REGULATION
on granting of licences for parallel import of medicinal products for human use and veterinary use.

Art. 1.

Scope and definitions.

This regulation applies to granting of parallel import licences by the Icelandic Medicines Agency. The regulation applies to medicinal products, both for human and veterinary use. , whether they have been granted a central marketing authorisation within the European Union (EU), or a national marketing authorisation within the European Economic Area (EEA). Import and wholesale distribution of parallel imported medicinal products is subject to the provisions of Regulation No 699/1996 on import and wholesale distribution of medicinal products.

The term parallel-imported medicinal product refers to a proprietary medicinal product which has a marketing authorisation in another country that is a party to the EEA agreement, and which is imported into Iceland from that country, the relevant medicinal product having a marketing authorisation in Iceland, or is sufficiently similar to another medicinal product already registered and having marketing authorisation in Iceland.

The term directly-imported medicinal product refers to a proprietary medicinal product which has a marketing authorisation in Iceland and is, if marketed in Iceland, imported via the distribution channels pertaining to the marketing authorisation holder.

Parallel-imported medicinal products may not be marketed unless the conditions of the licence are met. Publication of information in drug and price catalogues is subject to rules of procedure issued by the Icelandic Medicines Agency in consultation with the Icelandic Medicine Pricing and Reimbursement Committee, and published on the Agency's website.

Art. 2

Conditions for granting of a licence.

The following requirements must be met in order for the Icelandic Medicines Agency to issue a licence for parallel import of a medicinal product:

1. The directly-imported medicinal product, in relation to which an application for parallel import of a medicinal product has been submitted, must hold a marketing authorisation that is valid in Iceland. The directly-imported and the parallel-imported medicinal product must contain the same active substance(s) and have the same pharmaceutical form.

2. The parallel-imported medicinal product must be imported from an EEA country.

3. The parallel-imported medicinal product must have a valid marketing authorisation in the EEA country from whence it is imported (hereinafter termed the exporting country).

4. There must be no differences of therapeutic significance between the parallel- imported and the directly-imported medicinal product.

Art. 3

Application for licence.

An application for a licence for parallel import of a medicinal product shall be submitted to the Icelandic Medicines Agency on a form which is available on the Agency's website.

Each application is valid for one medicinal product in one pharmaceutical form and strength, from one exporting country.

A licence for parallel import of a medicinal product applies only to parallel import from the exporting country specified in the licence, and only for the marketing authorisation number specified in the parallel-import licence.

Art. 4

Difference between parallel-imported and directly-imported medicinal products.

The applicant shall state in the application for a licence for parallel import of medicinal products whether it differs in any way from the directly-imported medicinal product to which reference is made. The applicant shall in addition submit a summary explaining whether the difference has any significance in the comparison with the directly-imported medicinal product and, if so, what it entails.

In evaluating possible differences between the directly-imported medicinal product and the medicinal product for which the application for parallel import is made, the Icelandic Medicines Agency shall apply the same methods as are used in evaluation of medicinal products with respect to the granting of an Icelandic marketing authorisation.

Art. 5

Requirement for additional data for application regarding biological medicinal products.

In the case of an application for a licence for parallel import of biological medicinal products the Icelandic Medicines Agency may, in order to ensure the safety of patients, require further data to be submitted in addition to those which apply to other medicinal products.

Art. 6

Grounds for granting of licence.

A licence for parallel import of medicinal products is granted on the basis that the parallel-imported medicinal product is of same quality, and meets all the conditions which apply to the granting of a marketing authorisation for the directly-imported medicinal product.

Should it transpire, after the granting of a licence for parallel import of a medicinal product, that the medicinal product does not meet the conditions for the granting of the licence, the Icelandic Medicines Agency may revoke the licence.

Art. 7

Handling of an application.

On receipt by the Icelandic Medicines Agency, the application shall normally be validated within two weeks, in order to ascertain that it has been correctly filled out, and that all required documentation has been included according to the application form. In the case of some deficiency in the application, the Icelandic Medicines Agency requests updated or additional documentation as applicable, which are to be submitted to the Icelandic Medicines Agency within 30 days. An application is not valid until all required documentation have been received by the Icelandic Medicines Agency.

