The Pharmaceutical Act

No. 93/1994

CHAPTER I

Objectives and administration

Article 1

The objective of this Act is to ensure that the people of Iceland are provided with an adequate supply of necessary pharmaceuticals by the most efficient means of distribution on the basis of fair and equitable competition and in accordance with the rules which apply within the European Economic Area. With regard to trade in pharmaceuticals it shall always be kept in mind that the distribution of pharmaceuticals is an integral part of health services and those employed in the distribution of pharmaceuticals shall work with other professions of the health services towards fulfilling public health service objectives. It is, furthermore, the objective of this Act to ensure as far as possible the quality and safety of pharmaceuticals and pharmaceutical services, counter excessive use of pharmaceuticals and keep their costs to the minimum.

The Minister of Health and Social Security supervises the implementation of this Act. At the Ministry of Health and Social Security, the Director of Pharmaceutical Affairs is responsible for administering pharmaceutical matters on behalf of the Minister. The Director shall be educated as a pharmacist and may not have vested personal interests in the manufacturing, importation, or distribution of pharmaceuticals.

The Director of Pharmaceutical Affairs, the National Centre for Hygiene, Food Control and Environmental Protection, the Director General of Health, the State Drug Inspectorate, the Pharmaceutical Pricing Committee, the Committee on Pharmaceuticals and the Chief Veterinary Officer advise the Minister on the implementation of this Act.

Article 2

The State Drug Inspectorate is an independent institution under the administration of the Ministry of Health and Social Security. Its Director shall be a pharmacist, who shall not have vested personal interests in the manufacturing, importation or distribution of pharmaceuticals.

The State Drug Inspectorate shall be ensured with the proper staff and facilities required to carry out its duties. It is permitted to entrust independent research laboratories, in the country or abroad, to carry out research on behalf of the State Drug Inspectorate.

An annual surveillance fee shall be levied on the companies and institutions which the State Drug Inspectorate supervises. A regulation shall provide further provisions regarding surveillance fees and their collection after receiving proposals of the State Drug Inspectorate. Revenues from such fees shall be used to meet the costs of the surveillance and the fee shall be so calculated to cover the costs.

Article 3

The functions of the State Drug Inspectorate are as follows:

1. To administer professional surveillance of the importation of pharmaceuticals, pharmaceutical materials and raw materials for the manufacturing of pharmaceuticals;
2. To administer professional surveillance of the operation of pharmacies, pharmaceutical wholesalers, pharmaceutical production and of other companies, institutions, and individuals which sell, manufacture, import or package pharmaceuticals and related products;
3. To monitor the advertising of pharmaceuticals and ensure that the promotion and distribution is, in general, in accordance with present acts and rules.

The Minister may, if circumstances so warrant, issue a regulation entrusting the State Drug Inspectorate with the monitoring of other companies and other products than pharmaceuticals, provided such duties are related to other functions under this Act.

Article 4

The Committee on Pharmaceuticals, which is under the administration of the Minister of Health and Social Security, shall be made up of five persons having specialised knowledge in as many different areas of medicine and pharmacology as possible. The Minister appoints the Chairman of the Committee. Other members of the Committee, as well as five alternates, are appointed by the Minister in consultation with the Chairman. The Chief Veterinary Officer and another veterinarian, appointed by the Minister in consultation with the Chairman shall, in addition, sit on the Committee. Their alternates shall be appointed in a similar manner. The Committee is appointed for a four year term.

It is permitted to seek the advice of specialists and representatives of professional organisations as necessary.

The Committee on Pharmaceuticals shall carry out the following duties:

1. Register and delete pharmaceuticals from the national register in accordance with rules which apply within the European Economic Area;
2. Give opinions to the Minister regarding applications for pharmaceutical marketing authorisation in accordance with rules which apply within the European Economic Area;
3. Give opinions to the Minister regarding applications to import and sell unregistered pharmaceuticals on a prescription basis;
4. Give opinions to the Minister regarding authorisation to carry out experiments regarding pharmaceuticals (clinical research and research on the bioavailability of pharmaceuticals);
5. Other tasks which concern the enforcement of this Act or parallel acts, including co-operation with foreign pharmaceutical committees and foreign pharmaceutical registration committees.

