meeting the cost of maintaining the medicinal product registers provided for in this Act, pharmacovigilance, providing information on medicinal products for which marketing authorisation has been granted in Iceland and the necessary collaboration with foreign parties in connection with those medicinal products.
4. Product classification.
5. The agency's monitoring investigations and tests.
6. Scientific counselling and other specialist counselling.
7. Granting exemptions authorising the use of medicinal products for which marketing authorisation has not been granted in Iceland.
8. Issuing licences for clinical trials of medicinal products on humans.
9. Issuing licences and exemptions under the Narcotics and Psychotropic Substances Act.
10. Issuing certificates requested by medicinal product companies.
11. Issuing licences under this Act, other than marketing authorisations and licences for the parallel importation of medicinal products, including a fee reflecting the cost resulting from the work involved in issuing licences, such as the travelling expenses of staff of the Icelandic Medicines Agency within Iceland and abroad and the cost of bringing specialists to Iceland to assist the Icelandic Medicines Agency.
12. The issuing of the medicinal products price list.
13. Access to the medicinal products reference register.
14. Monitoring of the collection, handling, storage and distribution of blood and of quality and safety in the handling of human cells and tissues.
15. Granting authorisation for the sale of veterinary medicinal products in accordance with item 4 of the second paragraph of Article 11.
16. Monitoring to ensure compliance with the provisions of Article 47 on safety features on the packaging of medicinal products for humans.

After receiving proposals from the Icelandic Medicines Agency, the minister shall issue a tariff of charges for services provided, monitoring that is not covered by Article 77 and tasks assigned to the agency, or which the agency undertakes to perform under this Act. The amount of each fee shall take account of the cost of the service and the execution of individual tasks and shall be based on a financial budget in which reasoning is given for the determination of each fee. The fee may not exceed costs. The tariff of charges shall be published in Section B of the Government Gazette. Fees may be collected by attachment.

Article 89

Monitoring fee.

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

1. Medicinal product manufacturers, including centres where blood collection is carried out and blood-banks.
2. Medicinal product wholesalers.
3. Medicinal product brokers.
4. Pharmacy licence holders.
5. Holders of authorisations for the sale of medicinal products in ordinary shops.
6. Healthcare institutions and the workplaces of healthcare practitioners.
7. Veterinarians who have been granted pharmacy licences (*cf.* Article 35).
8. Importers and manufacturers of medicated animal feeds.

The monitoring fee shall be determined as follows:

1. Covering the activities of pharmacy licence holders: 0.3% of the total sum paid by Icelandic Health Insurance and/or other public entities to these parties in connection with medicinal product sales during the year preceding the assessment year, or of the total medicinal product procuring amount (the wholesale price without value-added tax) paid by these parties if this amount is higher than that paid by Icelandic Health Insurance and/or other public entities. In no case, however, may the monitoring fee be lower than ISK 250,850 per year.
2. Covering the activities of medicinal product manufacturers, including centres where blood collection is carried out and blood-banks, medicinal product wholesalers, medicinal product brokers, holders of veterinarians' pharmacy licences and holders of special licences for the sale of medicinal products: 0.3% of total medicinal product sales (the wholesale price without value-added tax) during the year preceding the assessment year. In no case, however, may the monitoring fee be lower than ISK 116,870 per year.
3. Covering the activities of veterinarians, healthcare institutions and the workplaces of healthcare practitioners: 0.3% of total medicinal product procurements (the wholesale price without value-added tax) during the year preceding the assessment year. In no case, however, may the monitoring fee be lower than ISK 25,950 per year.
4. Covering the activities of importers and manufacturers of medicated animal feeds: 0.3% of the total amount of medicinal product procurements for the medication of animal feeds. In no case, however, may the monitoring fee be lower than ISK 116,870 per year.

Sums in items 1-4 of the second paragraph are at the price level in December 2018. Minimum fees under items 1-4 of the second paragraph shall be revised once a year, on 15 January each year, 70% of their amount following the wage index and 30% following the consumer price index. Of the total sums in items 1-4 of the second paragraph, 70% shall be regarded as being due to wage costs and 30% to other costs, and this division shall be observed when sums are revised.