On receipt of the application the Icelandic Medicines Agency sends the applicant an invoice for the application fee.

The Icelandic Medicines Agency requests necessary information from the relevant authority in the exporting country, normally within two weeks of a valid application being received and the

application fee being paid. Should the requested information not have been received by the Icelandic Medicines Agency within two months of the request being sent, the request shall be reiterated.

The application fee will not be refunded if the application is refused.

The Icelandic Medicines Agency shall seek to complete its consideration of an application for a parallel-import licence for a medicinal product within 45 days of receipt of the requested information from the exporting country.

Should it transpire during assessment of the application that documentation is missing, or more documentation is required, the time which elapses while waiting for information from the applicant shall not be counted towards the 45 day period.

Art. 8

Labelling and product information leaflet.

Labelling and package leaflets for parallel-imported medicinal products are subject to the provisions of Regulation No 141/2011 on marketing authorisations for proprietary medicinal products and their labelling and package leaflets.

Art. 9

Repackaging and wholesale distribution.

The licence-holder for parallel import of a medicinal product is responsible for that the repackaging does not diminish in any way the quality of the medicinal product, and for the labelling and the package leaflet being in conformity with the provisions of Regulation No 141/2011 on marketing authorisations for proprietary medicinal products and their labelling and product information leaflets.

Repackaging and wholesale distribution are subject to the provisions of Regulation No 699/1996 on import and wholesale distribution of medicinal products.

The sticker on the outer packaging shall show the name of the manufacturer which carries out the repackaging.

In the case of a parallel-imported medicinal product which deviates from the directly-imported medicinal product in colour, appearance, taste, etc. or, in the case of an parenteral product, which deviates from the directly-imported medicinal product in the content of preservatives, this deviation shall be stated in the labelling of the parallel-imported medicinal product.

Art. 10

Summary of product characteristics, labelling and package leaflet of parallel-imported medicinal product.

On issue of a licence for parallel import of a medicinal product the Icelandic Medicines Agency issues a summary of product characteristics, labelling and package leaflet of the parallel-imported medicinal product. Such texts shall be the same as those of the relevant directly-imported medicinal product, with the exception of information applying specifically to the parallel-imported medicinal product, such as the name of the licence-holder, the name of the medicinal product, and shelf life.

Art. 11

Amendments to summary of product characteristics of the directly-imported medicinal product.

Should amendments be made to the summary of product characteristics, labelling or package leaflet of the directly-imported medicinal product, the Icelandic Medicines Agency issues new texts for the relevant parallel-imported medicinal product, which it sends to the product’s licence-holder.

The Medicines Agency also sends the licence-holder an invoice for the amendments, in accord with the Agency's tariff.

Art. 12

Other provisions on parallel-imported medicinal products.

A parallel-imported medicinal product is subject at all times to the same provisions as apply to the directly-imported medicinal product, e.g. with respect to limitations of prescription and weather the product is a prescription medicinal product or not.

Art. 13

Variations to conditions of a marketing authorisation for the medicinal product in the exporting country.

A licence-holder for parallel import of a medicinal product shall immediately notify the Icelandic Medicines Agency of all variations to the conditions of the medicinal product's marketing authorisation in the exporting country, on which the granting of the parallel-import licence for the medicinal product was based.

Art. 14

Information to marketing authorisation holder.

The parallel importer shall inform the holder of the marketing authorisation for the directly-imported medicinal product in the importing country of its intention to commence parallel import of the medicinal product to Iceland.

Art. 15

Cancellation of licence at licence-holder's request.

Should the a licence-holder for parallel import of a medicinal product request the cancellation of the licence, this shall be done according to the relevant guidelines published by the Icelandic Medicines Agency on its website.

Art. 16

Period of validity of licence for parallel import of a medicinal product.

A licence for parallel import is valid for five years from the date of issue, after which it expires, unless a renewal has been applied for under para. 2.

Should a licence-holder for parallel import of a medicinal product intend to renew the licence, this shall be done at least nine months before the expiry of the prior licence. Such an application may cover all strengths and pharmaceutical forms under the same product name, regardless of whether the licences for their parallel import expire at the same time. The new licence takes effect from the expiry date of the oldest existing licence under the new application.