In accordance with the rules of the European Economic Area, the manufacturers of proprietary pharmaceuticals or their agents shall communicate to the Committee all new information, as it comes, regarding registered pharmaceuticals and pharmaceuticals which are in the process of being registered.

Costs of the Committee´s work, including remuneration paid to Committee members and employees, shall be financed by the fees for initial and annual

registration of proprietary pharmaceuticals as well as other licence fees, such as marketing licence fees and clinical testing licence fees.

CHAPTER II

Definition of pharmaceuticals. Concept of pharmaceuticals.

Article 5

In accordance with the definition applicable within the European Economic Area, pharmaceuticals are defined according to this Act, as any substance or combination of substances, organic or inorganic, which are used to treat, relieve or prevent diseases or symptoms of diseases in human beings and animals. It includes, in addition, substances or combinations of substances which are used for diagnosing diseases, including radioactive substances intended for use on humans with the exception of radionuclides which are sealed radiation sources.

Substances, which are used for general or local anaesthetisation are considered as pharmaceuticals (general anaesthetics, local anaesthetics).

Substances in recognised pharmaceutical forms, which are used for the purpose of contraception or to increase the fertility of humans or animals are also considered as pharmaceuticals.

The provisions of this Act also apply to packaging and instruments containing pharmaceuticals.

The Minister issues a regulation with definition and further provisions concerning nursing products and medical devices, in accordance with the rules applicable within the European Economic Area.

CHAPTER III

Pharmacopoeia

Article 6

Iceland is a signatory to the European Pharmaceutical Register, including its annexes. The English edition of the Register applies in Iceland.

Other requirements regarding the form, quality and purity of pharmaceutical substances and excipients in the manufacturing of pharmaceuticals, as well as the methods of analysis and determination of these substances are in accordance with legal advertisements regarding the validity of Nordic and other European standards in Iceland.

Iceland is a signatory to the Pharmaceutical Inspection Convention (PIC). Guidelines regarding good manufacturing practice in the pharmaceutical industry, the GMP rules cf. Commission Directive/EEC as well as other guidelines issued by these parties shall apply in Iceland.

CHAPTER IV

Classification of pharmaceuticals. Verification of pharmaceutical formulae and registration of proprietary pharmaceuticals.

Article 7

Fully manufactured pharmaceuticals (pharmaceuticals which are ready, or practically ready, for use) may only be imported to the country, sold or dispensed after they have been granted a marketing authorisation or exemption and belong to one of the following classifications:

1. Registered pharmaceuticals, in accordance with the definition which applies within the European Economic Area, manufactured by recognised manufacturers subject to a standardised formula and bearing a generic or proprietary name. These pharmaceuticals shall be registered in the Register of Proprietary Pharmaceuticals as referred to in Article 10 and shall be sold or dispensed in unopened containers (consumer containers) from the manufacturer. Exceptions may be granted to the manufacturer container provision if a physician has requested this expressly on a prescription form.
2. Standardised formulae pharmaceuticals, produced by recognised manufacturers subject to a verified formula and bearing a valid generic name. The Committee on Pharmaceuticals determines the verification of formulae or the cancellation of a verification, as well as the container, packaging and package size of standardised formula pharmaceuticals.
3. Magistral formula pharmaceuticals, manufactured according to specific instructions on a prescription form (ordinatio magistralis) and having regard to valid pharmacopoeia or standards, provided that all acts and regulations are observed in all respects as well as the guidelines on good pharmaceutical manufacturing.

