Regulation

on the Registration of Parallel Imported Medicinal Products and the Issuing of Marketing Authorizations

No. 582/1995

Ministry of Health and Social Security
ICELAND
May 1996

REGULATION

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1. Definitions

Article 1

Parallel imported medicinal product means a proprietary medicinal product, for which a marketing authorization has been granted in another EEA country and which is imported from that country into Iceland where the proprietary medicinal product in question, from the same undertaking or body of undertakings, has already been registered and a marketing authorization for it issued in Iceland. No parallel imported medicinal product may be placed on the market in Iceland unless it has been approved by the health authorities, i.e. after registration and the issuing of a marketing authorization. A parallel imported medicinal product means both a medicinal product produced in Iceland and abroad.

Country of exportation means the country where a marketing authorization has been granted for the parallel imported medicinal product and from where the product is exported to Iceland.

The Acts of the European Council (EEC) concerning registered medicinal products, cf. Annex 1 to this Regulation, cf. Regulation No. 465/1995 on the Registration of Proprietary Medicinal Products and the Issuing of Marketing Authorizations, apply to parallel imported medicinal products as well, with the exemptions specified in this Regulation, such as, for example, that the same information is not required for parallel imported medicinal products as for registered proprietary medicinal products, as it is presumed that a parallel imported medicinal product and a registered proprietary medicinal product from the same undertaking or body of undertakings are of identical quality. If there is a difference between a parallel imported medicinal product and a registered proprietary medicinal product, an additional labelling in Icelandic is required on the packaging of the parallel import.

2. Conditions for the granting of marketing authorizations for parallel imported medicinal products

Article 2

The granting of marketing authorization for a parallel imported medicinal product is subject to the following conditions:

1. a marketing authorization has been granted for the relevant proprietary medicinal product in Iceland;
2. a marketing authorization has been granted for the parallel imported medicinal product in the country of exportation;
3. the country of exportation is an EEA country;
4. the holder of the marketing authorization for the parallel imported medicinal product in the country of exportation is also the holder of the marketing authorization for the relevant proprietary medicinal product in Iceland or party to the same undertaking or body of undertakings as the holder of the marketing authorization;
5. the medicinal products contain the same active ingredients and have the same therapeutical effect.

A marketing authorization may be granted for a parallel imported medicinal product notwithstanding a minor difference between this product and the relevant registered proprietary medicinal product regarding appearance or colouring agents, if this difference is not relevant to its therapeutical value. It shall be stated in the application whether the parallel imported medicinal product is in any way different from the registered proprietary medicinal product and a statement from the applicant on his assessment of how this difference, if any, changes the therapeutic value of the product must accompany the application. In such cases the State Committee on Pharmaceuticals shall assess the product on the basis of the same information as when assessing changes concerning registered proprietary medicinal products.

The State Committee on Pharmaceuticals can, if necessary, require more detailed data on parallel imported medicinal products than provided for in this Regulation, for example in the case of medicinal products derived from human or animal tissue.

3. Application for the registration of a parallel imported medicinal product

Article 3

General Provisions

An application for the registration of a parallel imported 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 Icelandic in three copies, cf. 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.

Each application is only valid for one medicinal product in one dosage form and one strength and for one country of exportation. 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 parallel imported medicinal product, 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 parallel imported medicinal product will be registered under one name and under the first application number for the relevant medicinal product.

Article 4

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.

Article 5

Documents and particulars accompanying an application

The application shall be accompanied by the following documents and particulars:

1. a receipt for the payment of the registration fee, invoiced by the State Committee on Pharmaceuticals, cf. Article 4 of this Regulation;
2. the text of the proposed label and/or immediate or outer packaging of the medicinal product, cf. Article 6 of this Regulation;
3. the text of the proposed package leaflet in Icelandic and instructions for use, if appropriate, and if required for the relevant registered proprietary medicinal product, cf. Article 7 of this Regulation;
4. two samples, from the country of exportation, of the package sizes of the medicinal product for which the application is made;
5. a confirmation of the granting of marketing authorization in the country of exportation;
6 information on the repackaging and/or the changes to labelling of the packaging of the medicinal product;
7. a statement on the variations if the parallel imported medicinal product differs in any way from the registered proprietary medicinal product, cf. Article 2 (2) of this Regulation.

Article 6

Labelling of packaging

Subject to paragraphs 2 and 3 of this Article, Regulation No. 418/1994 on the labelling of medicinal products for human use and veterinary medicinal products and on package leaflets, applies to the labelling of the packaging of parallel imported medicinal products.

