REGULATION

on the Registration of Proprietary Medicinal Products and the Issuing of Marketing Authorizations

1. Introduction and definitions

Article 1

A proprietary medicinal product is a medicinal product marketed in the original packaging from the manufacturer under an invented (brand) name or a common (generic) name, cf. Article 3 (3) and (4) of Regulation No. 418/1994 on the labelling of medicinal products for human use and veterinary medicinal products and on package leaflets. No proprietary medicinal product may be placed on the market unless it has been approved by the health authorities, i.e. after registration and the issuing of a marketing authorization.

The provisions of this Regulation apply both to the registration of and the issuing of marketing authorizations for proprietary medicinal products for human use and veterinary medicinal products.

The rules and guidelines in force within the EEA territory relating to registration, marketing authorization and requirements for proprietary medicinal products apply in Iceland as well, cf. Annex II, subdivision XIII to the EEA Agreement and the EEA Appendix to the Official Journal of the EC, Volume 3, ISSN 1022-9337, EFTA Publication Unit; for further details see Annex 1 to this Regulation.

The provisions of this Regulation concerning medicinal products for human use are in accordance with Council Directives 65/65/EEC, 75/318/EEC and 75/319/EEC, as amended, and the provisions concerning veterinary medicinal products are in accordance with Council Directives 81/851/EEC and 81/852/EEC, as amended.

The following are exempted from the provisions on registration and marketing authorization for medicinal products: whole blood, plasma or blood cells of human or animal origin, homeopathic medicinal products for which special registration is not required and medicinal gasses.

Separate regulations apply to the registration of and/or the issuing of marketing authorizations for parallel imported medicinal products, herbal remedies, homeopathic medicinal products, food supplements, such as vitamins and minerals, and specify which products are exempted from the provisions on registration and marketing authorization.

2. Application for registration

Article 2

General provisions

An application for the registration of a proprietary medicinal product shall be submitted to the State Committee on Pharmaceuticals on application forms available at the Committee's office.

For each application the application form shall be completed in three copies, cf. the guidelines set out in Annex 2 to this Regulation. Each application is signed and numbered by the State Committee on Pharmaceuticals and one copy is returned to the applicant.

Accompanying documents and particulars shall be submitted in one copy with the application, unless otherwise specified, together with a receipt for the payment of the registration fee, see also the provisions of Article 3 of this Regulation.

Documents and particulars accompanying applications for medicinal products for human use shall be in accordance with the existing guidelines of the European Union in "Notice to Applicants for marketing authorizations for medicinal products for human use in the European Union", and in case of veterinary medicinal products in "Notice to Applicants for marketing authorizations for veterinary medicinal products".

All documents accompanying an application for the registration of a proprietary medicinal product in the Register of Proprietary Medicinal Products shall be clear and legible and may be either in Icelandic, Danish, English, Norwegian or Swedish. The proposed summary of product characteristics (SPC), text of package leaflet and instructions for use, however, should also be submitted in Icelandic.

The State Committee on Pharmaceuticals may request further information and particulars regarding an application for registration or for changes concerning licensed proprietary medicinal products.

An application for the registration of a proprietary medicinal product will be rejected if it is not accompanied by a proposal for the labelling and package leaflet, cf. also Article 7 of Regulation No. 418/1994 on the labelling of medicinal products for human use and veterinary medicinal products and on package leaflets.

The State Committee on Pharmaceuticals will reject an application for the registration of a proprietary medicinal product if the documents and particulars accompanying the application are not in accordance with Article 4 of this Regulation and furthermore if, after verification of particulars and documents, it proves that the proprietary medicinal

product is harmful under the proposed conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared.

Each application is only valid for one proprietary medicinal product in one dosage form and one strength. A separate application must be submitted for each strength of the medicinal product in respect of powder for injections and if the application concerns one dosage form but different compositions, for example with or without a preservative, a separate application shall be submitted for each composition. Where an application is later submitted for the registration of other dosage forms or strengths of a proprietary medicinal product, or for the registration of new indications, reference must be made to the former (the first) application number of the same medicinal product, as the different dosage forms and strengths of a proprietary medicinal product will be registered under one name and under the first application number for the relevant medicinal product.

Article 3

Payment of registration fee

The registration fee shall be paid upon presentation of an invoice from the State Committee on Pharmaceuticals at the State Treasury, Sölvhólsgata 7, 101 Reykjavík, cf. the provisions of the existing Regulation on registration fees, annual fees and other licence fees for medicinal products, cf. Article 4 of the Pharmaceutical Act, No. 93/1994.

The fee is non-refundable even though the application is rejected.

3. Documents and particulars accompanying an application

Article 4

Administrative data

The following documents and particulars, as appropriate, shall accompany an application for the registration of a proprietary medicinal product and the application form shall be completed in accordance with the guidelines set out in Annex 2 to this Regulation:

1. Name of the medicinal product for which the application is made, its dosage form and strength and route of administration.
2. Name and address of applicant (anticipated holder of the marketing authorization) and his agent.
3. Name and address of manufacturer(s) of active ingredients and the final dosage form.

4. ATC-group (ATCvet-group in respect of a veterinary medicinal product), proposed classification for the dispensing of the medicinal product and name of contact person for the health authorities.

5. A complete statement of the ingredients of the medicinal product.

6. Sizes and type of packaging.

7. Shelf life and storage conditions.

8. List of countries where marketing authorization has been granted for the medicinal product or where an application for authorization has been submitted.

9. The manufacturer of a proprietary medicinal product shall be an authorized manufacturer of proprietary medicinal products in his country of residence; the application must be accompanied by a copy of his licence to manufacture proprietary medicinal products, issued by the health authority during the preceding two years. However, where the product is manufactured in a third country and the manufacturing site is yet to be recognized in Iceland, the application must also be accompanied by documents on the manufacturing site and manufacturing process, in order for the Icelandic health authorities to be able to assess the manufacturer's competence regarding the manufacturing of the product.

10. A confirmation of the marketing authorization for the proprietary medicinal product in the Nordic countries, in other EEA countries, in North-America and/or Australia, shall accompany every application where such authorizations exist,

11. The application shall include a table of contents of the documents submitted in support of the application, e.g. the number and titles of volumes of documentation. If samples are provided, it shall also be indicated.

Article 5

Data on quality, safety and efficacy

Article 4 of Council Directive 65/65/EEC and the Annex to Council Directive 75/318/EEC include provisions on the data on quality, safety and efficacy which must accompany an application for the registration of a medicinal product for human use. Similar provisions on the data which must accompany an application for the registration of a veterinary medicinal product are laid down in Article 5 of Council Directive 81/851/EEC and in the Annex to Council Directive 81/852/EEC.

The application shall be supported by chemical and pharmaceutical documentation, including a description of all the stages of the manufacturing process and information on the manufacturing site and manufacturing control. Methods of identification and assay of the ingredients of the medicinal product and the final product shall be described, as well as special studies, such as on sterilization, pyrogenicity, heavy metals and stability of the product.