Icelandic Health Insurance, Landspítali and the parties listed in the first paragraph shall be obliged to provide the Icelandic Medicines Agency with the information needed to levy monitoring fees.

If the parties listed in the first paragraph fail to provide the necessary information, the Icelandic Medicines Agency may estimate the monitoring fee. The fee reference base shall be estimated sufficiently high so that there will be no risk that the amounts estimated will be lower than they are in reality, and the monitoring fee shall then be determined on the basis of that estimate. A fee that has been levied may be revised if the fee reference base changes.

The monitoring fee shall be levied each year, retroactively. The due date for its payment shall be 30 days after the invoice date, and arrears interest shall be calculated from the due date. Determination and calculation of arrears interest shall be in accordance with the Interest

and Price Indexation Act. The Icelandic Medicines Agency shall collect fees under this Article, and the fees may be collected by enforcement measures.

SECTION XIX
Coercive measures.

Article 90
Cautions

In order to press for the implementation of measures under this Act, the Icelandic Medicines Agency may give the party in question a caution. At the same time, a suitable period of time shall be granted to take remedial measures if they are needed.

Article 91
Per diem fines.

When a party fails to comply with instructions within a specified period of time, the Icelandic Medicines Agency may impose *per diem* fines on him until the situation is rectified.

Per diem fines may amount to as much as ISK 500,000 per day. When the amount of a *per diem* fine is determined, consideration shall be given to factors including the scope and seriousness of the violation, how long it lasted and whether the violation was repeated.

Decisions by the Icelandic Medicines Agency to impose *per diem* fines may be enforced. If a fine under this Article has not been paid within 30 days of the Icelandic Medicines Agency's decision to impose it, arrears interest shall be paid on the fine amount. Decisions and calculations relating to arrears interest shall be in accordance with the Interest and Price-Indexation Act. Uncollected *per diem* fines, which are imposed up to the final day, shall not be waived even though the party later pays the relevant claim, unless the Icelandic Medicines Agency decides this specially. Fines under this Article shall go to the Treasury following deduction of the costs of their collection.

Article 92
Temporary suspension of marketing of medicinal products.

The Icelandic Medicines Agency may restrict the marketing of a medicinal product, active substance, intermediate substance, excipient that does not meet the requirements of this Act or of regulations issued hereunder. This means, amongst other things, that the Icelandic Medicines Agency may remove specific medicinal products, active substances, intermediate products or excipients from sale or distribution until deficiencies have been rectified.

Article 93
Halting the marketing of medicinal products.

The Icelandic Medicines Agency may halt the marketing of a medicinal product that does not meet the requirements of this Act or of regulations issued hereunder. This means, amongst other things, that the Icelandic Medicines Agency may remove specific medicinal products, active substances, intermediate products or excipients from sale or distribution, or recall them, permanently, and may seize such products. Furthermore, it may demand that the medicinal product, active substance, intermediate product or excipient in question be destroyed in a secure manner and/or recalled and kept until deficiencies have been rectified or the danger averted in a satisfactory manner.

Article 94

Temporary halting of activities.

If the Icelandic Medicines Agency considers that a particular activity or the use of a medicinal product, active substance, intermediate product or excipient poses such a serious hazard as to necessitate an immediate response on its part, it may halt the activity or use immediately, with police assistance if this is considered necessary.

Article 95

Police assistance.

The Icelandic Medicines Agency may seek police assistance if this is needed in applying coercive measures.

SECTION XX

Sanctions.

Article 96

Confiscation.

The Icelandic Medicines Agency may confiscate medicinal products, active substances, intermediate products or excipients that do not meet the requirements of this Act or of regulations issued hereunder and destroy them at the expense of the party in charge of them.

Article 97

Administrative fines.

