

Regulation 12.2.2014  
3952/03.01.01/2012

**4/2014**

**Regulation of the Finnish Medicines Agency**  
PARALLEL IMPORT OF MEDICINAL PRODUCTS

**Authorisation provisions**

2§ (4), 23a§ (3), 25§ (3) and 28§ of the Medicines Act (395/1987), as they appear in Act 773/2009 and 30o§ of Act 330/2013.

**Target groups**

Pharmaceutical factories  
Pharmaceutical wholesalers  
Persons responsible for placing medicinal products on the market  
Finnish Food Safety Authority  
National Institute for Health and Welfare  
Finnish Red Cross Blood Donor Service

**Period of validity**

The present Regulation shall enter into force on 12.2.2014 and remain in force until further notice.

**Regulation being repealed**

Regulation 6/2010 of the Finnish Medicines Agency

# TABLE OF CONTENTS

1. SCOPE .....	3	6.3 Issue and validity of the marketing authorisation .....	7
2. DEFINITIONS .....	3	6.4 Placing on the market .....	7
3. RELATIONSHIP TO OTHER REGULATIONS AND GUIDELINES .....	4	7. AMENDMENTS TO THE MARKETING AUTHORISATION .....	8
4. REQUIREMENTS FOR A MARKETING AUTHORISATION FOR PARALLEL IMPORT .....	4	8. RENEWAL OF MARKETING AUTHORISATION .....	8
5. KEY REQUIREMENTS FOR THE MARKETING AUTHORISATION .....	5	9. OTHER OBLIGATIONS RELATING TO THE MARKETING AUTHORISATION .....	9
5.1 Applicant .....	5	10. ADVICE AND GUIDANCE .....	9
5.2 Re-packaging .....	5	11. ENTRY INTO FORCE .....	9
5.3 Trade name .....	5	Distribution .....	10
5.4 Pack size and type .....	5	For information .....	10
5.5 Shelf life .....	5	ANNEX .....	10
6. APPLICATION FOR AND PROCESSING OF THE MARKETING AUTHORISATION .....	6	1. Guidelines for the completion of applications .....	10
6.1 Annexes to the application .....	6	2. Sample package .....	11
6.1.1 Sample package .....	6	3. Sales labels .....	11
6.1.2 Sales labels .....	6	4. Report concerning re-packaging .....	11
6.1.3 Patient information leaflet .....	6	5. Proof of payment .....	11
6.2 Processing of applications .....	6	6. Patient information leaflet .....	11

## 1. SCOPE

The present regulation shall apply to medicinal products imported in parallel. The present regulation shall not apply to the parallel distribution through a European Union (EU) centralised procedure of medicinal products that are the subject of a marketing authorisation and in respect of which separate guidelines are given in the following publications:

- EMEA Information Regarding Notifications of Parallel Distribution of Centrally Authorised Medicinal Products (EMA/Ho/13397/04) and (EMA/Ho/2368/Rev1);
- European Commission Communication C98/2016 (OJ C 229, 22.7.1998).

## 2. DEFINITIONS

For the purposes of the present regulation, the following definitions shall apply:

**Fimea:** the Finnish Medicines Agency;

**country of procurement:** the state from which the medicinal product is imported into Finland;

**directly imported product:** a medicinal product in respect of which parallel import takes place;

**Charges Decree:** Decree of the Ministry of Social Affairs and Health on charges for work done by the Finnish Medicines Agency;

**marketing authorisation for parallel import:** a marketing authorisation for a medicinal product that already has a marketing authorisation in Finland but where the party placing that medicinal product on the market is someone other than the holder of the marketing authorisation for products already in commercial circulation or the party entitled to import them;

**parallel importer:** a natural or legal person who is not the holder of a marketing authorisation for medicinal products in commercial circulation in Finland or an authorised representative of the importer of such products;

**inner packaging:** packaging that contains the medicine and which is in direct contact with the medicinal product;

**outer packaging:** packaging containing the inner packaging;

**repackaging:** moving the inner packaging of a medicinal product from one pack to another, re-labelling it and adding a patient information leaflet to the product.