Art. 17

Withdrawal of marketing authorisation for a directly-imported medicinal product.

Should a marketing authorisation for a directly-imported medicinal product be revoked for safety reasons, the parallel-import licence shall be revoked no later than from the same time. The Icelandic Medicines Agency notifies the licence-holder for parallel import of the medicinal product that the licence is revoked. If the marketing authorisation for the directly-imported medicinal product is revoked for reasons not related to safety in use of the medicinal product, the parallel-import marketing authorisation will not be revoked, unless the Icelandic Medicines Agency deems that there is a special

reason to do so, in order to protect the health and life of humans and animals. The Icelandic Medicines Agency notifies the licence-holder for parallel import of the medicinal product that the licence is revoked.

Should an Icelandic marketing authorisation for a directly-imported medicinal product be revoked for other reasons than safety in use of the medicinal product, the parallel-imported medicinal product retains the summary of product characteristics of the directly-imported medicinal product existing at the time of withdrawal.

A licence-holder for parallel import of a medicinal product is responsible for maintaining the summary of product characteristics if the marketing authorisation of the directly-imported medical product is revoked. The licence holder shall in such circumstances apply for revisions of the summary, labelling and product information leaflet, immediately as changes occur in the exporting country. An application for such changes shall be made to the Icelandic Medicines Agency as provided by Commission Regulation (EC) No 1234/2008 with subsequent amendments, cp. Regulation No 418/2010 implementing European Union Regulations regarding pharmaceutical issues (VIII) and Regulations No 1150/2013 implementing European Union Regulations regarding pharmaceutical issues (XII). The fee for the application shall be in accordance with the Icelandic Medicines Agency's tariff at any time. The application shall be accompanied, as applicable, by the medicinal product's approved summary of product characteristics, labelling and package leaflet in the exporting country, together with a proposal for updated texts in Icelandic. If the above-mentioned texts in the exporting country are in a language other than English, Danish, Norwegian or Swedish the licence-holder for parallel import of the medicinal product shall submit an English translation by a certified translator.

Art. 18

Special duties of licence-holder for parallel import of a medicinal product.

A licence-holder for parallel import shall systematically monitor any change that may be made to the medicinal product, e.g. with respect to the risk of counterfeiting, including the labelling and alterations to the design of the packaging, and inform the Icelandic Medicines Agency of any such change. In the case of a change in the composition, appearance or inner packaging of a parallel-imported medicinal product, or the marketing authorisation holder/manufacturer responsible for batch release, marketing authorisation number or status of marketing authorisation in the exporting country, with respect to the prerequisites on which the licence for parallel import was based when it was issued, an application shall be made to the Icelandic Medicines Agency for such changes, in order to ensure consistency at all times with the medicinal product from the exporting country. The medicinal product must not be imported until the Agency has granted its approval. Such applications are subject to a fee according to the Icelandic Medicines Agency's tariff.

In the case of minor changes which do not affect the summary of product characteristics, labelling or package leaflet of a parallel-imported medicinal product, the product may be imported; the Icelandic Medicines Agency shall however be notified of the change.
The licence-holder for parallel import is responsible for judging whether a change should be deemed minor.

Art. 19

Pharmacovigilance.

A licence-holder for parallel import of medicinal products shall collect adverse reaction reports of the medicinal product, and shall report these in accordance with rules issued by the Icelandic Medicines Agency.

Art. 20

The Icelandic Medicines Agency guidelines on licences for parallel import of medicinal products.

The Icelandic Medicines Agency publishes on its website further instructions on licences for parallel import of medicinal products. The date on which the instructions were last updated shall be published.

Art. 21

Penalties

Infringements of the provisions of this Regulation are subject to the provisions of Section XVII of the Medicinal Products Act No 93/1994 with subsequent amendments.

Art. 22

Entry into force

This Regulation, based on authority in para. 9 art. 7 and para. 7 art. 33 of the Medicinal Products Act No 93/1994 with subsequent amendments, take effect immediately. From that time Regulation No 582/1995 on registration and issue of marketing authorisations for parallel medicinal products are rescinded.

The provisions of this Regulation is in accordance with the Commission Communication of 30 December 2003 on parallel imports of medicinal products (COM(2003) 839 final).

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