The Minister, may, in consultation with the Committee on Pharmaceuticals grant an exemption from the aforementioned provisions in individual cases when exceptional circumstances prevail. In all such exemptions, it shall be ensured that the quantity of the pharmaceutical in question is restricted to the needs of the specific individuals for which it is intended.

Article 8

It is permitted that the registration of a pharmaceutical may only be granted subject to its restricted use in hospitals, specified wards, and/or on the prescription of specialists of the individual branches of medicine.

It is permitted to register a pharmaceutical and issue a marketing authorisation on approval for a limited period of time.

Article 9

In assessing proprietary pharmaceuticals and standardised formula pharmaceuticals the main factors to be considered are the pharmacodynamic and toxicological effects of the active ingredients in experiments on humans or animals, the quality of all ingredients, both active and inactive ingredients (excipients), which are used in the production of the pharmaceutical, the bioavailabilty of the active ingredients in their pharmaceutical forms, the storage life and efficacy of the

pharmaceutical in treating specific diseases, as well as the side effects, as provided for in the Nordic and other European rules which the Minister confirms.

The Committee on Pharmaceuticals reviews at five year intervals, whether the premises for the registration of a proprietary pharmaceutical are still valid.

Article 10

After receiving the proposals of the Committee on Pharmaceuticals the Ministry of Health and Social Security publishes a register of pharmaceuticals, the Register of Proprietary Pharmaceuticals, which lists registered proprietary pharmaceuticals according to pharmaceutical classifications or in another comparable format. The Register shall include i.e. information on indications, contraindications, dosage, principal side effects and maximum price of pharmaceuticals, as provide for in Article 40.

CHAPTER V

The prescription of pharmaceuticals. Prescription forms and the filling of prescriptions. Labelling of pharmaceuticals.

Article 11

A prescription form is a prescription for a pharmaceutical issued by a physician, dentist, or veterinarian who has a valid licence to practice medicine in the country. In emergency cases, pharmacists are permitted to dispense a pharmaceutical in the smallest available packaging without a prescription.

The person issuing a prescription shall sign it in his own hand and indicate his position (physician, dentist, veterinarian) or communicate by telephone in such a manner that he makes his identity clear. A prescription may be sent by facsimile or by computer network in any standardised format which enables the receiver to verify the identity of the sender. The person issuing the prescription thus verifies personally that he has issued a prescription for the specified amount of the pharmaceutical in question and given instructions regarding dosage or administration to the person concerned or his guardian.

The Director-General of Health supervises the prescribing of pharmaceuticals by physicians and the dispensing of pharmaceuticals by pharmacists in emergency cases.[The Chief Veterinary Officer supervises the prescribing of pharmaceuticals for animals.] [1]

Article 12

The Minister issues a regulation concerning prescription forms and the prescribing of pharmaceuticals, their dispensing and labelling. Such a regulation among other things provide for the following points:

1. Prescription forms;
2. Prescribing of pharmaceuticals;
3. Whether a given pharmaceutical may only be dispensed by prescription, in what quantity and how often on the basis of the same prescription form;

[1] Act 113/1994, Art.1

4. Manner in which pharmaceutical containers (consumer containers) of fully prepared pharmaceutical shall be marked;
5. Procedure for issuing prescriptions by telephone, facsimile or computer network;
6. Prescription of habit forming or narcotic pharmaceuticals.
7. Prescription of pharmaceuticals for use aboard ship or in aircraft;
8. Right of medical students and physicians without a licence to practice to prescribe pharmaceuticals;
9. Term of validity of prescriptions;
10. Labelling of pharmaceuticals.

CHAPTER VI

Advertising and promotions of pharmaceuticals

Article 13

Advertising of pharmaceuticals of any sort is prohibited except as provided for in this Chapter.