The Icelandic Medicines Agency may levy administrative fines on natural or legal persons that violate:

1. Provisions on the marketing of medicinal products (*cf.* Article 11).
2. Provisions on the obligation of wholesale authorisation holders to provide information (*cf.* Article 29).
3. Provisions on the licensing requirement for medicinal product trials on humans (*cf.* Article 22).
4. Provisions on medicinal product manufacturing (*cf.* Article 23).
5. Provisions on the manufacturing of active substances which are used in the manufacture of medicinal products for humans, and for which marketing authorisation has been granted (*cf.* Article 25).
6. Provisions on notification obligations concerning falsified medicinal products or active substances (*cf.* Article 26).
7. Provisions on the wholesale distribution of medicinal products and the obligations of wholesale authorisation holders (*cf.* Articles 28 and 29).
8. Provisions on the registration obligation of medicinal product brokers (*cf.* Article 31).
9. Provisions on the importing and manufacture of medicated animal feeds (*cf.* Article 32).
10. Provisions on the retailing of medicinal products (*cf.* Articles 33–37).
11. Provisions on the obligations of healthcare institutions regarding the procurement and storage of medicinal products (*cf.* Articles 42 and 43).
12. Provisions on safety features on the packaging of medicinal products for human use (*cf.* Article 47).
13. Provisions on the issuing of medicinal product prescriptions (*cf.* Article 49).
14. Provisions on the dispensing and supply of medicinal products by prescription (*cf.* Article 51).
15. Provisions on medicinal product advertising (*cf.* Articles 55–58).

16. Provisions on the obligations of marketing authorisation holders as regards pharmacovigilance (*cf.* Articles 62 and 64).

The minister may, in a regulation, determine the monetary amounts of administrative fines for violations of individual provisions of this Act within the framework set out in the fourth paragraph.

If the monetary amounts of fines have not been determined in a regulation, then when fines are determined, consideration shall be given to factors including the seriousness of the violation, how long it has lasted, whether the perpetrator has demonstrated a willingness to cooperate and whether the violation was repeated. Consideration shall also be given to whether the violation may be regarded as having been committed in the interests of the undertaking and whether it would have been possible to prevent the offence through management and monitoring. The Icelandic Medicines Agency may determine higher fines if the entity has profited by the violation. In such a case, the administrative fine shall be determined as anything up to twice the profit gained through the violation of this Act or of regulations issued hereunder, though within the framework set in the fourth paragraph.

Administrative fines imposed on natural persons may lie in the range ISK 10,000-10,000,000. Administrative fines imposed on legal persons may lie in the range ISK 25,000-25,000,000.

The due date for the payment of an administrative fine is 30 days after the decision to impose the fine was taken. If the administrative fine remains unpaid 15 days after the due date, arrears interest shall be paid on the fine, calculated from the due date. Decisions by the Icelandic Medicines Agency to impose administrative fines are enforceable and the fines shall go to the Treasury after deduction of the costs of imposition and collection. Decisions and calculations relating to arrears interest shall be in accordance with the Interest and Price-Indexation Act.

Administrative fines shall be imposed irrespective of whether violations are committed on purpose or through negligence.

The party to a case may only bring an appeal against a decision to impose an administrative fine before the courts. The deadline for lodging an appeal is three months from the date on which the decision was taken. Lodging an appeal shall postpone any enforcement measure.

Article 98

Right to be free from self-incrimination.

In a case which is directed against and individual, and which may be concluded with the imposition of an administrative fine or a charge made to the police, any person who there is reason to suspect of having broken the law shall have the right to refuse to answer questions or to hand over documents or objects unless it is possible to exclude the possibility that this could be of significance in determining the offence of which he is guilty. The Icelandic Medicines Agency shall give suspected persons guidance concerning this right..

Article 99

Prescription.

The Icelandic Medicines Agency’s authorisation to impose administrative fines under this Act shall expire when five years have elapsed from the time that the conduct ceased.

The period provided for in the first paragraph shall cease to apply when the Icelandic Medicines Agency informs a party of the initiation of an investigation into an alleged

violation. Termination of the period shall take legal effect vis-à-vis all those involved in the violation.

Article 100

Fines or imprisonment.