The application shall also be accompanied by:

1. a brief description of the method of preparation of the medicinal product;
2. a description of the manufacturing methods for the active ingredient, as well as the methods for and results of its quality control tests;
3. results of physico-chemical, biological and/or microbiological tests;
4. results of pharmacological and toxicological studies;
5. results of clinical trials.

The abovementioned documents shall be drawn up by experts with the necessary technical and professional qualifications and shall be signed, cf. the provisions of Article 1 of Council Directive 75/319/EEC and Article 6 of Council Directive 81/851/EEC, as appropriate.

In certain cases comprehensive data on safety and efficacy of the medicinal product are not required, cf. Chapter 4 of this Regulation.

Special requirements are laid down for data on vaccines, toxins, serums and allergens, cf. Council Directive 89/342/EEC, radiopharmaceuticals, cf. Council Directive 89/343/EEC and medicinal products derived from human blood or human plasma, cf. Council Directive 89/381/EEC. Special requirements apply to immunological veterinary medicinal products, cf. Council Directive 90/677/EEC.

Article 6

Foodstuffs obtained from animals

Where foodstuffs of animal origin are intended for human consumption, the necessary withdrawal period after administration of the veterinary medicinal product under normal conditions of use must, according to Article 5 of Council Directive 81/851/EEC, be indicated to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer. The application shall be accompanied by a report stating methods and results of studies covering the excretion of the substance in the target species.

The application shall also be accompanied by information from internationally recognized organizations, in particular Codex Alimentarius, on the maximum residue limits established for medicinal products in foodstuffs of animal origin, intended for human consumption, cf. also the provisions of Regulation No. 252/1995 on maximum residue limits for veterinary medicinal products in meat, offal, eggs and milk.

Article 7

Expert reports

According to Article 2 of Council Directive 75/319/EEC, on medicinal products for human use, and Article 7 of Council Directive 81/851/EEC, on veterinary medicinal products, the application shall be accompanied by expert reports on the quality, safety and efficacy of the relevant medicinal product.

The expert reports shall include a critical evaluation of the quality, safety and efficacy of the product and shall be drawn up by experts with the necessary professional qualifications and be dated and signed. Expert reports must accompany all applications, but reports on the safety and efficacy of medicinal products, other than new products, need not be as detailed. Guidelines on the preparation of expert reports are published in "Notice to Applicants", cf. the provisions of Article 2 of this Regulation.

Article 8

A summary of product characteristics (SPC)

A proposal in Icelandic for a summary of product characteristics (SPC) shall accompany every application, pursuant to the provisions of Article 4a of Council Directive 65/65/EEC, on medicinal products for human use, or Article 5a of Council Directive 81/851/EEC, on veterinary medicinal products. As to foreign medicinal products, the application must also be accompanied by a draft summary of product characteristics (SPC), in Danish, English, Norwegian or Swedish.

Guidelines on the preparation of the summary are set out in Annex 3 to this Regulation and in "Notice to Applicants", cf. the provisions of Article 2 of this Regulation.

A proposal for the summary of product characteristics should preferably be submitted on a diskette as well.

Article 9

Labelling of packaging and leaflets

The text of the proposed label and/or immediate or outer packaging of the medicinal product must accompany the application.

The text of the proposed package leaflet in Icelandic and instructions for use, if appropriate, must accompany every application.

The proposals for these texts should preferably be submitted on diskettes as well.

Proposals for labels and package leaflets accompanying an application shall be in accordance with the provisions of Regulation No. 418/1994 on the labelling of medicinal products for human use and veterinary medicinal products and on package leaflets. The State Committee on Pharmaceuticals will reject an application for registration of a proprietary medicinal product if the application is not accompanied by the abovementioned proposals, cf. the provisions of Article 7 of Regulation No. 418/1994.

Article 10

Samples

A sample of the medicinal product (one specimen) shall accompany every application, as well as samples of its accessories, if appropriate.

The State Committee on Pharmaceuticals and the State Drug Inspectorate may demand samples of the active ingredients and other important constituents of the medicinal product.

4. Types of applications

Article 11

A new medicinal product (Full application)

Applications for the registration of proprietary medicinal products, containing new chemical entities (NCE) not previously used in a registered proprietary medicinal product in Iceland, shall be accompanied by the particulars and documents set out in Article 4 of Directive 65/65/EEC, for medicinal products for human use, and Article 5 of Directive 81/851/EEC, for veterinary medicinal products, including data on safety and efficacy of the product.

When submitting an application for a new dosage form or a new strength of a registered proprietary medicinal product, reference is permitted to the data on the safety and efficacy accompanying the original application, but appropriate new data must also be submitted pursuant to the guidelines published in "Notice to Applicants", cf. the provisions of Article 2 of this Regulation.

When an application is submitted for the registration of a medicinal product containing a new combination of active substances, all of which are already marketed in Iceland, data on the safety and efficacy of each separate active ingredient are not required. Such an application must be accompanied by data on the safety and efficacy of the product's combination for which the application is made.

When an application is submitted for a new indication for a registered proprietary medicinal product, reference is permitted to the data on quality and safety accompanying the

original application, but appropriate data on the efficacy of the medicinal product, regarding the indication applied for, must also be submitted, as well as more detailed information on the safety of the use of the product, if appropriate, cf. also guidelines in "Notice to Applicants", cf. the provisions of Article 2 of this Regulation.

Article 12

An essentially similar medicinal product (Abridged application)

An abridged application may be submitted for the registration of an essentially similar medicinal product, in which case the results of safety and efficacy studies do not have to be provided.

An essentially similar product is a medicinal product that is equivalent to the original product, contains the same active ingredient(s) in the same amount and in identical dosage form and studies have demonstrated that their bioavailability is equivalent.

The registration of an essentially similar product can be applied for with an abridged application:

1. if the manufacturer of the original medicinal product has given his consent for reference to be made to his data on safety and efficacy,
2. with reference to published scientific literature,
3. when the medicinal product has been on the market for 6 years or more in the EEA territory and, in the case medicinal products manufactured with biotechnological methods, for 10 years. This restriction, however, will not be applied beyond the date of expiry of a patent protecting the relevant product.

Article 13

Hybrid Application

Hybrid application means an application for the registration of an essentially similar product with a different indication from that already authorized or a different method of administration or a different dosage schedule than already authorized. Appropriate data on the safety and/or efficacy of the product must accompany such applications, as indicated in the guidelines in "Notice to Applicants (Abridged Applications)", cf. Article 2 of this Regulation. This is also the case when applying for a different salt/ester/derivative of a substance or a suprabioavailable product.

5. Changes concerning registered proprietary medicinal products

Article 14

General provisions

The holder of the marketing authorization must take account of technical and scientific progress and make, accordingly, necessary amendments to the manufacture and control test methods for the registered proprietary medicinal product. Information on such changes shall be submitted to the State Committee on Pharmaceuticals for approval.

Article 15

Changes to the composition

A formal application for authorization for any changes to the composition of a registered medicinal product, regarding the quality and quantity of the excipients, must be submitted. Relevant documentation covering the changes, for which the application is made, must accompany the application, as well as the results of studies and validation of the control test methods. The application shall also be accompanied by an expert report on the consequences of the change in terms of the quality and efficacy of the medicinal product. No registration fee is collected for such applications.

