Guide on how to request a parallel import authorisation, renew a parallel import authorisation, and submit a variation of a parallel import authorisation

11.2022

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1. Introduction

This document contains guidelines for submitting an application for a parallel import authorisation, renewal of a parallel import authorisation or a variation of a parallel import authorisation for medicinal products for human use. In this document you will find a complete overview of the necessary elements for submitting an application.

2. Relevant legislation and policy documents

- Royal Decree dated April 19, 2001 regarding parallel import of medicinal products for human use and the parallel distribution of medicinal products and veterinary use.
- Law on medicinal products dated March 25, 1964
- Royal Decree regarding medicinal products for human and veterinary use dated December 14, 2006
- Law date July 20, 2006 concerning the Establishment and Operation of the Federal Agency for Medicines and Health Products
- Labelling of medicinal products
- European Commission guideline on "Excipients in the labelling and package leaflet of medicinal products for human use"

3. Abbreviations and definitions

3.1 List of abbreviations

- **AF:** application form
- **ATD:** anti-tampering device
- **DOC:** declaration of conformity
- **DOI:** declaration of integrity
- **EU:** European Union
- **FAMHP** Federal Agency for Medicines and Health Products
- **FMD**: Falsified Medicines Directive – European directive regarding falsified medicines, implemented in the law dated March 25, 1964 on medicines and the Royal Decree dated December 14, 2006 regarding medicinal products for human and veterinary use
- **GDP**: good distribution practice
- **GMP:** good manufacturing practice
- **MA:** marketing authorisation for marketing a medicinal product
- **MIA:** manufacturing and importation authorisation
- **NOT:** notification - document applicable to import from member states in eastern Europe
- **PAC:** post approval commitment
- **PIA:** parallel import authorisation
- **PIL:** patient information leaflet
- **PoP:** proof of payment
- **RD PI:** Royal Decree dated April 19, 2001 regarding parallel import of medicinal products for human use and the parallel distribution of medicinal products and veterinary use.
- **TA:** technical agreement
- **WDA:** wholesale distribution authorisation
- **WHO:** World Health Organization

3.2 List of Definitions

- **Mock-up:** flat draft, in colour, with the final font and final font size. Provides a clear picture of the three dimensional presentation of the package as will be used in the sale of the parallel imported medicinal product in Belgium.

- **Parallel distribution:** marketing in Belgium of a medicinal product for which an MA has been granted pursuant to article 3 of the directive (EU) no. 726/2004 on the determination of procedures by the Union for the granting of marketing authorisations and the surveillance of medicinal products for human and veterinary use and for the establishment of a European Medicines Agency (EMA), by a distributor independent of the marketing authorisation holder from another EU member state or a state that is a member of the European Economic Area and which has a NOT from the European Medicines Agency for parallel distribution.
- **Parallel import:** import to Belgium with the intent to sell in Belgium a medicine for which an MA has been granted in another EU member state or a state that is a member of the European Economic Area and for which a reference medicine exists. This parallel import is executed by a distributor that is not tied to the marketing authorisation holder of the reference medicine and has an authorisation for parallel import.
- **Responsible person:** person intended in article 90 (1e) (2) of the Royal Decree dated December 14, 2006 regarding medicines for human and veterinary use.
- **MA granted in member state of origin:** MA granted in another EU member state, namely the country of origin.

4. Application types

4.1 Parallel import authorisation request

If you want to import a medicine from another European member state or a state that is a member of the European Economic Area, and you want to sell the medicine on the Belgian market via parallel import, you must apply for a parallel import authorisation.
The conditions for doing so are described in article 3 (2) of the RD PI.

Submit a separate file for every authorisation request. An authorisation will be granted per composition, strength, pharmaceutical form, packaging type and medicine in the country of origin and per country of origin.
For the content of your file, see "5.2 What documents should I add to an application?".

The required fee for this type of file are included in the law dated July 20, 2006 concerning the Establishment and Operation of the Federal Agency for Medicines and Health Products and published in the Fees section on the FAMHP's website.

4.2 Renewing a parallel import authorisation

The stipulations for renewing a parallel import authorisation are described in article 7 (1) of the RD PI. The conditions are described in article 3 (2) of the RD PI (see "4.1 Application for a parallel import authorisation") remain applicable.

