Parallel import of medicinal products

Legal basis

Target groups
Pharmaceutical manufacturers
Pharmaceutical wholesalers
Persons responsible for placing a medicinal product on the market
Finnish Food Safety Authority
National Institute for Health and Welfare
Finnish Red Cross Blood Service

Period of validity
The regulation will enter into force on 25 January 2011 and will remain in force indefinitely.

Provision repealed
Administrative regulation 7/2005 issued by the National Agency for Medicines.
Table of contents

Table of contents ...................................................................................................................................2
Administrative regulation........................................................................................................................3
1. Scope of the administrative regulation...............................................................................................3
2. Definitions ..........................................................................................................................................3
3. Relation to other administrative regulations and normative guidelines ..............................................4
4. Preconditions of a marketing authorisation for parallel import ...........................................................4
5. More detailed requirements relating to marketing authorisation ........................................................5
  5.1 Applicant.......................................................................................................................................5
  5.2 Repackaging ................................................................................................................................5
  5.3 Trade name ..................................................................................................................................5
  5.4 Pack size and type .......................................................................................................................6
  5.5 Shelf life........................................................................................................................................6
6. Applying for a marketing authorisation and processing the application .............................................6
  6.1 Annexes to the application ...........................................................................................................6
    6.1.1 Sample package ....................................................................................................................6
    6.1.2 Labelling ................................................................................................................................6
    6.1.3 Package leaflet ......................................................................................................................6
  6.2 Application processing .................................................................................................................7
  6.3 Granting a marketing authorisation and its validity.......................................................................7
  6.4 Placing a product on the market...................................................................................................8
7. Variations to a marketing authorisation..............................................................................................8
8. Renewal of a marketing authorisation................................................................................................9
9. Other obligations relating to a marketing authorisation......................................................................9
10. Guidance and information..............................................................................................................10
11. Entry into force............................................................................................................................... 10
Distribution ...........................................................................................................................................11
For information.......................................................................................................................................11
ANNEX.................................................................................................................................................12
1. Fill-out instructions ...........................................................................................................................12
2. Sample package ..............................................................................................................................12
3. Labelling ........................................................................................................................................12
4. Declaration of repackaging ..............................................................................................................12
5. Proof of payment..............................................................................................................................13
6. Package leaflet ...............................................................................................................................13
Administrative regulation

1. Scope of the administrative regulation

This Administrative Regulation applies to parallel-imported medicinal products. This regulation does not apply to the parallel distribution of medicinal products that have obtained marketing authorisations through the centralised procedure of the European Union (EU), for which a instructions have been issued separately in the following publications:

- EMEA Information Regarding Notifications of Parallel Distribution of Centrally Authorised Medicinal Products (EMEA/Ho/13397/04) and (EMEA/Ho/2368/Rev1) as well as
- Communication C98/2016 (Official Journal of the European Communities C229, 22 July 1998) of the Commission of the EC.

2. Definitions

For the purposes of this Administrative Regulation:

Fimea refers to the Finnish Medicines Agency;

country of acquisition refers to the state from which the medicinal product is imported into Finland;

directly imported product refers to the medicinal product in respect of which parallel import takes place;

Decree on Fees refers to the Decree of the Ministry of Social Affairs and Health concerning activities of the Finnish Medicines Agency subject to fees (66/2010);

marketing authorisation for parallel import refers to a marketing authorisation for a medicinal product that already has a marketing authorisation in Finland but that is being placed on the market by a party other than the marketing authorisation holder for the product that is already on the market or a party authorised to import the product by the marketing authorisation holder;

parallel importer refers to a natural or legal person who is not the marketing authorisation holder for the medicinal product on the market in Finland or a party authorised to import the product by the marketing authorisation holder;

immediate packaging refers to the packaging in immediate contact with the medicinal product;

outer packaging refers to the packaging into which the immediate packaging is placed; and
repackaging refers to the transfer of the immediate packaging of the medicinal product from one package into another, the re-labelling of the product, and the addition of a package leaflet.