Article 14

Pharmaceuticals, which are registered in Iceland, may be advertised and promoted, in Icelandic, in journals and publications of health professions, which prescribe or distribute pharmaceuticals,

Advertisements for pharmaceuticals shall include the name of the manufacturer, name of the pharmaceutical, active ingredients, principal indications and contraindications which concern the use of the pharmaceutical in question, package sizes and price. In addition, they shall provide information regarding dosage and other significant factors concerning its administration and side effects. The aforementioned information shall always be indicated clearly and legibly and be in accordance with that contained in pharmaceutical registers.

Article 15

Prescription pharmaceuticals may be promoted among health professions, which prescribe or distribute pharmaceuticals in such a manner that it is unlikely that such advertisements will reach the general public.

Article 16

It is permitted to promote and advertise over-the-counter pharmaceuticals i.e. pharmaceuticals which may be purchased without prescription. Advertisements of pharmaceuticals shall be in compliance with the rules applying within the European Economic Area, which is further provided for by a regulation.

Pharmacies are permitted to advertise and promote their services, such as home delivery, price of over-the-counter pharmaceuticals and general discount rates.

Information given in advertisements shall always be depicted clearly and legibly and be in accordance with that contained in pharmaceutical registers, regulations concerning prescription forms and the prescribing of pharmaceuticals, their dispensing and labelling and any other rules in this regard.

Article 17

It is permitted to personally supply physicians, dentists or veterinarians with a pharmaceutical sample in the smallest package size without charge, on the condition that it is a newly registered pharmaceutical, neither habit forming nor narcotic, being introduced here on the market. Such supply is only permitted if the physician has signed and dated a request to this effect.

Any other supply or mailing of pharmaceutical samples for advertising purposes is prohibited.

Article 18

The State Drug Inspectorate ensures that advertisements are accurate. It may prohibit certain advertisements which provide incorrect or misleading information regarding a pharmaceutical. It may also demand that an advertiser issues a correction or provide supplementary information in the same manner. The State Drug Inspectorate shall seek the opinion of the Committee on Pharmaceuticals and/or the Competition and Fair Trade Authority in cases where doubt exists as to the legality of a pharmaceutical advertisement. Advertisers shall keep records of all advertisements, indicating where and when they appeared. The records shall be maintained for two years and shall be accessible to the State Drug Inspectorate.

Article 19

The registration of side-effects and a reporting requirement shall be in accordance with the rules which apply within the European Economic Area and under the direction of the Director General of Health in co-operation with the Committee on Pharmaceuticals.

CHAPTER VII

The establishment of pharmacies and licences to sell pharmaceuticals.

Article 20

Authorisation to sell pharmaceuticals is only granted to persons who have obtained a licence from the Minister.

The Minister issues a pharmaceutical licence to a person, who fulfils the following conditions and applies for such a licence.

1. Is a pharmacist licensed to practice in Iceland cf. the Act on Pharmacists;
2. Has worked as a pharmacist for three years. An exception may be made to this requirement if special circumstances so warrant;
3. Holds a commercial licence or has entered into an agreement with a party who holds a commercial licence.

Applications for a new pharmaceutical licence shall be submitted by the Minister to the relevant local authorities for an opinion. Assessment of the application shall, among other things, take into account the ratio of inhabitants to the pharmacy and the distance of the pharmacy to the next pharmacy. If the party giving the opinion opposes the granting of a new licence, the Minister is permitted to turn down the application.

Prior to the opening of the pharmacy, a certificate from the State Drug Inspectorate shall confirm that the location, facilities and staff meet the Directorate´s requirements.

The Minister is permitted to stipulate after-hours service by those licensed to sell pharmaceuticals.

The Minister may assign responsibility for the operation of pharmacies to the Board of Directors of health care centres in health care areas where no pharmacy is operated. The State Drug Inspectorate must grant its approval before the operation of such a pharmacy commences. The Board of Directors of the health care centre, which has been assigned the responsibility for the operation of a pharmacy is permitted to reach a service agreement, including the operation of a pharmacy, cf. Article 35, with an outside pharmacist, who holds a licence to operate a pharmacy.