A parallel import authorisation remains valid for five years. You need to apply for renewal in the last three months before the expiration of the parallel import authorisation. If you do not submit your renewal request before this date (expiration date of the parallel import authorisation minus three months), the parallel import authorisation will be withdrawn and all available packs of the medicine must be taken off the market. If the authorisation holder requests the withdrawal of the authorisation before this date (expiration date of the parallel import authorisation minus three months), permission may be granted for not withdrawing packs of the parallel imported medicine from the market if they were already on the market before the expiration date of the marketing authorisation.
For the content of your file, see "5.2 Which documents do I include in an application".

The required fee for this type of file are included in the law date July 20, 2006 concerning the Establishment and Operation of the Federal Agency for Medicines and Health Products and in the Fees section on the FAMHP's website.

4.3 Variation of a parallel import authorisation

There are three possible types of variations to a parallel import authorisation.

- A variation triggered by a change in the MA of the reference medicine in Belgium.
  The stipulations for this are described in article 7 (2) of the RD PI. The conditions are described in article 3 (2) of the RD PI (see "4.1 Application for a parallel import authorisation") remain applicable.
  Some examples of these changes are:

  - changes linked to the marketing authorisation holder and/or manufacturer for batch release (name and/or address);
  - revision of the patient information leaflet, both chemical-pharmaceutical and clinical;
    Some examples of chemical-pharmaceutical changes: changes to packaging size, storage conditions and excipients.
    Some examples of clinical changes: update of special precautions and addition of a side effect.
  - Change of medicine name.

- A variation triggered by a change in the MA of the medicine in the member state of origin.
  The conditions for this are described in article 7 (3) of the KB PI. The provisions are described in article 3 (2) of the RD PI (see "4.1 Application for a parallel import authorisation") remain applicable.
  Some examples of changes to the medicine in the country of origin are:

  - change of excipients,
  - change of manufacturer for batch release,
  - changes linked to the marketing authorisation holder (name and/or address),
  - change of packaging sizes,
  - change of packaging material/resources,
  - change of storage conditions,
  - change of expiration date,
  - change of indications.

- A variation due to a change in the information of the parallel importer or a change to the parallel import authorisation concerning elements that are not provided for in article 7 (2 and 3) of the RD PI.
  Some examples of these changes are:

  - variations in line with the FMD,
  - addition or removal of a packager,
  - addition or removal of a site for batch certification,
  - changes linked to the parallel importer (name and/or address),
  - for the approval of a sample or specimen of how the parallel imported medicine such as this is proposed for marketing in Belgium (primary, secondary... packaging) for commercialisation after use of PAC during conclusion of the file for a new request.

  For a variation triggered by a change in the marketing authorisation holder of the reference medicine in Belgium or a change to the MA of the medicine in the member state of origin, the applicant for a parallel import authorisation must submit a request to change the parallel import authorisation within six months. If this application for change of the parallel import authorisation is not submitted in time, the FAMHP will cancel the parallel import authorisation and the parallel import authorisation holder must take the imported medicine off the market.
  For the content of your file, see "5.2 Which documents do I include in an application?".

  The required fee for this type of file is included in the law dated July 20, 2006 concerning the Establishment and Operation of the Federal Agency for Medicines and Health Products and in the Fees section on the FAMHP's website.

5. Procedures for submitting an application

5.1 How to submit an application

You can submit an application, with the exception of samples, in electronic form to the FAMHP at parallelimport@fagg-afmps.be. You application will be sent via Eudralink. It is important that you ensure the tree structure is respected and the folder is added to your Eudralink as a zip file.
For more information on the tree structure, see "5.3 Tree structure of an application file".

The subject of the e-mail must be drafted as follows: <Type of application> <name of medicine - strength - pharmaceutical form> <(country of origin)>.

Samples must be sent by post. Attach a cover letter to your package, providing a clear inventory of its contents. Cover letters for specific submissions and corresponding samples must be bundled using a rubber band. The package may not contain loose samples. Indicate the procedure number (if known) in the cover letter and staple a printout of your application form to the cover letter.
Send the package to:

FAMHP
DG POST authorisation - Marketing Authorisations Division (variations and renewals) - Administrative Support - parallel import
Avenue Galilée/Galileelaan 5/03
1060 BRUSSELS

5.2 What documents do I include in an application?

You can find more information on the content of an application file in article 4 of the RD PI.
Use the correct titles for all documents and respect the tree structure. For more information on the tree structure, see "5.3 Tree structure of an application file".