The agent shall notify the date on which the changed composition, following its approval, will be ready for marketing.

Article 16

Changes to dosing schedule

A formal application for changes to the dosing schedule of a medicinal product must be submitted and it must be accompanied by documentation regarding the changes. Such applications shall be accompanied by an expert report, a proposal for a new summary of the product characteristics (SPC, cf. Annex 3) and a proposal for changes to the text on the medicinal product in the Register of Proprietary Medicinal Products (cf. Annex 4) and to the text of the package leaflet.

Article 17

Changes to the manufacture and control test methods

Approval for changes to manufacturing methods, quality requirements and/or control test methods for an active ingredient, an excipient and/or the medicinal product

itself must be applied for. Data on the possible consequences of the changes in terms of the quality and efficacy of the medicinal product must be submitted, as well as an assessment report from a qualified expert, concerning the changes.

Article 18

A new manufacturer

Approval for a new manufacturer of the dosage form, new site of manufacture and new contract manufacturer must be applied for. A copy of the manufacturing authorization of the manufacturer in question, issued by the relevant health authorities during the preceding two years, must be submitted, accompanied by a copy of the agreement with the contract manufacturer, if relevant. However, where the dosage form is manufactured in a third country, the application must also be accompanied by documents on the manufacturing site and the manufacturing process of the dosage form, in order for the Icelandic health authorities to be able to assess the manufacturer's competence regarding manufacturing of the product.

Approval for a new manufacturer or supplier of an active ingredient and for a new qualified person must be applied for.

Article 19

Changes to shelf life and storage conditions

Approval for a longer shelf life and for changes to the storage conditions of a medicinal product must be applied for, supported by relevant data. An application for approval for a longer shelf life shall, in principle, be accompanied by the results of studies on the shelf life of at least 3 batches. The maximum shelf life authorized for a proprietary medicinal product is 5 years.

Should the manufacturer wish to use a shorter shelf life than already authorized for the relevant proprietary medicinal product, it must be notified.

Article 20

Changes to packaging, labelling, instructions for use and package leaflets

Approval for any changes to types of packaging and/or their sales presentation must be applied for, accompanied by a specimen of the new packaging, information on the packaging material and quality, as well as data on the possible consequences of the changes in terms of the efficacy and quality of the medicinal product, including its shelf life.

Furthermore, approval for changes to the labelling, instructions for use, as well as the text of the package leaflet, must be applied for. Two specimens of the label/packaging

with the labelling changes, the instructions for use or package leaflets must be provided.

Article 21

New package sizes and deregistration of package sizes.

Approval for new sizes of the packaging of a medicinal product must be applied for. The application shall include information on the type of packaging and two specimens of the labelling and outer packaging, if appropriate. If the medicinal product comes in blister packs, two specimens of the inscribed blister pack must be included together with the outer packaging.

Approval for the deregistration of individual package sizes must be applied for to the State Committee on Pharmaceuticals.

Article 22

New name of manufacturer or holder of marketing authorization and new holder of marketing authorization or agent

Changes regarding the name of the manufacturer or holder of marketing authorization and changes regarding the holder of marketing authorization or agent must be notified.

Article 23

New information on adverse reactions

New information on adverse reactions, contra-indications and warnings, relating to the use of a proprietary medicinal product, must be reported and supported by relevant data. If the nature of the abovementioned information requires a change in the summary of product characteristics (SPC, cf. Annex 3), a proposal for a new summary of product characteristics must be included, together with a proposal for a change in the text on the medicinal product in the Register of Proprietary Medicinal Products (cf. Annex 4) and the text of the package leaflet.

6. Exemption from the classification as a prescription-only medicine

Article 24

An exemption from the classification of a proprietary medicinal product as a prescription-only medicine must be applied for to the State Committee on Pharmaceuticals. The conditions which the medicinal product must satisfy, as well as the documentation that must accompany the application, are indicated in Annex 5 to this Regulation, cf. also Council Directive 92/26/EEC.

7. Annual fee

Article 25

The marketing authorization holder shall pay an annual fee to the State Committee on Pharmaceuticals for each dosage form and strength of a proprietary medicinal product, pursuant to the provisions of the existing Regulation on registration fees, annual fees and other licence fees for medicinal products, cf. Article 4 of the Pharmaceutical Act 93/1994.

8. Period of validity for registrations and marketing authorizations

Article 26

Registration and marketing authorization for a proprietary medicinal product is granted for 5 years at a time.

If the holder of a marketing authorization for a proprietary medicinal product does not apply for a renewal within a set time limit, cf. the provisions of Article 27 of this Regulation, the registration and marketing authorization will expire.

9. Application for renewal of a registration

Article 27

An application for renewal of the registration of a proprietary medicinal product shall be to submitted to the State Committee on Pharmaceuticals, no later than three months before the expiry of the marketing authorization for the product, on an application form for the registration of proprietary medicinal products, together with the following documents:

1. the proposed summary of product characteristics (SPC, cf. Annex 3),
2. the proposed text in Icelandic for the Register of Proprietary Medicinal Products (cf. Annex 4),
3. the proposed package leaflet in Icelandic,
4. two specimens of the labels for the product and outer packaging, if appropriate,
5. a brief report on the quality (chemical/pharmaceutical data) and safety update of the product, based on the experience of its use, together with an updated expert report,
6. a chronological resumé of all changes concerning the medicinal product from the date of the granting or renewal of the marketing authorization,

7. a copy of the authorization of the manufacturer of the product or dosage form to manufacture medicinal products in his country of residence, issued by the competent authority during the preceding two years. If more than one company are responsible for the manufacture of the product, a copy of the manufacturing authorization of each company shall be included. See also the provisions of Article 4 (9) of this Regulation.

The application shall include a receipt for the payment of the fee for renewal of the registration, cf. Articles 2 and 3 of this Regulation.

10. Restricted registration

Article 28

The registration of a medicinal product may be restricted to use in hospitals, specified wards and/or to the prescription of specialists in certain branches of medicine, cf. the provisions of Article 8 of the Pharmaceutical Act No. 93/1994.

11. Applications for marketing authorizations and prices

Article 29

Applications for marketing authorizations

An applicant for a marketing authorization for a medicinal product may submit an application to the Ministry of Health and Social Security on a special application form, cf. Annex 6 to this Regulation, on receipt of a recommendation from the State Committee on Pharmaceuticals for the registration or renewal of registration of the product, including the approved summary of product characteristics (SPC), labelling of the packaging, text of the package leaflet and instructions for use, as appropriate.

The recommendation of the State Committee on Pharmaceuticals for the registration of a medicinal product expires if the applicant does not apply for marketing authorization for the relevant product within a period of one year.

Foreigners, applying for marketing authorization for a medicinal product in Iceland, must have an agent in Iceland.

Article 30

Applications for approval of prices

Approval of the price of a medicinal product must be applied for to the Ministry of Health and Social Security. The application may be submitted before a marketing authorization has been granted.