The fee for a pharmaceutical license shall be determined by the Minister of Finance.

Article 21

Each pharmaceutical licence is limited to the operation of a single pharmacy and the licensee is himself professionally responsible for the operation of the pharmacy. A licensee is permitted to apply for a licence to open up an outlet from his pharmacy in local communities where there are no pharmacies in operation. During the absence of the licensee, the daily operations of the pharmacy shall be entrusted to a pharmacist in consultation with the State Drug Inspectorate.

Practising physicians, dentists or veterinarians may not be owners, shareholders or employees of pharmacies [regarding, however, the sale of pharmaceuticals by veterinarians Article 30, paragraph 5, applies.][2]

Article 22

A pharmaceutical licence is revoked:

1. If the licensee has had his pharmacist or commercial licence revoked;
2. At the end of the year in which the licensee reaches the age of 70. After that time, the licence may be extended for a period of one year at a time, on the recommendation of the State Drug Inspectorate;
3. If the licensee ceases to practice;
4. Upon the death of the licensee. The estate of the deceased licensee may, however, operate the pharmacy for six months under the professional administration of a pharmacist subject to the agreement of the State Drug Inspectorate;

The Minister is permitted to revoke the pharmaceutical licence of the licensee if he violates the provisions of this Act or other acts and the violation is such that the licensee must be considered unfit to dispense pharmaceuticals. Loss of a professional licence is covered by the provisions of the Act on Pharmacists, No. 35/1978.

Upon retiring the licensee or his estate may sell the operation to a pharmacist, who has obtained a pharmaceutical licence according to the provisions of this Act.

---

[2] Act 113/1994. Art.2

CHAPTER VIII

The operation of pharmacies

Article 23

A pharmacy shall be clearly designated as such. Holders of pharmaceutical licences are permitted to give their pharmacies names and only such operations may be called pharmacies or dispensing chemists.

Article 24

Pharmacists are obliged to have for sale pharmaceuticals which may be sold in the country, keep sufficient stocks to meet the foreseeable prescription needs from the doctors, dentists and veterinarians practising in the area concerned and obtain pharmaceuticals which they do not have in stock as quickly as possible. Pharmacies, shall, furthermore, have for sale to the extent possible essential pharmaceutical supplies and equipment for nursing and medical treatment.

Pharmacy owners are obliged to provide the Ministry of Health and Social Security with information regarding their operations and keep records thereof provided that such actions is not in violation of other laws.

Pharmacy owners are obliged to provide consumers and health care professions with information on pharmaceuticals, their use and proper storage. They are, furthermore, obliged to provide information on the administration of pharmaceuticals and pharmaceutical care in co-operation with other health professions with the objective of reducing the risk of diseases and promoting health care in general.

Pharmacies shall keep computerised records of all information regarding their prescriptions in a format which has been approved by the Director General of Health and the Data Protection Commission, cf. Act No. 12/1989 on the Registration and Confidentiality of Personal Information. The Director General of Public Health may request this information for up to one year retroactively.

CHAPTER IX

Practical experience of students of pharmacology and pharmacy technicians. Obligation of pharmacy employees.

Article 25

Pharmacies shall provide students of pharmacology and pharmacy technicians with practical work experience in co-operation with the educational institutions concerned.

Article 26

Students of pharmacology, who have completed a four-year programme of studies and two months practical work experience in a pharmacy, may apply to the Minister for permission to serve as assistant pharmacists on a temporary basis. In such cases the student of pharmacology shall work together with and under the responsibility of a pharmacist.

Article 27

Employees of pharmacies are bound by confidentiality regarding all knowledge or suspicions, which they acquire in the course of their employment, concerning diseases or other personal information.

The obligation of the aforementioned parties to bear legal witness is covered by the rules of legal procedure.

CHAPTER X

Dispensing of pharmaceuticals.