5.2.1 Parallel import authorisation application

Application form
You can find the template on the FAMHP's website.

Name in tree structure: Application form.

Proof of payment
You can find the template on the FAMHP website.

Name in tree structure: PoP.

Draft for parallel import authorisation (= PIA)
You can find the template on the FAMHP website.
Fill in pages 1, 2 and 3 with the exception of points 5 and 8.

Name in tree structure: Draft PIA.

Patient information leaflet of the reference medicine in Belgium and in the country of origin

- Attach the most recently approved patient information leaflet of the reference medicine in Belgium in the three Belgian national languages. You can find the PIL of all medicines authorised in Belgium on the FAMHP's website.

  Name in tree structure:
  - PIL_reference_product_BE_NL
  - PIL_reference_product_BE_FR
  - PIL_reference_product_BE_DE

- Add the most recently approved patient information leaflet of the medicine in the country of origin.

  Name in tree structure:
  - PIL_product_country_of_origin

Translation of the patient information leaflet from the country of origin
This is a translation of the complete patient information leaflet for the medicine in the country of origin. This document is always required and must be delivered in one of the Belgian national languages (Dutch, French or German).

Name in tree structure: Translation

Declaration of conformity for the translation of the patient information leaflet from the country of origin
This is a declaration that indicates the translation of the patient information leaflet is consistent with the patient information leaflet from the country of origin. This declaration must be signed by the responsible person and must be dated.

Name in tree structure: Conformity_translation

Declaration of conformity for the patient information leaflet of the parallel imported medicine and the patient information leaflet of the reference medicine
This is a document wherein the file applicant declares the patient information leaflet for the parallel imported medicine, in the three Belgian national languages, is identical to the patient information leaflet of the reference medicine with the exception of differences from the medicine in the country of origin. This document must also specify the version of the patient information leaflet of the reference medicine.

This declaration must be signed by the responsible person and must be dated.

Name in tree structure: Declaration of Conformity

Revised patient information leaflet for parallel import
Start the patient information leaflet of the medicine for parallel import with the following information:

> "The medicine in this package is authorised as a parallel imported medicine.
>
> Parallel import is the import into Belgium of a medicine that has been granted a marketing authorisation in another European Union member state or in a country that is part of the European Economic Area and for which there is a reference medicine in Belgium. A parallel import authorisation is granted when certain legal requirements are met (Royal Decree dated April 19, 2001 regarding parallel import of medicines for human use and parallel distribution of medicines for human and veterinary use)."

- Name of imported medicine as it will be sold in Belgium: <Name + strength + pharmaceutical form>
- Name of the Belgian reference medicine: <Name + strength + pharmaceutical form>
- Imported from <Name of country of origin of the imported medicine>
- Imported by and packaged under the responsibility of <Name and full address of the importer>
- Original name of the imported medicine in the country of origin <Name + strength + pharmaceutical form>

Indicate in section "5. How to store x?" the storage conditions of the parallel imported medicinal product. These are the storage conditions as in the country of origin.
Indicate in section "6. Contents of the pack and other information", the composition of the parallel-imported medicinal product, i.e. the composition as in the country of origin. Also mention here the pack sizes and a description of the imported medicinal product as it is marketed in Belgium. Replace the authorisation number with the parallel import authorisation number.
If there are differences in the excipients between the parallel imported medicine and the reference medicine in Belgium, and these are excipients consistent with the guideline for excipients with known effect and the annex "Excipients an information for the patient information leaflet", then add the proper warning in section "2 When should you not <use> <take> this medicine, or when should you take extra care?".

The following information must also be added to section "6. Contents of packaging and other information" of the patient information leaflet:

- marketing authorisation holder of the imported medicine,
- manufacturer of the imported medicine,
- marketing authorisation holder of the reference medicine.

This creates a new patient information leaflet for the parallel imported medicine. Both the annotated version (annotations versus the reference medicine in Belgium) and clean version in Word format are requested.