12. Register of Proprietary Medicinal Products and Price List II

Article 31

Information on proprietary medicinal products will only be published in the Register of Proprietary Medicinal Products and Price List II, subject to the following conditions:

1. A marketing authorization has been granted for the medicinal product.
2. A text in Icelandic on the product, in full accordance with an approved summary of product characteristics (SPC) and the guidelines set out in Annex 4 to this Regulation, is available and ready for publishing in the Register of Proprietary Medicinal Products. The written text shall be submitted to the State Committee on Pharmaceuticals for approval, preferably on a diskette as well.
3. The final label and outer packaging of the product have been approved by the State Committee on Pharmaceuticals, as well as the inscribed blister pack and the outer packaging, if the medicinal product comes in blister packs, in the package sizes for which the marketing authorization is requested. Two specimens shall be submitted to the Committee for each package size.
4. The final package leaflet and instructions for use for the medicinal product, as appropriate, have been approved by the State Committee on Pharmaceuticals. Two specimens shall be submitted to the Committee.
5. The price of the product has been approved by the health authorities.

13. Application for revocation of a marketing authorization

Article 32

The holder of a marketing authorization may apply to the Ministry of Health and Social Security for revocation of the marketing authorization for a proprietary medicinal product or one of its dosage forms or strengths.

14. Withdrawal of marketing authorization

Article 33

Should it transpire that a medicinal product on the domestic market fails to comply with the laws and regulations in force governing medicinal products or with the terms of the marketing authorization, the Minister of Health, after obtaining the opinion of the State Committee on Pharmaceuticals and/or the State Drug Inspectorate, may withdraw its marketing authorization.

Notification of the issuing and revocation of marketing authorizations

Article 34

The Ministry of Health and Social Security shall notify the holder of the marketing authorization in question or his agent, the State Committee on Pharmaceuticals and the State Drug Inspectorate of the issuing and revocation of marketing authorizations, cf. the provisions of Article 29, 32 and 33 of this Regulation.

16. Evaluation of Applications

Article 35

15.

The State Committee on Pharmaceuticals shall seek to ensure that evaluation of applications for the registration of proprietary medicinal products is completed within 210 days from the date on which the Committee receives valid application documents.

17. Entry into force

Article 36

This Regulation is laid down in accordance with an authorization in Article 44 of the Pharmaceutical Act No. 93/1994 and shall enter into force on 1 September 1995. At the same time Regulation No 544/1991 on the registration of proprietary medicinal products in the Register of Proprietary Medicinal Products is repealed.

The Ministry of Health and Social Security,

18 August 1995.

Annex 1

The following Acts of the Council (EEC) concern registration, marketing authorization and requirements in respect of proprietary medicinal products in the European Economic Area, applicable in Iceland, cf. Annex II to the EEA Agreement. These Acts are published in Icelandic translation in the publication of the EEA Agreement, Annex II, Chapter XIII, and in the EEA Appendix to the Official Journal of the EC, Book 3, ISSN 1022-9337, EFTA Publication Unit.

1. Council Directive EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, as amended, (65/65/EEC, 66/454/EEC, 75/319/EEC, 78/420/EEC, 83/570/EEC, 87/21/EEC, 89/341/EEC, 89/342/EEC, 89/343/EEC, 89/381/EEC, 92/73/EEC)

2. Council Directive EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of medicinal products (75/318/EEC, (83/570/EEC, 83/571/EEC, 87/19/EEC, 89/341/EEC, 91/507/EEC)),

3. Council Directive EEC of 12 December 1977 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products (78/25/EEC, 81/464/EEC),

4. Council Directive EC of 31 March 1992 concerning the classification for the supply of medicinal products for human use (92/26/EEC),

5. Council Directive EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets (92/27/EEC),

6. Commission Directive EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use (91/356/EEC),

7. Council Directive EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (81/851/EEC, 90/676/EEC, 90/677/EEC, 92/74/EEC),

8. Council Directive EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products, as amended (81/852/EEC, 87/20/EEC, 92/18/EEC),

9. Council Directive EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (86/609/EEC),

10. Commission Directive EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (91/412/EEC),

11. Council Regulation (EEC) No. 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as amended.

Annex 2

Application Form for the Registration of a Proprietary Medicinal Product, pursuant to the provisions of the Pharmaceutical Act No. 93 of 20 May 1994

To be submitted to the State Committee on Pharmaceuticals, Eiðistorg 13-15, P.O.Box 180, 172 Seltjarnarnes.

Completed by the State Committee on Pharmaceuticals

Application received and fee paid.	Application no.:
Date:	
	Registration fee:
Signature:	

☐ **Medicinal product for human use**

☐ **Veterinary medicinal product**

☐ Ref. to a former application (medicinal product, reg.no.): _____

☐ Renewal of application (MTnr): _____

☐ **New medicinal product:**

- ☐ New active ingredient
- ☐ New combination of known active ingredients
- ☐ Produced with a new biotechnology
- ☐ New indication
- ☐ New dosage form
- ☐ New strength
- ☐ Change of composition
- ☐ Change of dosing schedule
- ☐ Other_____

☐ **Essentially similar medicinal product:**

- ☐ Reference permitted to the documentation for the original medicinal product
- ☐ Ref. to published scientific literature
- ☐ Original product documentation no longer protected

☐ **Other applications;** Essentially similar medicinal product which differs from authorized proprietary medicinal product as regards:

- ☐ Different salt/ester/derivative
- ☐ Different therapeutic use
- ☐ Different dosage form
- ☐ Different route of administration
- ☐ Different strength
- ☐ Different dosing schedule
- ☐ Suprabioavailability
- ☐ Other_____

Name of medicinal product:	
Dosage form:	Strength:
Route of administration:	

Applicant (anticipated holder of marketing authorization):	Agency:
Address:	Address:
P.O.Box:	P.O.Box:
Country:	Country:
Telephone number:	Telephone number:
Fax number:	Fax number:

ATC-group:

ATCvet-group:

Dispensing/classification proposed, etc.:

- ☐ Without prescription
- ☐ Without prescription in limited quantities
- ☐ By prescription only
- ☐ Maximum quantity allowed per prescription
- ☐ Controlled
- ☐ Only for use in hospitals/wards
- ☐ Authorization to prescribe limited to certain specialities
- ☐ Other_____

Contact person for the State Committee on Pharmaceuticals, the State Drug Inspectorate and the Ministry of Health and Social Security:

Name of contact person:	
Company:	
Address:	
Telephone number:	Fax number:

Manufacturer of final product:	Alternative manufacturer:
Address:	Address:
P.O.Box:	P.O.Box:
Country:	Country:
Telephone number:	Telephone number:
Fax number:	Fax number:
Stage of manufacture:	Stage of manufacture:

Contractor:	Alternative contractor:
Address:	Address:
P.O.Box:	P.O.Box:
Country:	Country:
Telephone number:	Telephone number:
Fax number:	Fax number:
Stage of manufacture:	Stage of manufacture:

Product development contractor:	Product development contractor:
Address:	Address:
P.O.Box:	P.O.Box:
Country:	Country:
Telephone number:	Telephone number:
Fax number:	Fax number:
Stage of manufacture:	Stage of manufacture:

Manufacturer of active ingredient:	Manufacturer of active ingredient:
Address:	Address:
P.O.Box:	P.O.Box:
Country:	Country:
Telephone number:	Telephone number:
Fax number:	Fax number:
Reference to Drug Master File and date of submission:	Reference to Drug Master File and date of submission:

Importer/manufacturer responsible for testing and final approval in EEA territory:	Location of testing and final approval in EEA territory
Address:	Address:
P.O.Box:	P.O.Box:
Country:	Country:
Telephone number:	Telephone number:
Fax number:	Fax number:

Address:	Address:
P.O.Box:	P.O.Box:
Country:	Country:
Telephone number:	Telephone number:
Fax number:	Fax number:

STATEMENT OF COMPOSITION

Date:_____

Signature:_____

Name of proprietary medicinal product:_____

Dosage form and strength:_____

Holder of marketing authorization:_____

Unit:

Name of ingredient:	Reference	Quantity	Standard	Type of substance

Unit: The unit by which quantity is indicated. Tablet, capsule, **ml** (injection, mixture, etc.), 1000 ml (infusions), g (powder, granules, ointment, cream, etc.)
Reference: INN, BAN, etc.
Standard: Ph.Eur., DLS, etc.
Type of substance: VI: active ingredient; **HJ:** auxiliary substance not classified elsewhere; **LI:** colouring agent; **RO:** preservative; **AO:** anti-oxidant; **ST:** stabilizer; **BR:** flavouring agent; **DR:** propellant.

Information on overage

Substance:	Quantity:	Unit:

Packaging:

Size:	Packaging type:
Shelf life:	Storage conditions:
Shelf life after first opening of container:	Storage conditions after first opening of container:
Shelf life after reconstitution:	Storage conditions after reconstitution:

Size:	Packaging type:
Shelf life:	Storage conditions :
Shelf life after first opening of container:	Storage conditions after first opening of container:
Shelf life after reconstitution:	Storage conditions after reconstitution:

Size:	Packaging type:
Shelf life:	Storage conditions :
Shelf life after first opening of container:	Storage conditions after first opening of container:
Shelf life after reconstitution:	Storage conditions after reconstitution:

Size:	Packaging type:
Shelf life:	Storage conditions :
Shelf life after first opening of container:	Storage conditions after first opening of container:
Shelf life after reconstitution:	Storage conditions after reconstitution:

Size:	Packaging type:
Shelf life:	Storage conditions :
Shelf life after first opening of container:	Storage conditions after first opening of container:
Shelf life after reconstitution:	Storage conditions after reconstitution:

Has this medicinal product been granted marketing authorization or has an application for marketing authorization for the product been submitted in other countries; which countries?

* In the Nordic Countries
* In other EEA States
* In other PER Countries
* In North America

Countries:	Name of proprietary medicinal product:	Type of application:	Status of application*	Date:

*): **SA**: authorized; **IV**: under consideration; **SY**: rejected; **DR**: withdrawn by manufacturer before authorization; **AF**: withdrawn by manufacturer after authorization; **AY**: authorization withdrawn by competent authority.

Place and date

Signature of applicant (anticipated holder of marketing authorization) or his agent

Please note that the application form must be completed as appropriate in each case. If the space available on the form is insufficient, reference may be made to accompanying documents.

Page 1 of the application form.

Application number: Completed by the State Committee on Pharmaceuticals.

If a former application has been made for the registration of the medicinal product, reference must be made to the former (first) application number of the same product.

"Renewal of application" refers for example to an application for renewal of the registration of a medicinal product before its marketing authorization expires, cf. section 9 of this Regulation.

Article 4 of Council Directive ((65/65/EEC) medicinal products for human use), Article 5 of Council Directive ((81/851/EEC), veterinary medicinal products) and Articles 2, 3 and 4 of this Regulation, specify which particulars and documents must accompany applications for the registration of proprietary medicinal products, e.g. applications for new medicinal products and also for essentially similar medicinal products, where it is not necessary to submit complete documentation on quality, safety and efficacy.

"Other applications" refers to applications for the registration of essentially similar medicinal products which differ from licensed medicinal products as regards any or some of the items listed on the application form under the heading "Other Applications".

The following are instructions on which documents must accompany the different types of other applications:

Different salt/ester/derivative:
Documents which prove that there is no change in the pharmacokinetics, toxicity and pharmacodynamics, which could change the safety/efficacy profile. Otherwise the medicinal product will be considered as a new active substance.

Different therapeutic use:
Clinical data on safety and efficacy. Preclinical data, if justified.

Different dosage form, different route of administration:
Clinical data on safety and efficacy. Pharmacokinetics. Preclinical data (for example local toxicology), if justified.

Different strength:
Data on bioavailability

Different dosing schedule:

a) different units/dose:
Data on bioavailability

b) different frequency and/or amount/dose (higher or lower) and/or daily doses:
Clinical data on safety and efficacy. Pharmacokinetics.

Suprabioavailable products:

a) same dosage intervals but reduced doses intended to achieve the same plasma/blood concentrations:
Data on bioavailability are often sufficient

b) *other dosage schedules:*
Clinical data on safety and efficacy. Pharmacokinetics.

Page 2 of the application form.

Please give detailed information on applicant and agent. The applicant is the anticipated holder of the marketing authorization.

ATC-group or a proposal for such classification, cf. "Guidelines for ATC classification" and "Anatomical Therapeutic Chemical (ATC) classification indexes". These publications can be ordered from the WHO Collaborating Centre for Drug Statistics Methodology, P.O.Box 100, Veitvet, N-0518 Oslo, Norway.

In cases of veterinary medicinal products, ATCvet classification or a proposal for such classification shall be indicated, cf. "Guidelines for ATCvet classification" and " ATCvet index", which can be ordered from Nordic Council on Medicines, P.O.Box 26, S-751 03 Uppsala, Sweden.

Dispensing/classification proposal shall be made.

See guidelines on non-prescription products in Annex 5 to this Regulation.

Pages 3 and 4 of the application form.

This is mostly self-explanatory. Fill in the relevant sections, as appropriate.

Page 5 of the application form.

All the ingredients of the medicinal product must be specified with the appropriate abbreviations listed beneath the table. For medicinal products in dosage forms that comprise a defined dosage unit, the quantity should be expressed per unit (tablets, capsules, etc.). In respect of medicinal products in solid or semi-solid dosage forms, such as ointments, powders and granules, the quantity should be expressed per gram, but per ml for medicinal products in liquid form (injections, mixtures etc.). In respect of infusions, however, the quantity should be expressed per 1000 ml. See also Regulation No. 418/1994 on the labelling of medicinal products for human use and veterinary medicinal products and on package leaflets and Annex 1 to that Regulation.

Where an overage of an active ingredient is used in the manufacture of the medicinal product it should be stated here and justification thereof should accompany the application.

Page 6 of the application form.

Here the packaging, sizes, types of packaging, shelf life and storage conditions must be indicated.

Page 7 of the application form.