If a parallel imported medicinal product differs in any way from the relevant registered proprietary medicinal product it should be specified on the packaging of the parallel imported medicinal product.

The text on the packaging of a parallel imported medicinal product may be in a foreign language provided that it is not inconsistent with the obligatory information in Icelandic on the packaging. An approved text in Icelandic can be glued over the foreign text.

Article 7

Package leaflets and instructions for use

Subject to paragraph 2 of this Article, Regulation No. 418/1994 on the labelling of medicinal products for human use and veterinary medicinal products and on package leaflets, applies to package leaflets for parallel imported medicinal products and registered proprietary medicinal products.

The text of the package leaflet for a parallel imported medicinal product shall be in accordance with the text of the package leaflet for the relevant registered proprietary medicinal product. However, it is prohibited to deviate from the text in respect of indications and dosages.

Analogous provisions apply to the package leaflet and instructions for use of a parallel imported medicinal product and the relevant registered proprietary medicinal product, as appropriate.

Proposals for the text of package leaflets and instructions for use, if appropriate, should preferably be submitted on diskettes as well.

Article 8

Repackaging. Opening of containers

When a parallel imported medicinal product must be repacked, relabelled, the seal of the container of the product broken or a package leaflet or instructions for use inserted into its packaging, this must be carried out by a person or an undertaking authorized to manufacture medicinal products. Where this person or undertaking is Icelandic, the Minister of Health and Social Security grants the license to manufacture medicinal products after obtaining the opinion of the State Drug Inspectorate, cf. the provisions of Chapter XII of the Pharmaceutical Act No. 93/1994. Where this person or undertaking is foreign, the application shall be accompanied by a copy of his licence to manufacture proprietary medicinal products, issued by the relevant health authorities during the preceding two years.

Article 9

Shelf life and storage conditions

The shelf life and storage conditions of a parallel imported medicinal product, which must be indicated both on its immediate and outer packaging, shall in principle be the same as for the relevant registered proprietary medicinal product.

Should the authorized shelf life of a parallel imported medicinal product in the country of exportation be different from the shelf life authorized in Iceland for the relevant registered proprietary medicinal product, then the shorter shelf life shall apply.

If the shelf life of a parallel imported medicinal product is changed in the country of exportation the shelf life authorized in Iceland may also be changed in the same way, but not beyond the authorized shelf life of the relevant registered proprietary medicinal product.

4. Changes concerning parallel imported medicinal products

Article 10

Changes to a parallel imported medicinal product

The holder of the marketing authorization for a parallel imported medicinal product is required to keep track of all changes made to it and notify them immediately in writing to the State Committee on Pharmaceuticals.

If the appearance of a parallel imported medicinal product, its ingredients, packaging or conditions for registration are changed after a marketing authorization has been granted, the product must only be sold subject to the approval of the State Committee on Pharmaceuticals for the changes.

Article 11

Change of marketing authorization number

Should the marketing authorization number of a parallel imported medicinal product be changed in the relevant country of exportation this must be notified in writing to the State Committee on Pharmaceuticals so that the reasons for the change can be investigated. The relevant medicinal product may nonetheless be sold unless the Committee decides otherwise.

Article 12

Changes to the terms of a marketing authorization

The holder of a marketing authorization for a parallel imported medicinal product can apply in writing to the State Committee on Pharmaceuticals for changes to be made to the terms of the marketing authorization for the product.

Article 13

Change of agency

The cancelling of an agency, held by the representative of a foreign holder of the marketing authorization for a parallel imported medicinal product, must be notified immediately in writing to the State Committee on Pharmaceuticals and a new agent notified simultaneously.

5. Evaluation of applications

Article 14

Evaluation of an application for the registration of a parallel imported medicinal product will not be started until all necessary supporting documents and particulars have been sent to the State Committee on Pharmaceuticals and the registration fee has been paid.

The State Committee on Pharmaceuticals shall seek to ensure that evaluation of an application for the registration of a parallel imported medicinal product is completed within 120 days from the date on which the Committee receives valid application documents.

When evaluating an application for the registration of a parallel imported medicinal product the State Committee on Pharmaceuticals shall request information from the competent authorities of the country of exportation, if necessary. The time needed for evaluation of an application for the registration of a parallel imported medicinal product can therefore be longer than 120 days if the Committee does not receive information from the country of exportation in time and if the Committee considers that, in addition to the documents accompanying the application, further information is needed from the applicant.

The State Committee on Pharmaceuticals may also, if there is a special need for it, lay down specific requirements which have to be met before the Ministry of Health and Social Security can grant a marketing authorization for a parallel imported medicinal product.