Name in tree structure:
- PIL_PI_NL_annotated
- PIL_PI_NL_clean
- PIL_PI_FR_annotated
- PIL_PI_FR_clean
- PIL_PI_DE_annotated
- PIL_PI_DE_clean

Samples or specimens
Following samples must be submitted for each file:

- a sample or specimen of the reference medicine as it is marketed in Belgium (primary, secondary... packaging);
- a sample or specimen of the parallel imported medicine as it is marketed in the member state of origin (primary, secondary... packaging);
- a sample or specimen of the parallel imported medicine as it will be marketed in Belgium (primary, secondary... packaging).

In principle, the labelling requirements are fully applicable to samples or specimens of parallel imported medicines rendering their marketed form in Belgium.

For instructions on submitting samples or specimens: see "5.1 How to submit an application".

You must add scans/images of the submitted samples or specimens in the electronic file.

Name in tree structure:

- Scan/pictures primary packaging
- Scan/pictures secondary packaging
- …

If you do not yet dispose of a sample or specimen of the parallel imported medicine as it will be for sale in Belgium to submit, working with a PAC is possible. You must then add the PAC to the electronic file. This document must be signed by the responsible person and must be dated. If you work with a PAC, you must submit the mock-up.

Name in tree structure: PAC samples

It is not necessary to submit a mock-up for every file. It is however possible that during processing of your file, the FAMHP will ask for a mock-up.

Declaration of safety features
In order to make sure a parallel import authorisation is in line with the European directive regarding falsified medicines or FMD, the company must submit a declaration of safety features that indicates the extent to which the readability of packaging will or will not be affected by adding safety features. This declaration differs depending on what safety features are added. You will find more information on this in the national Q&A on parallel import.

This declaration must be dated and signed by the person responsible.

Name in tree structure: STATEMENT FMD

ATD efficacy
This document contains a substantiated motivation proving the ATD used is just as effective as that of the reference medicine on the Belgian market.

If the parallel importer cannot yet submit a substantiated motivation because the reference medicine on the Belgian market does not yet contain the ATD, it is possible to add a PAC ATD efficacy to the electronic file.

Name in tree structure: MOTIVATION ATD

Declaration of integrity (DOI)
A declaration from the responsible person that the original state of the medicine to be imported has not been changed directly nor indirectly. This declaration contains at least the following information:

The original state of the medicine has not been changed directly or indirectly.

- The medicine has been imported from (country of origin) without changes.
- The primary packaging has not been affected in a way that could influence the stability of the medicine.
- Storage and transport are temperature controlled and meet current GDP guidelines.
- The safety features on the packaging from the country of origin shall be verified in line with Article 10 of the delegated Regulation (EU) 2016/161, where applicable.

Changes to packaging[1] (under GMP conditions).
- Outer packaging (country of origin) contains the same information as the reference medicinal product in the three national languages.
- Primary packaging (country of origin) contains the same information as the reference medicinal product in the three national languages.

[1] If there are various packages, the changes to all packages must be reported (primary packaging, secondary packaging, tertiary packaging ...).

- Patient information leaflet (country of origin) is replaced by the Belgian patient information leaflet.
- The safety features on the packaging from the country of origin shall be removed in line with article 16.1 of the delegated Regulation (EU) 2016/161, where applicable.
- The required safety features have been added or replaced in line with article 79bis of the Royal Decree of 14 December 2006, where applicable.

This declaration must be dated and signed by the person responsible.

Name in tree structure: Declaration of Integrity

Contract between importer/packager and applicant
If the applicant is not the importer and/or packager of the medicine, he/she must provide the technical modalities of the contract binding the applicant and the other parties to the FAMHP.

Name in tree structure: Contract [name company]

MIA:
A MIA for medicines is delivered by the competent authorities. This authorisation is valid from the date of issue. Validity of the MIA will be reviewed during validation of the file. This must be submitted for both the packager and the party responsible for batch certification.

Name in tree structure: MIA [name company]

GMP certificate
A GMP certificate is a certificate issued after inspection by the competent authorities. A GMP certificate is valid for three years starting on the date of inspection. The validity of this certificate will be reviewed during the validation of the file submitted.
This must be submitted for both the packager and the party responsible for batch certification.