The marketing and/or registration status of the medicinal product in other countries must be indicated. The countries of particular interest in this context are the Nordic countries, other Western European countries, North America and Australia.

PER means the cooperation of certain countries relating to the assessment of medicinal products; those are: Austria, Australia, the United Kingdom, Finland, the Netherlands, Ireland, Iceland, Italy, Canada, Norway, New Zealand, Switzerland, Sweden, South Africa, Hungary and Germany.

Annex 3

Summary of product characteristics (SPC)
Medicinal products for human use

This summary shall be in Icelandic, as well as Danish, English, Norwegian or Swedish, if the relevant product is not Icelandic, and shall include the following information (see also special guidelines on pages 28-29):

1. Name of the medicinal product
2. Active ingredient(s)
3. Dosage form
   - 3.1 Dispensing/classification
4. Clinical particulars
   - 4.1 Therapeutic indications
   - 4.2 Posology and method of administration
   - 4.3 Contra-indications
   - 4.4 Special warnings and special precautions for use
   - 4.5 Interaction
   - 4.6 Pregnancy and lactation
   - 4.7 Effects on the ability to drive
   - 4.8 Undesirable effects
   - 4.9 Overdose and toxic effects
5. Pharmacological particulars
   - 5.1 Pharmacotherapeutic group (ATC)
   - 5.2 Mechanism of action
   - 5.3 Pharmacokinetics
   - 5.4 Preclinical particulars
6. Pharmaceutical particulars
   - 6.1. Complete qualitative and quantitative composition (name of all ingredients)
     - 6.1a Properties of the dosage form
   - 6.2 Suspending/diluting (in what/with what can the product be suspended/diluted)
   - 6.3 Shelf-life
   - 6.4 Storage conditions
   - 6.5 Packaging (size and type)
   - 6.6 Instructions for use/handling of the product
   - 6.7. Disposal of residues
7. Holder of marketing authorization
8. MTnr
9. Dates (cf. the guidelines)
10. Date of this version of the summary of product characteristics.

Summary of product characteristics (SPC)
Veterinary medicinal products

This summary shall be in Icelandic, as well as Danish, English, Norwegian or Swedish if the relevant product is not Icelandic, and shall include the following information: (see also special guidelines on pages 28-29):

1. Name of the medicinal product
2. Active ingredient(s)
3. Dosage form
   - 3.1 Dispensing/classification
4. Clinical particulars
   - 4.0 Species of animal
   - 4.1 Therapeutic indications (for target species)
   - 4.2 Posology (for target species) and method of administration
   - 4.3 Contra-indications
   - 4.4 Special warnings and special precautions for use
   - 4.5 Interaction
   - 4.6 Pregnancy and lactation
   - 4.8 Undesirable effects
   - 4.9 Overdose and toxic effects
   - 4.10 Foodstuffs obtained from animals
5. Pharmacological particulars
   - 5.1 Pharmacotherapeutic group (ATCvet)
   - 5.2 Mechanism of action
   - 5.3 Pharmacokinetics
   - 5.4 Preclinical particulars
6. Pharmaceutical particulars
   - 6.1. Complete qualitative and quantitative composition (name of all ingredients)
     - 6.la Properties of the dosage form
   - 6.2 Suspending/diluting (in what/with what can the product be suspended/diluted)
   - 6.3 Shelf-life
   - 6.4 Storage conditions
   - 6.5 Packaging (size and type)
   - 6.6 Instructions for use/handling of the product
   - 6.7 Disposal of residues
7. Holder of marketing authorization
8. MTnr
9. Dates (cf. the guidelines)
10. Date of this version of the summary of product characteristics.

Guidelines on the Summary of product characteristics (SPC)

Cf. the existing EU guidelines: Summary of Product Characteristics, published in the "Notice to Applicants for marketing authorization for medicinal products for human use" and "Notice to Applicants for marketing authorization for veterinary medicinal products".

The summary shall be in Icelandic, as well as Danish, English, Norwegian or Swedish, if the relevant product is not Icelandic. A separate summary must be submitted for each dosage form. The summary must use the same headings in the same order as indicated here below. Sub-headings that are obviously irrelevant shall be omitted. Where information on an item is unavailable or unacceptable, it should be mentioned.

1. **Name of the medicinal product**

2. **Active ingredient(s):** Active ingredient(s) expressed qualitatively and quantitatively. The ingredient(s) shall be indicated by the international non-proprietary name (INN) recommended by WHO, or in another manner, cf. the provisions of Annex 1 to Regulation No. 418/1994 on the labelling of medicinal products for human use and veterinary medicinal products and on package leaflets.

3. **Dosage form** (cf. Annex 2 to Regulation No. 418/1994, if possible)

   3.1 **Dispensing/classification** (subject to non-prescription, subject to prescription, etc.) or a proposal for the classification for the dispensing of the medicinal product.

4. **Clinical particulars:**

   4.0 **Species of animal** (in respect of veterinary medicinal products)

   4.1 **Therapeutic indications** (preferably in accordance with ICD (International Classification of Diseases) or, in respect of psychotropic medicinal products, DSM (Diagnostic and Statistical Manual of Mental Disorder), latest editions).

   4.2 **Posology** (for each species of animal in respect of veterinary medicinal products)

      4.2a Dosages for adults, children and, if appropriate, the elderly or certain groups of patients (the dosage form and method of administration must be specified, if appropriate).

      4.2b Monitoring of administration and dosages (measurement of plasma/blood concentration etc.).

   4.3 **Contra-indications** (only in cases where the medicinal product should absolutely not be given).

   4.4 **Special warnings and special precautions for use:**

      4.4a Serious risks must be indicated first in a prominent manner, for example by using a different type font.

      4.4b Pathological conditions where special precaution is needed, such as liver or renal insufficiency, other diseases or certain age-groups (children, the elderly).

   4.5 **Interaction** (only clinically meaningful interactions).
   Interactions shall be grouped in the following manner:

      a) medicinal products used for the same indication,

      b) food, certain foodstuffs etc.,

      c) medicinal products used for other indications,

      The following information should be given for each interaction:

      1) mechanism of action (if known),

      2) consequences for plasma/blood concentrations, other laboratory and clinical parameters,

      3) recommendations: (e.g. not recommended association, dose adjustment or other).

4.6 **Pregnancy and lactation:** Harmful effects on the fetus, if known, must be described and the period during pregnancy, where the risk is greatest, must be stated (for example during the first three months or at the end). Where extensive experience of its use leaves no suspicion of harmful effect on the fetus it should be indicated. Reference may be made to results from experiments on animals or other types of experiments.

If the product is not excreted or not known to be excreted in the breast-milk, the mention of this will suffice. Other main possibilities are that the product is excreted in quantities that are likely or unlikely to have harmful effects on the infant. In cases of veterinary medicinal products similar information must be given under the heading **"Pregnancy and lactation".**

4.7 **Effects on the ability to drive**

4.8 **Undesirable effects:** All frequent and serious undesirable effects at least shall be listed. The prevalence of the undesirable effects shall be indicated if possible, for example by grouping them according to frequency: **(Frequent (>1 %); Rare (0,1-1 %); Very rare (<0,1 %)).** Undesirable effects should also be grouped with regard to the organs within each group of prevalence. If certain circumstances tend to increase or reduce the possibility of undesirable effects, it should be mentioned.