Article 28

A pharmacist or an assistant pharmacist shall be responsible for dispensing prescriptions and having final supervision regarding that the prescription for a pharmaceutical or toxic product has been properly filled.

The Minister may grant a pharmacy technician limited permission to dispense pharmaceuticals from an outlet of a pharmacy, handling only standardised packaging according to a list which is approved by the State Drug Inspectorate, acting on the proposal of the Chief District Medical Officer and a pharmacist. If a pharmacy technician is not available to fulfil such a position in a pharmacy outlet the same permission may be granted to another responsible representative whom the pharmacy owner employs for the purpose, subject to the approval of the State Drug Inspectorate.

CHAPTER XI

Importation and wholesale of pharmaceuticals.

Article 29

Authorisation to import fully manufactured pharmaceuticals and pharmaceutical substances and distribute them on a wholesale basis is granted solely to those who have obtained a licence from the Minister.

For a wholesale pharmaceutical licence a fee determined by the Minister of Finance shall be paid

Article 30

To obtain a wholesale pharmaceutical licence a pharmaceutical wholesaler must fulfil the following conditions.

1. It must be under the direction of a pharmacist who has a valid licence to practice in the country but is not a holder of a licence to operate a pharmacy.
2. It must have at its disposal premises, facilities and staff which, in the estimation of the State Drug Inspectorate, fulfil requirements regarding the storage and handling of pharmaceuticals.

Should the licensee not adhere to the requirements regarding facilities and staff, or other factors regarding the handling of pharmaceuticals or violates in any manner whatsoever the provisions of this Act or others, his licence may be revoked.

Pharmaceutical wholesalers are not permitted to open pharmaceutical packaging. They are not permitted to alter the labelling on pharmaceutical packaging, except under the responsibility of the manufacturer and subject to the prior approval of the Committee on Pharmaceuticals. The State Drug Inspectorate monitors that such an alteration is made in a secure manner.

[Pharmaceutical wholesalers are permitted to sell pharmaceuticals to pharmaceutical licensees, to institutions which have a pharmacist in their service and are operated in accordance with the Act on Health Care Services or other acts, to physicians and dentists to use in their own surgeries or during house calls and to those experimental laboratories which undertake pharmaceutical research. Costs incurred by physicians and dentists for such pharmaceutical purchases are a part of their operating expenses.

Pharmaceutical wholesalers, furthermore, are permitted to sell pharmaceuticals for animals to veterinarians to use in their own surgeries and during veterinary visits. The Minister, shall, in consultation with the Chief Veterinary Officer, issue a regulation determining the pharmaceuticals which veterinarians may sell and those, which only they, themselves, must administer to the animals. Furthermore, the regulation shall determine which information should accompany pharmaceuticals given to animals, products of which are meant for human consumption and which records shall be kept regarding the sale of pharmaceuticals for animals.][3]

Pharmaceutical wholesalers are obliged to keep computerised sales record in a format approved by the Ministry of Health and Social Security and furthermore to provide the Ministry with information regarding their operations and keep records thereof.

CHAPTER XII

Production of pharmaceuticals

Article 31

Authorisation to manufacture pharmaceuticals is granted solely to those who have obtained a licence from the Minister.

For a license to manufacture pharmaceuticals, a fee, determined by the Minister of Finance, shall be paid.

Article 32

To obtain an authorisation to manufacture pharmaceuticals a company must fulfil the following conditions:

1. It must be under the direction of a pharmacist who has a valid licence to practice in the country or another person who is no less qualified.
2. It must have at its disposal premises, facilities and staff which, in the estimation of the State Drug Inspectorate, fulfil requirements regarding the storage and handling of pharmaceuticals.

[3] Act 113/1994, Art.3

Should the licensee not fulfil the requirements regarding facilities and staff, or other factors regarding the handling of pharmaceuticals or violates in any manner whatsoever the provisions of this Act or others, his license may be revoked. Manufacturers of pharmaceuticals must provide the Ministry of Health and Social Security with information regarding their operations and keep records thereof.