3. Relation to other administrative regulations and normative guidelines

In addition to this regulation, the provisions of the following administrative regulations issued by the Finnish Medicines Agency (Fimea) must be complied with in parallel import as applicable:

- Fimea Administrative Regulation 5/2010, Pharmacovigilance
- Fimea Administrative Regulation 2/2010, Veterinary pharmacovigilance
- Fimea Administrative Regulation 1/2009, Applying for and maintaining a marketing authorisation and registration for a medicinal product
- Fimea Administrative Regulation and Normative Guideline 4/2009, Product defects
- Fimea Administrative Regulation 1/2010, Labelling and package leaflets for medicinal products

The following Normative Guidelines issued by Fimea must also be observed:

- Normative Guideline 2/2010, Reporting adverse drug reactions
- Normative Guideline 1/2010, Labelling and package leaflets for medicinal products

The import, wholesale and marketing of a medicinal product marketed with a marketing authorisation for parallel import must comply with separate provisions concerning the import, wholesale and marketing of medicinal products.

4. Preconditions of a marketing authorisation for parallel import

The precondition for the issuance of an authorisation is that the conditions set out in section 21d of the Medicines Act (395/1987) are met. If this is not the case, an application must be filed to obtain a marketing authorisation for the medicinal product in accordance with the Fimea administrative regulation on applying for and maintaining a marketing authorisation and registration for a medicinal product.

Pursuant to section 21d of the Medicines Act, parallel import may only be initiated in respect of a medicinal product that has a valid marketing authorisation in Finland. Said medicinal product must also have a valid marketing authorisation in the country of acquisition. The country of acquisition must be a member of the EU/EEA.

When processing the marketing authorisation application for a parallel-imported medicinal product, it will be confirmed that the similarity between the products is such that they can be considered as the same medicinal product. The medicinal products need not be identical in all respects, but they must use the same active ingredient and their formulations must be similar to the extent that formulation variations do not give rise to differences in the therapeutic efficacy or safety of the products. The
marketing authorisation application may be rejected on the grounds that the medicinal product to be imported is not sufficiently similar to the product that has already been granted a marketing authorisation in the Member State of destination or its origin does not have a sufficient connection to the product that already has an authorisation in the Member State of destination.

The parallel-imported medicinal product and the medicinal product on the market must not differ from each other in any way that has therapeutic significance. The excipients of the products and/or their quantities may differ slightly from each other; for example, a different colouring agent may be used.

5. More detailed requirements relating to marketing authorisation

5.1 Applicant

An application for a marketing authorisation for parallel import may be filed by the parallel importer. The parallel importer acquires the medicinal product from the country of acquisition, repackages it or has it repackaged, and is responsible for placing the product on the market.

5.2 Repackaging

Repackaging must be carried out at a pharmaceutical factory that has obtained an authorisation for the industrial manufacture of medicinal products, as specified in more detail in the authorisation concerning the pharmaceutical factory in question. Good Manufacturing Practice must be complied with in repackaging. Repackaging must occur within the EU/EEA.

5.3 Trade name

The trade name for a parallel-imported medicinal product may be the same as or different from the trade name of the medicinal product on the market. If the parallel-imported medicinal product has a trade name different from that of the medicinal product on the market, it must meet the requirements set out in the Fimea administrative regulation on applying for and maintaining a marketing authorisation and registration for a medicinal product. The trade name may also differ from the trade name used in the country of acquisition. For this reason, the immediate packaging may bear two different trade names. This must be specifically mentioned on the outer packaging.

The applicant for a marketing authorisation is personally responsible for any legal matters relating to the trade name.
5.4 Pack size and type

The pack size and type of the parallel-imported medicinal product may differ from the pack size and type of the medicinal product on the market in Finland, provided that the differences are not likely to pose a threat to public health. For example, such difference may be that of the packaging method employed: the direct importer may use a bottle, while the parallel importer uses a blister pack.