4.9 **Overdose and toxic effects:** Which dose levels cause toxic effects and how does the toxicity manifest itself? The treatment for toxicity should be described, if possible.

4.10 **Foodstuffs obtained from animals:** The withdrawal period necessary between the last administration of the product to animals and the human consumption of foodstuffs from such animals must be indicated.

5. **Pharmacological particulars:**

5.1 **Pharmacotherapeutic group**(ATC or ATCvet group or a proposal for such classification).

5.2 **Mechanism of action and efficacy** (a brief description).

5.3 **Pharmacokinetics:**

5.3a Information concerning active ingredient(s) (absorption, distribution, excretion, dose-effect curves, time-effect curves).

5.3b Information concerning the patient (sex, age, liver or renal insufficiency, other diseases, smoking etc.).

5.4 **Preclinical particulars.** Significant information for the assessment of the clinical use of the product that does not feature elsewhere in the summary.

6. **Pharmaceutical particulars:**

6.1. Complete qualitative and quantitative **composition** (name of all ingredients)

6.1a Properties of the dosage form: Special galenic properties. Characteristics such as colour, form, size, marking and taste.

6.2. **Suspending/diluting** (in what/with what can the product be suspended/diluted; problems of adsorption to syringes and tubes)

6.3. **Shelf-life** (shelf-life of the medicinal product and after reconstitution of the product).

6.4. **Storage conditions** (approved conditions for storage).

6.5. **Packaging** (sizes and types of packaging).

6.6. Instructions for **use/handling** of medicinal product

6.7. **Disposal of residues** (instructions on how to dispose of residues that are potential causes of environmental pollution).

7. **Holder of marketing authorization** (name, address).

8. **Marketing authorization number** (application number).

9. **Date of first registration of medicinal product and last renewal of registration.**

10. **Date of this version** of the summary of product characteristics.

Annex 4

Guidelines on the text in the Register of Proprietary Medicinal Products

The text shall be in Icelandic under these headings in the following order:

Name of medicinal product.
Marketing authorization holder and registration number.
Name of dosage form and ATC-group (ATCvet-group in respect of veterinary medicinal products).
Description of contents, cf. the provisions of Annex 1 to Regulation No. 418/1994 on the labelling of medicinal products for human use and veterinary medicinal products and on package leaflets.
Properties: Pharmacotherapeutic group and a description of the mechanism of action, sometimes in comparison with other medicinal products or categories of medicinal products. Pharmacokinetics: absorption, bioavailability (utilization), period from administration until maximum concentration in blood and/or maximum effect is obtained, distribution and volume(s) of distribution, binding to plasma proteins, elimination (metabolism, metabolites, excretion, blood half-life, possibly body clearance, elimination, duration of action, specially in cases of sustained release products). The influence of age and diseases on pharmacokinetics, if appropriate.
Indications: List of diseases/symptoms of diseases. Names (definitions) must be in accordance with ICD if possible.
Contra-indications: Absolute contra-indications should be specified first. Relative contra-indications can be listed under this heading or under the heading "Warnings". A special mention must be made of allergy in cases of cross-allergy or whole categories of medicinal products.
Warnings: Here mention can be made of diseases or pathological conditions where the use of the medicinal product may be a potential risk. Other factors of warning concerning the use of the product may also be mentioned.
Pregnancy and lactation: Harmful effects on the fetus, if known, must be described and the period during pregnancy, where the risk is greatest, must be stated (for example during the first three months or at the end). Where extensive experience of the use of the medicinal product leaves no suspicion of harmful effect on the fetus, it should be indicated. Reference may be made to results from experiments on animals or other types of experiments.

If the product is not excreted or not known to be excreted in the breast-milk, the mention of this will suffice. Other main possibilities are that the product is excreted in quantities that are likely or unlikely to have harmful effects on the infant. In cases of veterinary medicinal products, similar information must be given under the heading **"Pregnancy and lactation".**
Undesirable effects: All frequent and serious undesirable effects at least shall be listed. The prevalence of the undesirable effects shall be indicated if possible, for example by grouping them according to frequency: **(Frequent (>1 %); Rare (0,1-1 %); Very rare (<0,1 %)).** Undesirable effects should also be grouped according to organs within each group of prevalence. If certain circumstances tend to increase or reduce the possibility of undesirable effects, it should be mentioned.
Interaction: Clinically meaningful interactions must be reported. Mention must be made of the medicinal product affected and the nature of the effect (for example enhanced efficacy); it is not sufficient to state that interaction occurs. The mechanism of interaction may be described.
Overdose and/or toxic effects: Available information on overdosage and the effects of overdosage, if they can be foreseen, must be put forward. Symptoms (toxic effects) of overdosage and diagnosis of overdosage, if appropriate, must be described. The treatment for overdose shall be described and the antidotes, where they exist, indicated by name.
Dosages for adults: Normal doses, normal initial doses and maintenance doses msut be indicated. It should be stated how often the product must be taken daily, when, whether to be taken with meals etc. How fast the doses should be increased or reduced, as appropriate, and maximum daily doses should be indicated. Here it may be necessary to distinguish between different indications, dosage forms and routes of administration (such as intramuscular or intravenous), in which cases it is often best to use sub-headings for the sake of clarity. Where certain age- or patient-groups need different dose levels, it should be mentioned here.

Dosages for children: It should be mentioned here if the medicinal product is not intended for children under a specific age. In certain cases reference can be made to dose levels for adults, for example if they are the same in relation to body weight. Dosages for children may be relative to age but it is more accurate to use body weight as a frame of reference (mg/kg of bodyweight). Sometimes it is clearest to present the doses in tablets.
Note: Here it is possible to mention various information on the use and handling of the product. The suspending/diluting of the product, its shelf-life and possible photosensitivity (sensitivity to light) before and/or after suspending/diluting can be mentioned here.
Other information: Other information on the product that must be mentioned.
Veterinary medicinal products: In cases of veterinary medicinal products, the withdrawal period necessary between the last administration of the veterinary medicinal product to animals and the human consumption of foodstuffs from such animals must be indicated.
Appearance: The appearance of the dosage form, such as size, form, colour and the marking of tablets may be described.
Packaging: Sizes of packaging and types of container (such as vials, blister packs).

Annex 5

Exemption from the classification as a prescription-only medicine

An application for exemption from the requirement of prescription must be made to the State Committee on Pharmaceuticals.

The main characteristics of a non-prescription medicinal product must be its suitability for self-medication. This means that the patient must be able to diagnose the disease with reasonable certainty or identify the symptoms of a disease previously diagnosed by a physician. The patient must also be able to assess the results of the treatment.

Information on the safety of the medicinal product must be given, not only when used correctly but also when used incorrectly or misused.

Non-prescription medicinal products must not be addictive, e.g. they must neither give a feeling of well-being nor stimulate the central nervous system and neither increase tolerance levels nor cause symptoms of withdrawal.