6. Annual fee

Article 15

The marketing authorization holder shall pay an annual fee to the State Committee on Pharmaceuticals for each dosage form and strength of a parallel imported 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.

7. Period of validity for registrations and marketing authorizations

Article 16

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

If the holder of a marketing authorization for a parallel imported medicinal product does not apply for a renewal within a set time limit, cf. the provisions of Article 17 of this Regulation, the registration and marketing authorization will expire.

8. Application for renewal of a registration

Article 17

An application for renewal of the registration of a parallel imported medicinal product shall be 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 parallel imported medicinal products.

The application shall include a receipt for the payment of the registration fee, cf. the provisions of Article 4 of this Regulation.

The application for renewal of the registration of a parallel imported medicinal product shall be accompanied by the same documents as the application for its registration, cf. the provisions of Articles 3 to 9 of this Regulation.

9. Restricted registration

Article 18

The registration of a parallel imported medicinal product may be restricted, as with the relevant registered proprietary medicinal product, 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.

10. Applications for marketing authorizations and prices of parallel imported medicinal products

Article 19

Applications for marketing authorizations

An applicant for a marketing authorization for a parallel imported medicinal product may submit an application to the Ministry of Health and Social Security on a special application form, cf. Annex 3 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 name of the parallel imported medicinal product, labelling, package sizes, packaging, package leaflet and instructions for use, as appropriate.

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

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

Article 20

Special provisions on marketing authorization for parallel imported medicinal products

A marketing authorization for a parallel imported medicinal product confers on the holder of the marketing authorization the right to market the product in accordance with existing laws, regulations and administrative provisions in Iceland.

The marketing authorization of a parallel imported medicinal product only applies to exportation from the country/countries and the manufacturer(s) named in the licence.

Article 21

Applications for approval of prices

Approval of the price of a parallel imported medicinal product must be appliced for to the Ministry of Health and Social Security. The application may be submitted before a recommendation for registration has been delivered, but information on the approved price will not be given until after marketing authorization has been granted.

11. Register of Proprietary Medicinal Products and Price List II

Article 22

Information on parallel imported 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 parallel imported medicinal product;

2. 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 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;

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

4. the price of the product has been approved by the health authorities.

12. Application for revocation of a marketing authorization

Article 23

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

13. Withdrawal of marketing authorization

Article 24

An Icelandic marketing authorization for a parallel imported medicinal product ceases to apply when:

1. the marketing authorization for the product in the country of exportation ceases to apply;

2. the marketing authorization for the relevant proprietary medicinal product in Iceland ceases to apply;

3. it transpires that a parallel imported medicinal product on the market in Iceland fails to comply with the laws and regulations in force governing parallel imported medicinal products or with the terms of the marketing authorization. In such cases the Minister of Health, after obtaining the opinion of the State Committee on Pharmaceuticals and/or the State Drug Inspectorate, may withdraw the marketing authorization.

   If the marketing authorization for the relevant proprietary medicinal product is cancelled in Iceland for commercial reasons, the Minister of Health and Social Security can grant an authorization to prolong the marketing authorization of a parallel imported medicinal product for a limited period of time, after obtaining the opinion of the State Committee on Pharmaceuticals.

   If the marketing authorization for the relevant proprietary medicinal product is cancelled in Iceland for reasons of safety, the marketing authorization for the proprietary medicinal product and the parallel imported medicinal product will be revoked at the same time.

14. Notification of the issuing and revocation of marketing authorizations

Article 25

The Ministry of Health and Social Security shall notify the holder of the marketing authorization in question or his agent and the State Committee on Pharmaceuticals and the State Drug Inspectorate, of the issuing and revocation of marketing authorizations, cf. the provisions of Article 19 to 21, 23 and 24 of this Regulation.

15. Entry into force

Article 26

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 forthwith.

The Ministry of Health and Social Security,

18 October 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.

Rules, laid down by the Commission of the European Union, on parallel imported medicinal products are discussed in more details in the *Official Journal of the European Communities* No. C 115/5 of 6 May 1982.