### 3. RELATIONSHIP TO OTHER REGULATIONS AND GUIDELINES

In addition to the present regulation, parallel imports shall comply with the requirements of the following regulations issued by the Finnish Medicines Agency (Fimea):

- Fimea regulation 4/2013, Pharmacovigilance;
- Fimea regulation 1/2012, Veterinary pharmacovigilance;
- Fimea regulation 2/2013, Applications for and maintenance of marketing authorisations and registration of medicinal products;
- Fimea regulation and guidelines 4/2009, Product faults;
- Fimea regulation 3/2013, Sales labels and patient information leaflets for medicinal products.

The following Fimea guidelines should also be given due consideration:

- Guidelines 2/2013, Reporting the side effects of medicines;
- Guidelines 1/2009, Reporting the side effects of medicines administered to animals;
- Guidelines 1/2013, Sales labels and patient information leaflets for medicinal products.

The import, wholesale and marketing of medicinal products that are to be sold under a marketing authorisation for parallel import shall be subject to separate provisions on the import of medicinal products, on the pursuit of medicine wholesale and on marketing.

### 4. REQUIREMENTS FOR A MARKETING AUTHORISATION FOR PARALLEL IMPORT

Obtaining a licence shall require fulfilment of the requirements laid down in § 21d (773/2009) of the Medicines Act (395/1987). In other cases, a marketing authorisation shall be applied for in respect of the medicinal product, in accordance with the Fimea regulation on applications for and maintenance of marketing authorisations and registration of medicinal products.

Parallel import under § 21d of the Medicines Act may only commence in respect of a medicinal product that has been granted a marketing authorisation in Finland. Such a medicinal product shall also have a valid marketing authorisation in the country of procurement. The country of procurement shall be in the EU/EEA.

When processing applications for marketing authorisations in respect of medicinal products that are to undergo parallel import, it shall be ensured that the products are sufficiently similar that they may be regarded as the same medicinal product. The medicinal products need not be identical in all respects, but they shall use the same active ingredient and have a sufficiently similar formulation so that any differences in formulation do not give rise to any difference in the therapeutic effect or safety of the products. An authorisation application may be abandoned on the grounds that the medicinal product that is to be imported is not sufficiently similar to a product that has already been granted a marketing authorisation in the Member State of destination or that its origin has an insufficient link to a product that has obtained an authorisation in the Member State of destination.

There may not be any therapeutic difference between the medicinal product that is to undergo parallel import and a medicinal product already in commercial circulation. Product excipients and/or their quantities may differ from each other to a small extent; for example, they may have a different colouring agent.

## 5. KEY REQUIREMENTS FOR THE MARKETING AUTHORISATION

### 5.1 Applicant

A marketing authorisation for parallel import may be applied for by a parallel importer. The parallel importer shall procure the medicinal product from the country of procurement, re-pack or re-package it, and take responsibility for placing the product on the market.

### 5.2 Re-packaging

Re-packaging shall be done at a pharmaceutical factory licensed for the industrial production of medicines, as stipulated in detail in the relevant pharmaceutical factory's licence. Good production practices shall be followed during re-packaging. Re-packaging shall be carried out in the EU/EEA.

### 5.3 Trade name

The trade name of a medicinal product that is to undergo parallel import may be the same as or different from the trade name of a medicinal product already in commercial circulation. If the trade name of a medicinal product that is to undergo parallel import is different from that of a medicinal product already in commercial circulation, it shall fulfil the requirements stipulated in the Fimea regulation on applications for and maintenance of marketing authorisations and registration of medicinal products. The trade name may also differ from the trade name in the country of procurement. For this reason, two different trade names may appear on the inner packaging. This shall be mentioned separately on the outer packaging.

The holder of the marketing authorisation shall be responsible for any legal factors relating to the trade name itself.

### 5.4 Pack size and type

The pack size and type for a medicinal product that is to undergo parallel import may differ from the pack sizes and types for medicinal products in commercial circulation in Finland, provided such differences are not likely to pose a threat to public health. Such differences may include the packaging method; a direct importer might use a bottle and a parallel importer might use a blister pack.