Fines, or imprisonment of up to two years, unless more severe sanctions are prescribed under the present Act or other acts of law, shall be imposed for violations of:

1. Provisions on the marketing of medicinal products (*cf.* Article 11).
2. Provisions on licensing requirements for clinical trials of medicinal products on humans (*cf.* Article 22).
3. Provisions on the manufacture of medicinal products (*cf.* Article 23).
4. Provisions on the manufacture of active substances to be used in the manufacture of medicinal products for human use for which marketing authorisation has been granted (*cf.* Article 25).
5. Provisions on the notification obligation concerning falsified medicinal products or active substances *(cf.* Article 26).
6. Provisions on the obligations of wholesale authorisation holders (*cf.* Article 29).
7. Provisions on authorisation for brokers of medicinal products (*cf.* Article 31).
8. Provisions on the retailing of medicinal products (*cf.* the second paragraph of Article 33 and Articles 34-37).
9. Provisions on the issuing of medicinal product prescriptions (*cf.* Article 48).
10. Provisions on the dispensing of medicinal products by prescription (*cf.* Article 51).

Fines, or imprisonment of up to six years, unless more severe sanctions are prescribed under other acts of law, shall be imposed for violations of:

1. Provisions on the wholesale distribution of medicinal products, including medical product importing (*cf.* Article 28).
2. The provision on pharmacy licences (*cf.* the first paragraph of Article 33).

Fines may be imposed on legal persons even though it is not possible to demonstrate guilt on the part of their managers or staff or other individual who work in their service, providing that the violation resulted in, or could have resulted in, an advantage for the legal person. However, legal persons shall not be punished if the violation resulted from an accident. Furthermore, legal persons may be fined in the same way if their managers or staff, or other individuals who work in their service are guilty of violations or if a violation results from unsatisfactory equipment or work supervision.

Article 101

Criminality, confiscation, attempted violations and accessory capacity.

Violations of the present Act are punishable by fines or imprisonment, irrespective of whether they are committed on purpose or through negligence.

Profits, direct or indirect, resulting from violations of the provisions of this Act that are punishable by fines or imprisonment, may be confiscated by a court order.

Attempted violations, or acting as an accessory in violations, of this Act shall be punishable according to the provisions of the General Penal Code.

Article 102

Charges to the police.

The Icelandic Medicines Agency may refer violations to the police.

If an alleged violation of this Act is punishable by both administrative fines and sanctions, the Icelandic Medicines Agency shall assess whether to refer the matter to the police or whether it is to be concluded by an administrative decision by the agency. In the event of major violations, however, the Icelandic Medicines Agency shall refer them to the police. Violations shall be regarded as major if the action was committed in a particularly reprehensible manner or under circumstances that seriously increase the criminality of the violation. Furthermore, the Icelandic Medicines Agency may, at any stage of proceedings, refer a case involving violations of this Act for criminal investigation. Consistency shall be observed in the resolution of comparable cases.

Referral to the police of matters by the Icelandic Medicines Agency shall be accompanied by copies of the materials on which the suspicion of a violation is based. The provisions of Sections IV-VII of the Administrative Procedure Act shall not apply to decisions by the Icelandic Medicines Agency to refer matters to the police.

The Icelandic Medicines Agency may provide the police or the prosecutory authority with information and materials that the agency has gathered and are related to violations referred to in the second paragraph. The Icelandic Medicines Agency may participate in police measures related to the investigation of violations referred to in the second paragraph.

The police and the prosecutory authority may provide the Medicines Agency with information and materials that they have gathered and are related to violations referred to in the second paragraph. The police may participate in measures by the Icelandic Medicines Agency related to the investigation of violations referred to in the second paragraph.

If the prosecutor considers there are insufficient grounds for bringing an action over the alleged criminal activity which also falls under administrative sanctions, he or she may send the case back to the Icelandic Medicines Agency for processing and further decision.

Article 103

Authorisation for appeals.

Unless otherwise specified in this Act, appeals may be lodged with the minister against administrative decisions taken under this Act. The Administrative Procedure Act shall apply regarding the right of appeal and procedure.

SECTION XXI

Miscellaneous provisions.

Article 104

Ownership of medicinal product undertakings by physicians, dentists, veterinarians, nurses and midwives.