Annex 2

Application Form for the Registration of a Parallel Imported 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. Date: Signature:	Application no.: Registration fee:

- ☐ **Medicinal product for human use**
- ☐ **Veterinary medicinal product**
- ☐ Ref. to a former application (medicinal product, reg.no.): _____
- ☐ Renewal of application (MTnr): _____

- ☐ **New parallel imported medicinal product:**
- ☐ **New dosage form of parallel imported medicinal product:**
- ☐ **New strength of parallel imported medicinal product:**

Name of parallel imported medicinal product:	
Name of registered proprietary medicinal product:	
Dosage form:	Strength:
Route of administration:	
Name (INN) of active ingredient(s):	
Country of exportation:	MTnr in the country of exportation:
Manufacturer responsible for the parallel imported medicinal product:	
Importer responsible for importation to the country of exportation, if other than country of manufacture:	

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:

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:

Information on the parallel imported medicinal product to be registered:

Holder of marketing authorization in the country of exportation:	Manufacturer responsible:
Address:	Address:

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

Importer of medicinal product in the country of exportation:	
Address:	Address:

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

Name and quantity of active ingredient(s) per unit (e.g. per tablet, ml etc.):

Registered proprietary medicinal product:	Parallel imported medicinal product:

Information on the registered proprietary medicinal product:

Name of medicinal product: _____

Marketing authorization number (MTnr): _____

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

Packaging: Registered proprietary medicinal product:	**Packaging: Parallel imported medicinal product**
Size:	Size:
Packaging type:	Packaging type:
Shelflife:	Shelf life:
Storage conditions:	Storage conditions:
Shelf life after first opening of container:	Shelf life after first opening of container:
Storage conditions after first opening of container:	Storage conditions after first opening of container:
Shelflife after reconstitution:	Shelf life after reconstitution:
Storage conditions after reconstitution:	Storage conditions after reconstitution:

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

Packaging cont.: Registered proprietary medicinal product:	Packaging cont.: Parallel imported medicinal product
Size:	Size:
Packaging type:	Packaging type:
Shelf life:	Shelf life:
Storage conditions:	Storage conditions:
Shelf life after first opening of container:	Shelf life after first opening of container:
Sto rage conditions after first opening of container:	Storage conditions after first opening of container:
Shelf life after reconstitution:	Shelf life after reconstitution:
Storage conditions after reconstitution:	Storage conditions after reconstitution:

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

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

To be completed in case of changes to labelling of packaging or repackaging:

1. Site where labelling changes take place:

Company:	
Address:	
Telephone number:	Fax number:

Person responsible for batch release after labelling changes:

Company:	
Address:	
Telephone number:	Fax number:

Describe changes to labelling of packaging in a special document.

2. Site where repackaging takes place:

Company:	
Address:	
Telephone number:	Fax number:

Person responsible for batch release after repackaging:

Company:	
Address:	
Telephone number:	Fax number:

Describe repackaging and new type of packaging in a special accompanying document.

Place and date

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

Annex 3

Application Form for Marketing Authorization for a Parallel Imported 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 parallel imported medicinal product:	Name of registered proprietary medicinal product:
Dosage form and strength:	
Active ingredient(s):	
Manufacturer:	
Country of exportation:	MTnr in the country of exportation:

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. 582/1995 on the Registration of Parallel Imported Medicinal Products and the Issuing of Marketing Authorizations

Article 1

The heading of Chapter 10 shall read as follows:
10. Applications for prices and marketing authorizations

Article 2

Article 19 of the Regulation shall read as follows:

Applications for prices

Approval of the price of a parallel imported medicinal product must be applied for to the Ministry of Health and Social Security. The application may be submitted before a recommendation for registration has been delivered, but no information on the approved price will be given unless the Committee has approved the registration or renewal of registration of the product.

Article 3

Article 20 of the Regulation shall read as follows:

Applications for marketing authorizations

An applicant for a marketing authorization for a parallel imported medicinal product may submit an application to the State Committee on Pharmaceuticals on a special application form, cf. Annex 3 to this Regulation, subject to the Committee's approval for the registration or renewal of registration of the product, including approval for the name of the parallel imported medicinal product, labelling, package sizes, packaging, package leaflet and instructions for use, as appropriate.

An application for marketing authorization must be accompanied by confirmation of the approval of the health authorities for the price of the 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 six months.

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

Article 4

Article 21 of the Regulation shall read as follows:

Special provisions on marketing authorization for parallel imported medicinal products

A marketing authorization for a parallel imported medicinal product confers on the holder of the marketing authorization the right to market the product in accordance with existing laws, regulations and administrative provisions in Iceland.

The marketing authorization of a parallel imported medicinal product only applies to exportation from the country/countries and the manufacturer(s) named in the licence.

Article 5

Article 22 of the Regulation shall read as follows:

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

Article 6

Article 23 of the Regulation shall read as follows:

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

Article 7

Article 24 (3) shall read as follows:

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

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 Seltjarnarnes.

(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, 20 November 1995.

Ingibjörg Pálmadóttir

Eggert Sigfússon.