Name in tree structure: GMP [name company]

WDA
This is an authorisation issued by the competent authorities that determines that a company is authorised for distributing medicines in conformity with the GDP of the European Commission or with other provisions that offer equivalent guarantees. This must be submitted for the parallel import authorisation holder as well as for the distributor of the parallel imported medicine.

Name in tree structure: GDP and/or WDA [name company]

Specific mechanism
Ten member states have joined the European Union on May 1, 2004. This has led to new rules for parallel import. These rules were revised with the admission of Romania and Bulgaria.

Rules have been agreed upon by the EU and the new member states to prevent the import of medicines from newly admitted member states to "old" member states where a patent or supplemental protection certificate applies to that medicine. In the admission treaty, this is called a "specific mechanism".

Concretely, this means that if a medicine is to be imported parallel to an "old" member state from Bulgaria, Estonia, Hungary, Croatia, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia or the Czech Republic where a patent or supplemental protection certificate still applies, the owner of the patent or the supplemental protection certificate, or his/her representative, can object to the parallel import of this medicine due to breach of patent rights.

You will find stipulations of this in article 11 (2) of the RD PI.

The parallel importer must inform the owner of the patent or supplemental protection certificate, or his/her representative of their intentions to do this one month prior. This document must be added to the file as proof.

Name in tree structure: Specific mechanism

5.2.2 Changes type a), b) and c) and renewal of a parallel import authorisation

For these applications you must provide all documents listed under point "5.2.1. Application for a parallel import authorisation".

In addition, the following documents must be added to the submission:

- In case of a change to a parallel import authorisation: add an annotated and clean draft version of the parallel import authorisation.

  Name in tree structure:
  - Draft PIA_annotated
  - Draft PIA_clean

- In case of a change to the revised patient information leaflet for parallel import: always add the current, approved version (= current) as well as a new version (= draft). An annotated version and a clean version of this new version are requested.

  Name in tree structure:
  - PI_Product – adapted version leaflet - current
    - PIL_PI_NL_current
    - PIL_PI_FR_current
    - PIL_PI_DE_current

  - PI_Product – adapted version leaflet - draft
    - PIL_PI_NL_annotated
    - PIL_PI_NL_clean
    - PIL_PI_FR_annotated
    - PIL_PI_FR_clean
    - PIL_PI_DE_annotated
    - PIL_PI_DE_clean

For more details, see "5.3 Tree structure of an application file".

5.3 Tree structure of an application file

Make sure the tree structure is respected when submitting a file. Make sure the names used for manufacturers are not too long. This causes errors when uploading your file into our database. We ask you to limit the full name of the document to a maximum of thirty characters. Always use the proposed tree structure names for the naming of documents.

5.3.1 New parallel import authorisation application

Name of primary folder
Name of folder
Name of subfolder
Document name

<Name strength pharmaceutical form imported medicinal product>
- 01 Application form
  - Application form
- 02 Generic documents
  - POP (Proof of Payment)
  - DOC (Declaration of Conformity)
  - DOI (Declaration of Integrity)

- Specific mechanism
- 03 PIA (only in case of new PIA or in case of changes)
  - Draft PIA
- 04 Enterprises
  - Contracts [name company]
  - GMP certificates [name company]
  - MIA (Manufacturing and Importation Authorisation) [name company]
  - WDA and/or GDP [name company]
- 05 Leaflets
  - Reference_product_BE
    - PIL_reference_product_BE_NL
    - PIL_reference_product_BE_FR
    - PIL_reference_product_BE_DE
  - Product_in_country_of_origin
    - PIL_product_country_of_origin
    - Translation
    - conformity_translation
  - PI Product – adapted version leaflet
    - PIL_PI_NL_annotated
    - PIL_PI_NL_clean
    - PIL_PI_FR_annotated
    - PIL_PI_FR_clean
    - PIL_PI_DE_annotated
    - PIL_PI_DE_clean
- 06 Samples
  - Generic documents
    - STATEMENT FMD
    - MOTIVATION ATD
    - PAC (samples; FMD …)
    - Mock-up
  - Reference_product_BE
    - Scan/pictures primary packaging
    - Scan/pictures secondary packaging
    - …
  - Product_in_country_of_origin
    - Scan/pictures primary packaging
    - Scan/pictures secondary packaging
    - …
  - PI_product
    - Proposed
    - Scan/pictures primary packaging
    - Scan/pictures secondary packaging
    - …