### 5.5 Shelf life

The shelf life approved in the country of procurement shall be approved as the shelf life for a medicinal product that is to undergo parallel import, but such shelf life may not be longer than that approved for a medicinal product already in commercial circulation in Finland. The use-by date of a parallel import product shall always be clearly visible on both the inner and outer packaging.

## 6. APPLICATION FOR AND PROCESSING OF THE MARKETING AUTHORISATION

A marketing authorisation for parallel import shall be applied for using the application form attached to the present regulation, which has also been published on the Fimea website ([www.fimea.fi](http://www.fimea.fi)). When completing the application form, the completion guidelines attached to the form shall be followed and the required reports shall be attached to the form.

### 6.1 Annexes to the application

#### 6.1.1 Sample package

A sample package shall be required for one pack size and for each country of procurement separately. The country of procurement shall be stated clearly on each sample package.

#### 6.1.2 Sales labels

When labelling products for parallel import, the Fimea regulation on sales labels and patient information leaflets for medicinal products shall be complied with. The outer packaging and patient information leaflet for the product for parallel import shall also bear the name and address of the parallel importer and the re-packer, and the name of the manufacturer in the country of procurement.

When preparing proposed sales labels, due consideration should be given to the Fimea guidelines on sales labels and patient information leaflets for medicinal products.

#### 6.1.3 Patient information leaflet

Patient information leaflets for products for parallel import shall comply with the Fimea regulation on sales labels and patient information leaflets for medicinal products ([www.fimea.fi](http://www.fimea.fi)). When preparing proposed patient information leaflets, due consideration should also be given to the Fimea guidelines on sales labels and patient information leaflets for medicinal products.

### 6.2 Processing of applications

The application and annexes thereto shall be sent to Fimea (please refer to the address details on the Fimea website: [www.fimea.fi](http://www.fimea.fi)). An application shall undergo a preliminary check following receipt. The preliminary check shall ensure that the application has been prepared properly and that it contains all the required

documents and their annexes. Any shortcomings in the application shall immediately be reported to the applicant, who shall send the missing documents within two weeks. If the application is not supplemented, the applicant shall be requested to withdraw the application. In the event of withdrawal, the fee for processing the application and the application itself, together with its documents, shall be returned to the applicant at the applicant's expense.

Once the application has undergone the preliminary check, Fimea shall send an enquiry to the authorities in the country of procurement to ensure that the medicinal product in question has a valid marketing authorisation in the country of procurement. Details including the manufacturer, the holder of the marketing authorisation, the complete composition, the shelf life, and the storage conditions shall be verified at the same time.

The processing of the case shall give due consideration to the fact that this does not constitute the usual scientific assessment involved in the marketing authorisation procedure, but rather processing of the case under an administrative procedure. The application shall be processed in accordance with the processing times laid down in § 10a of the Medicines Decree (693/1987), but giving due consideration to the time taken to verify information with the authorities in the country of procurement and to request any additional explanations from the applicant.

### **6.3 Issue and validity of the marketing authorisation**

A marketing authorisation shall be issued in accordance with § 24(1) of the Medicines Act (773/2009), for a period of five years calculated from the date of issue. The marketing authorisation shall, however, be valid for no longer than the period during which the medicinal product in question, in respect of which the parallel import will take place, has a valid marketing authorisation in the country of procurement. It shall be the duty of the parallel importer to check that every consignment that is to be imported has a valid marketing authorisation in the country of procurement. If the marketing authorisation ceases to be valid in the country of procurement, the parallel importer shall report the same to Fimea immediately.

An annual charge for the medicinal product undergoing parallel import shall be paid in accordance with the Charges Decree. The authorisation shall cease to be valid or shall lapse if the annual charge is not paid by the deadline.

In the event of such lapse of the marketing authorisation, the parallel importer shall immediately withdraw from sale any medicinal products from parallel import that are in commercial circulation (from wholesalers, pharmacies, hospital pharmacies and dispensaries).