Article 33

Pharmacies shall produce magistral formula pharmaceuticals or obtain them as quickly as possible. It is permitted to produce standardised formula pharmaceuticals in pharmacies if the specified requirements are fulfilled. License for their production may be restricted to certain prescribed forms.

CHAPTER XIII

Pharmaceutical services in hospitals and other health institutions.

Article 34

Hospitals are permitted to operate special hospital pharmacies, which supervise and are responsible for acquiring and storing pharmaceuticals and controlling their administration in individual wards. The operation of a hospital pharmacy shall be financially separated from other hospital operations.

The Chief Pharmacist is the director of the hospital pharmacy and shall be appointed by the Hospital Board of Directors concerned.

The Board of Directors may seek tenders for the operation of hospital pharmacies to provide the services specified in this Chapter; such operations must fulfil all other requirements of the legislation concerning the operation and management of pharmacies.

Article 35

In hospitals and other institutions, operated under the Health Care Service Act or other special acts, where no pharmacy is operated, a pharmacist shall supervise and be responsible for acquiring pharmaceuticals and controlling their administration.

Should no pharmacist, cf. Article 1, be employed by the institution, the Board of Directors of the institution shall reach an agreement with an outside holder of a licence to sell pharmaceuticals for pharmaceutical services, such as supervision of pharmaceutical procurement and control their administration. Such agreements are subject to the approval of the State Drug Inspectorate.

Article 36

A hospital pharmacy is permitted to dispense pharmaceuticals to a patient who is discharged from hospital and to outpatients. A hospital pharmacy may only dispense prescriptions bearing hospital markings and issued by its physicians.

Article 37

A committee comprised of three to five members shall be established at each hospital of more than a single ward to advise on the choice of pharmaceuticals. On such a committee at least one member shall be a practising physician of the hospital

and another shall be a practising pharmacist employed at the hospital. As a rule, when there is a choice of two or more equivalent pharmaceuticals, steps should be taken to ensure that the less expensive pharmaceutical be chosen for hospital use.

Article 38

The Hospital Board of Directors should ensure that the premises and facilities of the hospital pharmacy or that of the pharmaceutical storage of the hospital are suitable for the said purpose and shall abide by the ruling of the State Drug Inspectorate in this respect.

CHAPTER XIV

Price of pharmaceuticals

Article 39

The pricing of all non-prescription medicines is without restriction.[The Pharmaceutical Pricing Committee determines the pricing of non-prescription pharmaceuticals for animals, cf. Article 40][4]

Article 40

[The Pharmaceutical Pricing Committee determines the maximum wholesale and retail price both of prescription pharmaceuticals and all pharmaceuticals for animals][5].

Importers and manufacturers of pharmaceuticals as well as their agents shall seek the approval of the Pharmaceuticals Pricing Committee as to maximum wholesale prices and all price changes on prescription pharmaceuticals and veterinary pharmaceuticals.

The Committee shall be comprised of three members appointed by the Ministry of Health and Social Security for the term of his office, of which one shall be nominated by the Supreme Court of Iceland. The Minister appoints the Chairman. Alternates shall be appointed in the same manner. When the maximum wholesale prices for pharmaceuticals are on the agenda, the representative of the organisation of pharmaceutical wholesalers takes a seat on the Committee and when the maximum retail prices for pharmaceuticals are on the agenda the representative appointed by the pharmacy owners´ organisation takes a seat on the Committee. When [the maximum retail price for pharmaceuticals for animals][6] is on the agenda, the representative of the organisation of veterinarians takes a seat on the committee and the Chief Veterinary Officer is also consulted. If during the conduct of the committee´s work there is a tie vote, the chairman casts the deciding vote.