5.3.2 Application for renewing a parallel import authorisation

Name of primary folder
Name of folder
Name of subfolder
Document name

<Name strength pharmaceutical form imported medicinal product>
- 01 Application form
  - Application form
- 02 Generic documents
  - POP (Proof of Payment)
  - DOC (Declaration of Conformity)
  - DOI (Declaration of integrity)
  - Specific mechanism

- 03 PIA (only in case of new PIA or in case of changes)
  - Draft PIA_annotated
  - Draft PIA_clean
- 04 Enterprises
  - Contracts [name company]
  - GMP certificates [name company]
  - MIA (Manufacturing and Importation Authorisation) [name company]
  - WDA and/or GDP [name company]
- 05 Leaflets
  - Reference_product_BE
    - PIL_reference_product_BE_NL
    - PIL_reference_product_BE_FR
    - PIL_reference_product_BE_DE
  - Product_in_country_of_origin
    - PIL_product_country_of_origin
    - Translation
    - conformity_translation
  - PI_Product – adapted version leaflet - current
    - PIL_PI_NL_current
    - PIL_PI_FR_current
    - PIL_PI_DE_current
    - PI_Product – adapted version leaflet - draft
    - PIL_PI_NL_annotated
    - PIL_PI_NL_clean
    - PIL_PI_FR_annotated
    - PIL_PI_FR_clean
    - PIL_PI_DE_annotated
    - PIL_PI_DE_clean
- 06 Samples
  - Generic documents
    - STATEMENT FMD
    - MOTIVATION ATD
    - PAC (samples ; FMD …)
    - Mock-up
  - Reference_product_BE
    - Scan/pictures primary packaging
    - Scan/pictures secondary packaging
    - …
  - Product_in_country_of_origin
    - Scan/pictures primary packaging
    - Scan/pictures secondary packaging
    - …
  - PI_product
    - Present
      - Scan/pictures primary packaging
      - Scan/pictures secondary packaging
      - …
    - Proposed
      - Scan/pictures primary packaging
      - Scan/pictures secondary packaging
      - …

5.3.3 Application for variation a), b) and c) for a parallel import authorisation

Name of primary folder
Name of folder
- Name of subfolder
- Document name
- <Name strength pharmaceutical form imported medicinal product>

- 01 Application form
- Application form
- 02 Generic documents
- POP (Proof of Payment)
- DOC (Declaration of Conformity)
- DOI (Declaration of integrity)
- Specific mechanism

- 03 PIA (only in case of new PIA or in case of changes)
  - Draft PIA_annotated
  - Draft PIA_clean
- 04 Enterprises
  - Contracts [name company]
  - GMP certificates [name company]
  - MIA (Manufacturing and Importation Authorisation) [name company]
  - WDA and/or GDP [name company]
- 05 Leaflets
  - Reference_product_BE
    - PIL_reference_product_BE_NL
    - PIL_reference_product_BE_FR
    - PIL_reference_product_BE_DE
  - Product_in_country_of_origin
    - PIL_product_country_of_origin
    - Translation
    - conformity_translation
  - PI_Product – adapted version leaflet - current
    - PIL_PI_NL_current
    - PIL_PI_FR_current
    - PIL_PI_DE_current
  - PI_Product – adapted version leaflet - draft
    - PIL_PI_NL_annotated
    - PIL_PI_NL_clean
    - PIL_PI_FR_annotated
    - PIL_PI_FR_clean
    - PIL_PI_DE_annotated
    - PIL_PI_DE_clean
- 06 Mock-up_samples
  - Generic documents
    - STATEMENT FMD
    - MOTIVATION ATD
    - PAC (samples ; FMD …)
    - Mock-up
  - Reference_product_BE
    - Scan/pictures primary packaging
    - Scan/pictures secondary packaging
    - …
  - Product_in_country_of_origin
    - Scan/pictures primary packaging
    - Scan/pictures secondary packaging
    - Etc.
  - PI_product
    - Present
      - Scan/pictures primary packaging
      - Scan/pictures secondary packaging
      - …
    - Proposed
      - Scan/pictures primary packaging
      - Scan/pictures secondary packaging
      - …