### **6.4 Placing on the market**

The rules concerning the placing on the market of medicinal products that have been granted a marketing authorisation, as contained in the Fimea regulation on applications for and maintenance of marketing authorisations and registration of medicinal products, shall also apply to medicinal products that are imported in parallel. The parallel importer shall report separately with regard to each country of procurement on the first occasion of placing products on the market from a new country of procurement.

According to § 29(1)(3) of the Medicines Act, if a medicinal product is not placed on the market within three years of the date of issue of the marketing authorisation for

parallel import, or if trade has been suspended for an uninterrupted period of three years, the marketing authorisation for parallel import of the medicinal product shall lapse.

## 7. AMENDMENTS TO THE MARKETING AUTHORISATION

The parallel importer shall monitor any changes to the original medicinal product in commercial circulation. If any amendments that require permission are made to the patient information leaflet of the product in commercial circulation, the parallel importer shall immediately send new proposed patient information leaflets to Fimea for approval. In addition to the cover letter and new patient information leaflet proposals, the report shall also be accompanied by the documents approved previously, on which the amendments shall be clearly marked.

Any amendments made on the initiative of the parallel importer (for example an amendment concerning a new pack size) shall be applied for/reported in accordance with the rules concerning changes to medicinal products in the Fimea regulation on applications for and maintenance of marketing authorisations and registration of medicinal products.

Amendments relating to sales labels or patient information leaflets shall be reported in accordance with the aforementioned Fimea regulation 90 days prior to implementation of the amendment. The amendment may be made unless Fimea reports that it has not been approved. The parallel importer shall also apply for/report all changes to the product in the country of procurement in accordance with the aforementioned regulation.

When applying for a new country of procurement in addition to the countries of procurement already included in the marketing authorisation for parallel import that has been issued, the holder of the marketing authorisation shall submit to Fimea an application for extension of the original marketing authorisation for parallel import in relation to the country of procurement.

A charge for processing applications shall be paid in accordance with the Charges Decree in force at any time. At the time of issue of the present regulation, Decree 233/2013 has been in force since 1 April 2013.

## 8. RENEWAL OF MARKETING AUTHORISATION

In accordance with § 24 of the Medicines Act, a marketing authorisation for a medicinal product that is to undergo parallel import shall be valid for a period of five years, following which it shall be renewed. The application for renewal of a marketing authorisation shall be submitted to Fimea no later than nine months prior to expiry of the marketing authorisation in the case of human medicines, and no later than six months prior to expiry of said authorisation in the case of veterinary medicines. The marketing authorisation shall remain in force while the renewal application is being processed. If no application is submitted, the marketing authorisation shall lapse or cease to be valid.

The marketing authorisation for a medicinal product that is to undergo parallel import shall be renewed at least once, following which said authorisation shall be valid until further notice. An authorisation may, however, be renewed on a second occasion for a period of five years on grounds of medicinal safety.



Applications for the renewal of a marketing authorisation for parallel imports shall be made in writing using the same form as for the marketing authorisation for parallel imports.

In addition to the application form, the application shall also include confirmation that the medicinal product from the country of procurement has a valid marketing authorisation and that said authorisation has not been amended by the parallel importer.

## 9. OTHER OBLIGATIONS RELATING TO THE MARKETING AUTHORISATION

Pursuant to Chapter 4a of the Medicines Act, a parallel importer shall have the obligation to monitor the side effects and product faults of his medicinal products and to report them to Fimea. The parallel importer shall keep records of the origin of the medicinal products imported in parallel, as well as of the quantities imported and the consignment numbers, in order to track re-packaged consignments and to manage and report any relevant product faults. Such information should be sent to Fimea immediately upon request.

The parallel importer shall also send regular medicinal safety reviews in accordance with the Fimea regulations concerning medicinal safety, as well as a review (Clinical Overview) containing key data for evaluating the risk-benefit ratio of the medicinal product in the manner required by the rules relating to applications for and maintenance of marketing authorisations and registration of medicinal products in situations where there is no longer a medicinal product corresponding to a direct importer's product on the market in Finland.

The parallel importer shall also be subject to the Act on mandatory reserve supplies (979/2008).