The Committee shall monitor the purchase and manufacturing prices of pharmaceuticals and the wholesale and retail pricing of pharmaceuticals and make price determinations based on its observations. The Committee is, furthermore,

[4] Act 113/1994, Art.4
[5] Act 113/1994, Art.5, paragraph a.
[6] Act 113/1994, Art.5, paragraph b.

responsible for the publication of a price schedule which shows the maximum prices of prescription pharmaceuticals [and all pharmaceuticals for animals.][7]

The costs of the Committee´s work, including remuneration of committee members is paid by the State Treasury.

Article 41

The Minister, after receiving proposals from the State Social Security Institute, determines the participation of social security in pharmaceutical costs of health insured persons in accordance with the existing Social Security Act and the annual budget.

CHAPTER XV

Surveillance, legal proceedings and penalties

Article 42

Surveillance according to this Act or other instructions is the responsibility of the State Drug Inspectorate.

Article 43

Disputes arising as the result of infringements against this Act shall be prosecuted in the manner of criminal offences, unless the acts makes express provision otherwise.

CHAPTER XVI

Final provisions

Article 44

The Minister of Health and Social Security is permitted to issue necessary regulations providing for further details of the implementation of this Act.

Article 45

This Act shall come into force 1 July 1994.

From this same date the Act on Distribution of Pharmaceuticals, No. 76/1982 and the Pharmaceutical Act No. 108/1984, as subsequently amended, are repealed, with the exception of the provisions of Chapter X of the Pharmaceutical Act regarding the Pharmaceutical Distribution Fund, Articles 39 to 48 inclusive, which expire on 1 June 1995. One-third of the assets of the Pharmaceutical Distribution Fund shall then be donated to the Icelandic Pharmacological Collection at Neströð, in the municipality of Seltjarnarnes and two-thirds shall be turned over to the Pharmaceutical Society of Iceland to be used in support of precautionary and information campaigns regarding pharmaceuticals in pharmacies.

[Furthermore, exempted are provisions of Chapter IX of the Pharmaceutical Act, No.108/1984, Articles 32-38 together with Article 50, paragraph 4 on the pricing of pharmaceuticals and the Pharmaceutical Pricing Committee and provisions in Chapters II, III, VI, on the Distribution of Pharmaceuticals No. 76/1982, Articles 2- 6,

[7] Act 113/1994, Art.5, paragraph c.

Articles 9-13 and Articles 27-34 which deal with the establishment of pharmacies. licence to sell pharmaceuticals and outlets of pharmacies. These provisions of the Pharmaceutical Act and the Act on the Distribution of Pharmaceuticals expire 1 November 1995, cf. section 3 of the temporary provisions.][8]

Temporary Provisions

1. The regulations which have been issued on the basis of the Pharmaceutical Act, No. 108/1984 and the Act on the Distribution of Pharmaceuticals, No. 76/1982, as subsequently amended, shall remain in effect until new regulations have come into force, provided that their provisions do not conflict with this Act.

2. Present pharmacy owners retain their licence to sell pharmaceuticals following the entry into force of Chapter VII of this Act. The pharmacies operating on a co-operative basis in Akureyri and Selfoss and the University of Iceland Pharmacy have until 1 June 1995 to meet the requirements of this Act. Physicians and local authorities shall retain their licences for the sale of pharmaceuticals until 1 June 1995 and after that until a person who meets the provisions under this Act applies for the said licence. Notwithstanding the provisions of the Act on the Distribution of Pharmaceuticals , No. 76/1982, Article 6, paragraph 2, the Minister may extend licenses for the sale of pharmaceuticals until the provisions of Chapter VII take effect.

3. The provisions of Chapters VII and XIV will, however, not enter into force until 1 November 1995. The same applies to a decision on the remuneration for the supply of pharmaceuticals to veterinarians provided for in Article 30.

Done in Reykjavík, 20 May 1994

Vigdís Finnbogadóttir

Guðmundur Árni Stefánsson

[8] Act 122/1994, Art.1