The effects of non-prescription medicinal products must not be such that symptoms of serious diseases are concealed.

A medicinal product, which contains a new active ingredient (NCE) or is an injectable preparation or infusion, is always subject to prescription. It is not possible to apply for exemption from the requirement of prescription until considerable experience of its use has been gained.

An application for authorization to sell medicinal products without prescriptions must be accompanied by following information/particulars:

- Name of the proprietary medicinal product, holder of marketing authorization, registration number/marketing authorization number, dosage form and strength.
- Common (generic) name of active ingredient(s).
- Indication for which application for non-prescription is made, both for adults and children, as appropriate
- Type and size of packaging for non-prescription medicinal products.
- An indication of any sale of the medicinal product not subject to prescription in other EEA countries, PER countries or North America and the date of authorization for the non-prescription sale must be made.
- A resumé of pharmaco-toxicological data with regard to non-prescription sale. Here it must be stated that the medicinal product has minor toxic effects, instructions given on its use during pregnancy, and it should also be stated that it is neither mutagenic nor carcinogenic. Relevant references to scientific literature must be made.
- Indications, for which application for non-prescription is made, must comply with the registered indications for the medicinal product. These indications must be discussed on the basis of the benefit/risk of selling the medicinal product without prescription.
- The type and frequency of undesirable effects must be specified. If certain risk groups need to be warned against using the product owing to undesirable effects, it must be specified.
- Toxic effects resulting from overdosage must be described.
- A proposal in Icelandic for the labelling and/or package leaflet for non-prescription sale, in accordance with Regulation No. 418/1994 on the labelling of medicinal products for human use and veterinary medicinal products and on package leaflets.
- If new information on the product appears after an application has been made for non-prescription sale and this information is relevant to the outcome of the consideration of the application, the applicant must immediately send them to the State Committee on Pharmaceuticals. This also applies to medicinal products after authorization for their sale without prescription has been granted.

In cases of veterinary medicinal products, similar information must accompany an application for authorization to sell veterinary medicinal products without prescriptions.

Annex 6

Application Form for Marketing Authorization for a Proprietary Medicinal Product, pursuant to the provisions of the Pharmaceutical Act No. 93 of 20 May 1994

To be submitted to the Ministry of Health and Social Security, Pharmaceutical Department, Laugavegur 116, 150 Reykjavík.

Registration No.: MTnr:

☐ New marketing authorization
☐ Renewal of marketing authorization
☐ Other:

Name of medicinal product:
Dosage form and strength:
Active ingredient(s):

Holder of marketing authorization:	Agency:
Address:	Address:
P.O.Box:	P.O.Box:
Country:	Country:
Telephone number:	Telephone number:
Fax number:	Fax number:

Period of validity
of marketing authorization:_____

Granting of marketing authorization:

Place and date — Place and date

Signature of applicant (holder of marketing authorization) or his agent — Signature of the Ministry of Health and Social Security.

REGULATION

concerning the (1st) amendment of Regulation No. 465/1995 on the Registration of Proprietary Medicinal Products and the Issuing of Marketing Authorizations

Article 1

The heading of Chapter 11 shall read as follows:

11. Applications for prices and marketing authorizations

Article 2

Article 29 of the Regulation shall read as follows:

Applications for prices

Approval of the price of a medicinal product must be applied for to the Ministry of Health and Social Security.

Article 3

Article 30 of the Regulation shall read as follows:

Applications for marketing authorizations

An applicant for a marketing authorization for a medicinal product may submit an application to the State Committee on Pharmaceuticals on a special application form, cf. Annex 6 to this Regulation, subject to the Committee's approval for the registration or renewal of registration of the product, including approval for the summary of product characteristics (SPC), labelling of the packaging, text of the package leaflet and instructions for use, as appropriate.

An application for marketing authorization must be accompanied by:

1. A text in Icelandic on the product, in full accordance with the approved summary of product characteristics (SPC) and the guidelines set out in Annex 4 to this Regulation, which shall be ready for publishing in the Register of Proprietary Medicinal Products. The text should preferably be submitted on a diskette as well.
2. A confirmation of the approval of the health authorities for the price of the medicinal product.

The recommendation of the State Committee on Pharmaceuticals for the registration of a medicinal product shall expire if the applicant does not apply for marketing authorization for the relevant product within a period of one year.

Foreigners, applying for marketing authorization for a medicinal product in Iceland, must have an agent in Iceland.

Article 4

Article 31 of the Regulation shall read as follows:

Information on proprietary medicinal products will only be published in the Register of Proprietary Medicinal Products and Price List II, subject to the following conditions:

1. A marketing authorization has been granted for the medicinal product.

2. The text in Icelandic on the product for publishing in the Register of Proprietary Medicinal Products has been approved by the State Committee on Pharmaceuticals.

3. The final label and outer packaging of the product have been approved by the State Committee on Pharmaceuticals, as well as the inscribed blister pack and the outer packaging, if the medicinal product comes in blister packs, in the package sizes for which marketing authorization is requested. Two specimens shall be submitted to the Committee for each package size.

4. The final package leaflet and instructions for use for the medicinal product, as appropriate, have been approved by the State Committee on Pharmaceuticals. Two specimens shall be submitted to the Committee.

5. In cases of new/different package sizes, the price of the product must have been approved by the health authorities.

Article 5

Article 32 of the Regulation shall read as follows:

The holder of a marketing authorization may apply to the State Committee on Pharmaceuticals for revocation of the marketing authorization for a proprietary medicinal product or one of its dosage forms or strengths.

Article 6

Article 33 of the Regulation shall read as follows:

Should it transpire that a medicinal product on the domestic market fails to comply with the laws and regulations in force governing medicinal products or with the terms of the marketing authorization, the State Committee on Pharmaceuticals may withdraw its marketing authorization.

The State Committee on Pharmaceuticals may, where necessary, seek the opinion of the State Drug Inspectorate regarding a decision on the withdrawal of marketing authorization for a medicinal product.

Article 7

Article 34 of the Regulation shall read as follows:

The State Committee on Pharmaceuticals shall notify the holder of the marketing authorization in question or his agent, the Ministry of Health and Social Security and the State Drug Inspectorate of the issuing and revocation of marketing authorization for medicinal products, cf. the provisions of Article 30, 32 and 33 of this Regulation.

Article 8

Annex 6 to this Regulation, is hereby amended as follows:

(a) The words "the Ministry of Health and Social Security, Pharmaceutical Department, Laugavegur 116, 150 Reykjavík" shall be replaced by the words: the State Committee on Pharmaceuticals, Eiðistorg 13-15, P.O.Box 180, 172 Seltjarnames.

(b) The words "Signature of the Ministry of Health and Social Security" shall be replaced by the words: Signature of the State Committee on Pharmaceuticals.

Article 9

This Regulation, which is laid down in accordance with an authorization in Article 44 of the Pharmaceutical Act No. 93/1994, shall take immediate effect.

The Ministry of Health and Social Security, 15 November 1995.

Ingibjörg Pálmadóttir

Rannveig Gunnarsdóttir.