## 10. ADVICE AND GUIDANCE

The Finnish Medicines Agency shall provide advice and guidance concerning the application of the present standard upon request.

## 11. ENTRY INTO FORCE

The present regulation shall enter into force on 12.2.2014 and shall remain in force until further notice.

Sinikka Rajaniemi  
Director General

Merja Laakso  
Marketing Authorisation Coordinator

## Distribution

Pharmaceutical factories  
Pharmaceutical wholesalers  
Persons responsible for placing medicinal products on the market  
Finnish Association of Parallel Importers of Medicines (SLRTY)  
Finnish Food Safety Authority (Evira)  
National Institute for Health and Welfare  
Finnish Red Cross Blood Donor Service

## For information

Ministry of Social Affairs and Health  
Ministry of Employment and the Economy  
Ministry of Agriculture and Forestry  
Social Insurance Institution of Finland  
National Supervisory Authority for Welfare and Health (Valvira)  
The Consumer Authority  
Pharma Industry Finland  
Finnish Association of Veterinary Medicine Importers  
Finnish Food Safety Authority  
Pharmaceutical wholesalers  
Health Food Union  
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, School 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 Pharmacists' Society  
Association of Finnish Local and Regional Authorities  
University of Helsinki pharmacy  
University of Eastern Finland pharmacy

## ANNEX

### 1. Guidelines for the completion of applications

The form may be completed in Finnish, Swedish or English. A separate application form must be completed for each product. If a marketing authorisation for parallel import of the same medicinal product from more than one country of procurement

is being applied for, a separate application must be completed for each country of procurement.

The following basic details concerning the medicinal product must always be given on the application form: name, strength, pharmaceutical form and active ingredient(s) of the medicinal product. The following details must also be given on the form: pack size(s) and pack type(s). Complete information is also required concerning the parallel importer and details of the medicinal product in the country of procurement. This includes the name, strength and marketing authorisation number of the medicinal product, the holder of the marketing authorisation in the country of procurement and the manufacturer of the medicinal product. The necessary information concerning the medicinal product already in commercial circulation must also be given on the form.

## **2. Sample package**

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

## **3. Sales labels**

Proposed Finnish/Swedish proofs for sales labels for each pack size must be enclosed (for example designed using computer software).

The sales labels must be presented for both the outer and inner packaging. If the trade names on the outer and inner packaging differ, this must be mentioned separately on the outer packaging. In cases where the outward appearance of the medicinal product (for example its colour) differs from that of the original medicinal product in commercial circulation, this must be mentioned on the outer packaging. Separate proposed sales labels must be submitted for each country of procurement.

## **4. Report concerning re-packaging**

The application must include a report concerning re-packaging. The operating licence of the pharmaceutical factory carrying out the re-packaging or a certificate containing the corresponding information provided by the authority must be attached to the application.

## **5. Proof of payment**

Proof that the processing fee has been paid (for example a copy of the payment receipt) must be attached to the application. The processing fee must be paid before the application is submitted to Fimea. The proof of payment must state the name, strength and pharmaceutical form of the medicinal product, as well as the name of the applicant. The processing fee is determined in accordance with the Decree of the Ministry of Social Affairs and Health on charged services by Fimea. Fimea's bank details are published on the Fimea website ([www.fimea.fi](http://www.fimea.fi)).

## **6. Patient information leaflet**

Proposed patient information leaflets in Finnish and Swedish must be attached to the application.

Obligation of the parallel importer to provide information to the marketing authorisation of the original product in commercial circulation in Finland

With regard to parallel imports from the new Member States that have acceded to the European Union since 1 May 2004, written evidence must be attached to the application to the effect that the parallel importer has reported his application to the holder of the marketing authorisation for the original product in commercial circulation in Finland one month prior to submitting his application to Fimea. A copy of such written notification should be attached to the application.

Regulation

**ISSN-L 1798-6567**

**ISSN 1798-6567**

**fimea**

Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency  
P.O. Box 55, 00034 FIMEA, Finland | Tel. +358 (0)29 522 3341 | kirjaamo@fimea.fi | www.fimea.fi | Registration number 0921536-6