5.5 Shelf life

The shelf life approved in the country of acquisition is approved as the shelf life of the parallel-imported medicinal product. However, it may not be longer than the shelf life approved for the medicinal product on the market in Finland. The expiry date of the parallel-imported product must always be clearly visible on both the immediate and the outer packaging.

6. Applying for a marketing authorisation and processing the application

An application for a marketing authorisation for parallel import must be filed using the enclosed application form that is also published on the Fimea website (www.fimea.fi). The application form must be filled out in accordance with the enclosed fill-out instructions and accompanied by the required declarations.

6.1 Annexes to the application

6.1.1 Sample package

A sample package of one pack size is required, separately for each country of acquisition. The country of acquisition must be stated clearly on each sample package.

6.1.2 Labelling

The labelling of parallel-imported products must comply with the provisions of the Fimea administrative regulation on the labelling and package leaflets for a medicinal product. The outer packaging and package leaflet of the parallel-imported product must also bear the name and address of the parallel importer and repackager and the name of the manufacturer in the country of acquisition.

The Fimea Normative Guideline 1/2010, Labelling and package leaflets for medicinal products, must be observed when drafting the labelling proposal.

6.1.3 Package leaflet

The package leaflets for parallel-imported products must comply with the provisions of the Fimea administrative regulation on the labelling and package leaflets for a medicinal product (www.fimea.fi). The Fimea normative guideline on labelling and package leaflets for medicinal
products must also be observed when drafting the package leaflet proposals.

6.2 Application processing

The application complete with the required enclosures must be submitted to Fimea (for address information, see the Fimea website www.fimea.fi). Once an application has been received, it undergoes a preliminary validation. The purpose of the preliminary validation is to ensure that the application is appropriately prepared and that it contains all the required documents and enclosures. The applicant will be notified of any deficiencies in the application without delay, in which case the applicant must submit the omitted documents within two weeks. If the omitted documents are not provided, the applicant is requested to withdraw the application. In connection with the withdrawal of the application, the processing fee and the application complete with the enclosed documents will be returned to the applicant at the applicant's expense.

When the application has undergone the preliminary validation, Fimea will send a query to the authorities in the country of acquisition to confirm that the medicinal product in question has a valid marketing authorisation in the country of acquisition. In this connection, Fimea will also verify the accuracy of the information concerning, e.g., the manufacturer, the marketing authorisation holder, the complete composition of the product, the shelf life, and the storage conditions.

Whilst processing the application, it will be taken into account that the matter is not subject to the ordinary scientific evaluation used in the marketing authorisation procedure but that it is being processed as an administrative procedure. The application will be processed within the time limits set out in section 10a of the Medicines Decree (693/1987) with due consideration for the time needed for verifying the accuracy of the information with the authorities in the country of acquisition and to make any requests for further clarifications from the applicant.

6.3 Granting a marketing authorisation and its validity

Pursuant to section 24(1) of the Medicines Act (773/2009), a marketing authorisation is granted for five years from the date of its issuance. Nevertheless, the marketing authorisation is only valid for as long as the medicinal product in respect of which parallel import takes place has a valid marketing authorisation in the country of acquisition. The parallel importer is obligated to confirm that every batch to be imported has a valid marketing authorisation in the country of acquisition. If the marketing authorisation expires in the country of acquisition, the parallel importer must inform Fimea accordingly without delay.

The annual fee for a parallel-imported medicinal product must be paid as provided in the Decree on Fees. The marketing authorisation expires if the annual fee is not paid by the prescribed date.

When a marketing authorisation expires, the parallel importer must immediately withdraw the parallel-imported medicinal products on the
market from medicinal product wholesalers, pharmacies, hospital pharmacies and dispensaries.

