Medicinal Products Act no. 100/2020

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.

In trading in medicinal products, it must at all times be borne in mind that distribution constitutes part of the health services, and entities involved in distribution shall cooperate with other entities in the health services in striving to achieve the public goals defined in the health services at any given time.

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 may only be used after they have been approved by Landspítali's Medicinal Products Committee, are normally expensive, require great care in their use 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:* A declaration by a physician, dentist, veterinarian, nurse or midwife stating that the issuer is prescribing the specific medicinal product in the specified quantity and has given instructions on its dosage and use. The issuer shall certify the prescription by means of his or her signature.

12. *Pharmaceutical supervision:* An individually-tailored service given by the pharmacist to the patient, aimed at maximising the effect of the patient's treatment with medicinal products, and so enhancing the patient's quality of life. It consists of the pharmacist's stating the aim of the treatment and use of the medicinal product to the patient and seeking the best methods of achieving this aim in collaboration with the patient and other healthcare professionals.
13. *Medicinal product database:* A database operated for the purpose of ensuring quality in the health services and patient safety, maintaining general supervision of prescriptions, supervision of habit-forming and narcotic drugs and sharing information about individuals' medicinal product prescriptions for purposes including enhancing safety in the issue of prescriptions by physicians, maintaining supervision of medicinal product costs and preparing schedules on quality development in the health services and scientific research.
14. *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.
15. *Brokering of medicinal products:* All activities in connection with the purchase or sale of medicinal products, other than wholesale distribution, that consist of negotiating business deals independently and on behalf of another legal or natural person, with the exception of handling the products.
16. *Centralised medicinal product card:* An electronic 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
17. *Intermediate product:* A mixture of active ingredients and excipients intended for further processing in the manufacture of medicinal products.
18. *Parallel importation of medicinal products:* When an entity other than the marketing authorisation holder engages in the importation of, or trading in, a specific medicinal product for which marketing authorisation has been granted.
19. *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.
20. *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.
21. *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
22. *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, brokerage, 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, herbal medicinal products and natural 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 and the workplaces of healthcare professionals.
8. To grant licences for, and supervise sales by veterinarians of, medicinal products intended to be used for animals.
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 and regulations issued hereunder.
15. To attend to the tasks entrusted to the agency under the Medical Equipment Act.
16. To monitor the supply of medicinal products in such a way that medicinal product shortages will have the minimum impact on patient safety.
17. To grant licences for the manufacture and importation of medicated animal feeds.
18. To grant licences for the sale of medicinal products for veterinary use in accordance with point 4 of the second paragraph of Article 11.
19. To attend to other tasks relevant to the application of this Act, including collaboration with overseas institutions in the field of medicinal products.

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.

The Icelandic Medicines Agency may process personal data, including personal data of a sensitive nature, on individuals' use of medicinal products with a view to ensuring sufficient supply, quality and safety of medicinal products and services and to the monitoring of entities subject to supervision and meeting other responsibilities under this Act, taking account of the obligations imposed by the Personal Data Act.

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.