Practising physicians and dentists may not be the owners of such a large share in an undertaking that is operated on the basis of a medicinal product manufacturing authorisation, an authorisation for the wholesale distribution of medicinal products, an authorisation for the brokering of medicinal products or a pharmacy licence that this will have an appreciable effect on their financial security. The same shall apply regarding their spouses and children under the age of 18 years

Nurses or midwives who are licensed to prescribe medicinal products may not be the owners of such a large share in an undertaking that is operated on the basis of a medicinal product manufacturing authorisation, an authorisation for the wholesale distribution of medicinal products, an authorisation for the brokering of medicinal products or a pharmacy

licence that this will have an appreciable effect on their financial security. The same shall apply regarding their spouses and children under the age of 18 years.

Practising veterinarians may not be the owners of such a large share in an undertaking that is operated on the basis of a medicinal product manufacturing authorisation, an authorisation for the wholesale distribution of medicinal products or an authorisation for the brokering of medicinal products that this will have an appreciable effect on their financial security. The same shall apply regarding their spouses and children under the age of 18 years.

Article 105

Authorisation for issuing regulations.

The minister shall set out, in regulations, more detailed provisions on the application of this Act concerning:

1. Quality and safety in the handling of human cells and tissues (*cf.* item 13 of Article 6).
2. The collection, handling, storage and distribution of blood (*cf.* item 13 of Article 6).
3. The granting of marketing authorisation for medicinal products (*cf.* the first paragraph of Article 21).
4. The granting of marketing authorisation for homeopathic medicinal products and herbal medicinal products and their registration (*cf.* the second paragraph of Article 21),
5. Clinical trials of medicinal products on humans (*cf.* Article 22).
6. The manufacture of medicinal products and active substances (*cf.* Article 27),
7. The dose dispensing of medicinal products (*cf.* the second paragraph of Article 27).
8. The importing, wholesale distribution and brokering of medicinal products (*cf.* Article 28 and the third paragraph of Article 31).
9. Medicated animal feeds (*cf.* Article 32),
10. Pharmacy licences and pharmacies (*cf.* Article 33).
11. Medical product services in healthcare institutions (*cf.* the first paragraph of Article 46).
12. Landspítali's medicinal products committee and the medininal products committee of the Healthcare Development Centre (*cf.* the second paragraph of Article 46).
13. Safety features on the packaging of medicinal products (*cf.* Article 47).
14. Medicinal product prescriptions and the dispensing of medicinal products (*cf.* the first paragraph of Article 53).
15. The prohibition or restriction of the use of antibiotics (*cf.* the second paragraph of Article 53).
16. Dentists' authorisations to prescribe medicinal products (*cf.* the third paragraph of Article 53).
17. Veterinarians' authorisation to prescribe medicinal products (*cf.* the fourth paragraph of Article 53).
18. Conditions for granting nurses and midwives authorisations to prescribe medicinal products (*cf.* the fifth paragraph of Article 53).
19. Medicinal product advertising (*cf.* the first paragraph of Article 60).
20. The obligation of marketing authorisation holders to maintain a register of medicinal product advertisements (*cf.* the second paragraph of Article 60).
21. Demands made of marketing authorisation holders in connection with pharmacovigilance (*cf.* the first paragraph of Article 65).
22. Medicinal product pricing and cost participation (*cf.* the eighth paragraph of Article 66).

The minister may furthermore set out further provisions on the implementation of this Act in regulations, including as regards the following:

1. Monitoring by Icelandic Medicines Agency (*cf.* the second paragraph of Article 6).
2. Granting authorisation for the parallel importation of medicinal products (*cf.* the third paragraph of Article 21).
3. Conditions for the compassionate use of medicinal products (*cf.* the fourth paragraph of Article 21).
4. On-line sales of medicinal products (*cf.* the third paragraph of Article 41).
5. The obligation of healthcare practitioners to inform the Icelandic Medicines Agency of side-effects that are suspected of being related to medicinal products (*cf.* the first paragraph of Article 63).
6. The right of patients, their families and the keepers of animals to inform the Icelandic Medicines Agency of side-effects which are suspected of being related to medicinal products (*cf.* the third paragraph of Article 65).
7. The implementation of a pharmacovigilance system (*cf.* the fourth paragraph of Article 65).
8. The medicinal products price list and the substitute list (*cf.* the third paragraph of Article 69).
9. The provision and handling of information on medicinal products in connection with medicinal product statistics (*cf.* the fourth paragraph of Article 73).
10. The monetary amount of administrative fines (*cf.* the second paragraph of Article 96).