6.4 Placing a product on the market

The provisions on placing medicinal products with marketing authorisations on the market contained in the Fimea administrative regulation on applying for and maintaining a marketing authorisation and registration for a medicinal product also apply to parallel-imported medicinal products. The parallel importer must submit a separate notification each time when products from a new country of acquisition are placed on the market for the first time.

If a medicinal product has not been placed on the market within three years of the granting of the marketing authorisation for parallel import or if its supply to the market has been continuously suspended for three years, the marketing authorisation for the parallel-imported medicinal product expires.

7. Variations to a marketing authorisation

The parallel importer must keep track of any changes to the original product on the market. If the package leaflet for the product on the market is changed in a manner requiring authorisation, the parallel importer must submit new proposed package leaflets without delay to Fimea for approval. In addition to a covering letter and the new proposed package leaflets, the notification must include the previously approved documents in which the changes have been clearly marked.

When variations have been initiated by the parallel importer (e.g. a change regarding a new pack size), authorisation or notification will be required as set out in the provisions concerning variations to medicinal products contained in the Fimea administrative regulation on applying for and maintaining a marketing authorisation and registration for a medicinal product.

Fimea must be notified of any changes to the labelling or package leaflets in accordance with the aforementioned administrative regulation 90 days prior to implementing the change. The variation can be implemented unless Fimea states that it is not approved. Furthermore, the parallel importer must also submit notifications/applications for authorisation for any variations to the product effected in the country of acquisition in compliance with the aforementioned administrative regulation.

When applying for authorisation for a new country of acquisition in addition to the countries of acquisition already included in a previously granted marketing authorisation for parallel import, the marketing authorisation holder must submit an application for extension concerning the countries of acquisition with regard to the original marketing authorisation for parallel import.
A processing fee is payable for the application as provided in the Fimea Decree on Fees.

8. Renewal of a marketing authorisation

Pursuant to section 24(1) of the Medicines Act, a marketing authorisation for a parallel-imported medicinal product is valid for a period of five years, after which it must be renewed. The renewal application must be filed with Fimea no later than six months prior to the date of expiry of the marketing authorisation. The marketing authorisation will remain valid during the time the renewal application is being processed. If no application is filed, the marketing authorisation expires, i.e. ceases to be valid.

A marketing authorisation for a parallel-imported medicinal product must be renewed at least once, after which the marketing authorisation will be valid indefinitely. However, for valid reasons pertaining to medicinal product safety, the marketing authorisation can be renewed once for an additional five-year period.

Applications for the renewal of a marketing authorisation for parallel import must be made in writing using the same form as when applying for a marketing authorisation for parallel import.

In addition to the application form, the application must be accompanied by a confirmation that the medicinal product has a valid marketing authorisation in the country of acquisition and that there have not been any changes to the marketing authorisation with regard to the parallel importer.

9. Other obligations relating to a marketing authorisation

Pursuant to section 30(1) of the Medicines Act, the parallel importer must keep track of any adverse effects and product defects in their medicinal products and notify Fimea accordingly. For the purpose of tracing the repackaged batches and properly addressing and reporting any product defects detected, the parallel importer must keep record of the origin, imported quantities and batch numbers of the parallel-imported medicinal products. This information must be submitted to Fimea without delay upon request.

The parallel importer must also submit periodic safety update reports as provided in the Fimea administrative regulations on pharmacovigilance and applying for and maintaining a marketing authorisation and registration for a medicinal product in the event that the corresponding medicinal product imported by the direct importer is no longer on the market in Finland.

The parallel importer is also subject to the provisions of the Act on Compulsory Stockpiles of Drugs (979/2008).
10. Guidance and information

If necessary, Fimea will provide information and guidance on the application of this regulation.

11. Entry into force

This Administrative Regulation enters into force on 25 January 2011. Any applications concerning parallel import submitted after that date must comply with the provisions of this Administrative Regulation.

Director General

Sinikka Rajaniemi

Coordinator for
Marketing Authorisations

Merja Laakso
Distribution

Pharmaceutical manufacturers
Pharmaceutical wholesalers
Persons responsible for placing medicinal products on the market
The Finnish Parallel Drug Importers' Foundation (SLRTY)
Finnish Food Safety Authority
National Institute for Health and Welfare
Finnish Red Cross Blood Service

For information

Ministry of Social Affairs and Health
Ministry of Employment and the Economy
Ministry of Agriculture and Forestry
Social Insurance Institution

National Supervisory Authority for Welfare and Health
Consumer Agency
Pharma Industry Finland
Finnish Importers of Veterinary Medicines
Finnish Food Safety Authority
Pharmaceutical Goods Wholesalers
Central Organisation of Health and Food Trade in Finland
University of Helsinki, Faculty of Veterinary Medicine
University of Helsinki, Faculty of Pharmacy
University of Helsinki, Faculty of Medicine
University of Eastern Finland, Faculty of Health Sciences

University of Oulu, Faculty of Medicine
University of Tampere, Faculty of Medicine
University of Turku, Faculty of Medicine
Åbo Akademi, Department of Biochemistry and Pharmacy
Association of Finnish Pharmacies
Finnish Veterinary Association
Finnish Pharmacists’ Association
Finnish Dental Association
Finnish Medical Association
Finnish Association of Pharmacists
Association of Finnish Local and Regional Authorities
University Pharmacy
Kuopio University Pharmacy
ANNEX

1. Fill-out instructions

The form may be filled out in Finnish, Swedish or English. A separate application form must be filled out for each product. If marketing authorisation is applied for parallel import of the same product from several countries of acquisition, separate applications must be submitted for each country of acquisition.

The application form must always contain the basic information of the medicinal product: the name of the medicinal product, its strength, pharmaceutical form and the active substance(s). The following information must also be entered on the form: pack size(s) and type(s). Complete information concerning the parallel importer and information concerning the medicinal product in the country of acquisition are also required. These include the name of the medicinal product, its strength, marketing authorisation number, marketing authorisation holder in the country of acquisition, and the manufacturer of the medicinal product. The required information concerning the medicinal product on the market must also be entered on the form.

2. Sample package

A sample package of one pack size is required, separately for each country of acquisition. The country of acquisition must be stated clearly on each sample package.

3. Labelling

Proposed labelling for each pack size in Finnish/Swedish must be enclosed in the form of a draft (e.g. as prepared using a computer program).

The labelling of both the outer and the immediate packaging must be submitted. If the trade names on the outer and immediate packaging differ from each other, this must be specifically mentioned on the outer packaging. In cases where the appearance of the medicinal product (e.g. its colour) differs from the original medicinal product on the market, this must be mentioned on the outer packaging. Separate labelling proposals must be submitted for each country of acquisition.

4. Declaration of repackaging

The application must contain a declaration of repackaging. The authorisation of the pharmaceutical factory carrying out the repackaging or a certificate containing the corresponding information and issued by a competent authority must be enclosed with the application.
5. Proof of payment

A certificate for the payment of the processing fee, such as a copy of the payment receipt, must be enclosed with the application. The processing fee must be paid before filing the application with Fimea. The name of the medicinal product, its strength and pharmaceutical form, as well as the name of the applicant, must be indicated on the receipt. The processing fee is payable in accordance with the Decree of the Ministry of Social Affairs and Health concerning activities of the Finnish Medicines Agency subject to fees. Fimea’s bank accounts are posted on the Fimea website (www.fimea.fi).

6. Package leaflet

Proposed package leaflets in Finnish and Swedish must be enclosed with the application.

Parallel importer’s obligation to notify the marketing authorisation holder for the original product on the market in Finland.

For parallel import from new states which joined the European Union after 1 May 2004, a written certificate must be enclosed with the application to show that the parallel importer has given a written notification to the marketing authorisation holder for the original product on the market in Finland one month prior to filing the application with Fimea. A copy of the written notification must be enclosed with the application.