The minister may publish, as a regulation, the rules of the European Union on the European Medicines Agency and also regulations on the European Union's rules on medicinal product issues, with adaptations taking account of the EEA Agreement and the Convention Establishing the European Free Trade Association.

The minister may refer to the foreign original editions of regulations when giving effect to the European Union's regulations that are adopted in the Agreement on the European Economic Area through the standard procedure. The foreign original edition shall be published in Series C of the Government Gazette.

SECTION XXII
Incorporation and commencement.
Article 106
Incorporation.

This Act is passed in order to incorporate in Icelandic law the following acts:

1. Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.
2. Council Regulation (EC) No. 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products.
3. Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.
4. 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.
5. 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.

6. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.
7. Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.
8. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
9. 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.
10. 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.
11. Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors.
12. 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.
13. Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 amending Regulation 1901/2006 on medicinal products for paediatric use.
14. 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.
15. Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products (recast).
16. 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.
17. 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.
18. 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.
19. REGULATION (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and

establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products.

20. 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.
21. DIRECTIVE 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance.
22. Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance.
23. Regulation (EU) No 1258/2013 of the European Parliament and of the Council of 20 November 2013 amending Regulation (EC) No 273/2004 on drug precursors.
24. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.
25. Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use.
26. Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance.

Article 107

Commencement.

This Act takes effect on 1 January 2021. As of the same date, the Medicinal Products Act, No. 93/1994, and the Sale of Medicinal Products Act, No. 30/1963, shall stand repealed.

Regulations issued under Act No. 93/1994 shall remain in force to the extent that they are compatible with the present Act.

Article 108

Amendments to other acts of law.

On the commencement of the present Act, the following amendments shall be made to other acts of law:

1. *The Veterinarians and Animal Health Services Act, No. 66/1998*: The word *lyfseðilskyldum* in Article 8 shall be replaced by the word *ávísunarskyldum* [both words mean “subject to prescription”]. In the same Article, the words *afhenda eða* (“supply or”) shall be deleted.
2. *The Media Act, No. 38/2011:* The word *lyfseðilskyld* in the fourth paragraph of Article 37 shall be replaced by the word *ávísunarskyld* [both words mean “subject to prescription”].
3. *The Health Insurance Act, No. 112/2008:* The following sentences shall be deleted from point 6 of the first paragraph of Article 29: “Full cost participation by health insurance may be granted for pharmaceuticals (medicinal products) which the Medicinal Products Pricing Committee, in consultation with specialists at Landspítali and the Icelandic Health Insurance, cf. Section XV of the Medicinal Products Act, has determined are to be subject to licences and under special quality control.”

4. *The Health Security and Communicable Diseases Act, No. 19/1997:* The words "according to Article 27" in the fourth paragraph of Article 3 shall be replaced by "according to Article 74".
5. *The Environmental Agency Act, No. 90/2002:* The words "the Medicinal Products Act, No. 93/1994, with subsequent amendments" in item a of the second paragraph of Article 1 shall be deleted.

Interim provisions.

I.

All positions at the medicinal products pricing committee shall be abolished on the commencement of this Act. All employees of the medicinal products pricing committee shall be offered employment at the Icelandic Medicines Agency or Landspítali, as appropriate, as of the same date. The provisions of Article 7 of Act No. 70/1996 shall not apply to the disposal of job positions under this provision.

The Icelandic Medicines Agency, or Landspítali, as appropriate, shall, as from the commencement of this Act, take over the assets of the medicinal products pricing committee and also its rights and obligations regarding the implementation of the acts of law that come under the committee's purview at that time.

II.

Authorisations for the manufacture, importing and wholesaling of medicinal products, and pharmacy licences, granted under the Medicinal Products Act, No. 93/1994, shall remain in force. Undertakings that manufacture active substances to be used in the manufacture of medicinal products for human use and have marketing authorisations, and undertakings that engage in brokering of medicinal products shall register with the Icelandic Medicines Agency under the present Act before 1 March 2022.