Guideline for submitting an application for a parallel import license or variations to a parallel import license

07.2026

Federal Agency for Medicines and Health Products
Avenue Galilée 5/03
1210 BRUSSELS
www.fagg.be

Content

1. Introduction 3
2. Relevant legislation and policy documents 3
3. Abbreviations, definitions and explanations 3
3.1 List of abbreviations 3
3.2 Definitions and explanations 3
4. Types of applications 4
4.1 Application for an authorisation for parallel import (PIA) 4
4.2 Application for a variation to a PIA 4
4.2.1 Change(s) to the MA of the medicinal product from the country of origin 4
4.2.2 Change(s) to the MA of the reference medicinal product 4
4.2.3 Change(s) to the PIA 4
5. Content of the application relating to a PIA 5
5.1 Application 5
5.2 Generic Documents 5
5.3 PIA 6
5.4 Enterprises 6
5.5 Leaflets 7
5.5 Content and packaging 8
5.5.1 Generic documents 8
5.5.2 Pictures & Mock-up 8
5.5.3 RMA 9
6. Procedure for submitting an application 9
6.1 Electronic submission of an application 9
6.2 Tree structure of the application 10
6.3 Physical samples 11
6.3.1 Request of physical samples 11
6.3.2 Sending physical samples by post 12
6.4 Payment 12
Annex I 13

1. Introduction

This document is a guideline for submitting an application for a new parallel import license or an application for variations to a parallel import license for medicinal products of human use. This document provides a complete overview of the content of the dossier for parallel import and how to submit this dossier.

2. Relevant legislation and policy documents

- Royal Order dated November 10, 2025 regarding parallel distribution and parallel import of medicinal products for human use
- Law on medicinal product dated March 25, 1964
- Royal Order regarding medicinal products of 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 product for human use"

3. Abbreviations, definitions and explanations

3.1 List of abbreviations

- **AF:** application form
- **ATD:** anti-tampering device
- **DCP:** Decentralized Procedure
- **DOC:** declaration of conformity
- **DOI:** declaration of integrity
- **EEA:** European Economic Area
- **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 Order dated December 14, 2006 regarding medicinal products for human and veterinary use
- **GDP:** Good Distribution Practices
- **GMP:** Good Manufacturing Practices
- **MA**: Marketing Authorisation
- **MIA:** Manufacturing and Importation Authorisation
- **MRP:** Mutual Recognition Procedure
- **NOT:** notification
- **PAC:** Post-Approval Commitment
- **PIA:** Parallel Import Authorisation
- **PIL:** Patient Information Leaflet
- **RO PI:** Royal Order on Parallel import
- **RMA:** Risk Minimization Activities
- **RMP:** Risk Management Plan
- **WDA:** Wholesale Distribution Authorisation
- **WHO:** World Health Organization

3.2 Definitions and explanations

A complete list of definitions is given in Artikel 2 of the RO PI.

Additional explanations:

- **Responsible person:** person who is qualified and responsible for compliance to the legal obligations applicable to the wholesale of medicinal products, as described in Article 90 (1) (2) of the Royal Order of 14 December 2006 on medicinal products for human and veterinary use
- **Marketing Authorisation (MA)**: an official approval granted by a competent authority (in Belgium the Federal Agency for Medicines and Health Products – FAMHP) after rigorous evaluation and control, which is required in order to place a medicinal product on the market. Each authorised medicinal product receives a marketing authorisation number.
- **Registration:** homeopathic and traditionally used herbal medicinal products are registered on the basis of a simplified scientific dossier before they are allowed to be placed on the market. Each registered medicinal product receives a registration number.

4. Types of applications

4.1 Application for an authorisation for parallel import (PIA)

If you want to import a medicinal product from another European Member State or a state that is member of the EEA, and you want to sell this medicinal product on the Belgian market through the principle of parallel import, you must apply for a parallel import authorisation.

The conditions for granting a parallel import license are (as described in Article 6 of the RO PI):

- The MA of the Belgian reference medicinal product is valid at time of application
- The MA of the medicinal product from the country of origin is valid at time of application
- The parallel imported medicinal product is similar to the reference medicinal product

4.2 Application for a variation to a PIA

Once a PIA has been granted and in the event of a change, an application for a variation to a PIA must be submitted. There are three types of variations to a PIA.

4.2.1 Change(s) to the MA of the medicinal product from the country of origin

The stipulations are described in Article 13 of the RO PI. The conditions described in Article 6 of the RO PI (see section "4.1 Application for an authorisation for parallel import") remain applicable.

Submitting a variation is required for following changes to the MA of the medicinal product in the country of origin:

- Change in pack size
- Change in batch releaser
- Change in storage conditions or shelf life
- Change in composition of the excipients
- Change in the appearance of the medicinal product itself
- Change in appearance of the inner/outer packaging (e.g. change blister resulting in a DEC)
- Change in the name of the medicinal product
- Change in the content of the package (e.g. change in blister material)
- Change in the name or address of the MAH
- Any other change that can have an impact on being equal or nearly equal to the reference medicinal product

4.2.2 Change(s) to the MA of the reference medicinal product

The stipulations are described in Articles 17 and 18 of the RO PI. The conditions described in Article 6 of the RO PI (see section "4.1 Application for an authorisation for parallel import") remain applicable.

The submission of a variation to a PIA is required for any change to the MA of the reference medicinal product, e.g. changes to the patient information leaflet, the packaging or the RMA's, etc.

A variation must also be submitted for following specific additional changes to the reference medicinal product:

- Change in composition of the excipients
- Change in the form of administration
- Change in the content of the package
- Withdrawal of the MA of the reference medicinal product – at request of the MAH

4.2.3 Change(s) to the PIA

The stipulations are described in Article 20 of the RO PI. The conditions described in Article 6 of the RO PI (see section "4.1 Application for an authorisation for parallel import") remain applicable.

Submitting a variation is required for following changes to the PIA:

- Deletion or addition of a pack size
- Change in the pack size of the PI medicinal product
- Repackaging, because of the safety features
- Change in the name of the PI medicinal product
- Change in the name/address of the PIA holder
- Removal or addition of a legal entity (e.g. repackager, batch releaser)

5. Content of the application relating to a PIA

Content of an application for a PIA
The requirements for the content of the application are stipulated in Article 7 of the RO PI.

All documents and information required for the application for a PIA are enlisted below.

A separate application needs to be submitted for each license you wish to obtain. A license is issued per composition, per strength, per pharmaceutical form and per country of origin.

Content of an application for a variation to a PIA
The requirements for the content of an application for a variation are stipulated in Article 13, §2 of the RO PI. An application needs to be submitted per variation and per PIA.

The required documents differ per type of variation. An overview of the classification of the variations, as well as the documents required for each classification, can be found in Annex I – Classification of variations.

Please make use of the correct titles for all documents and respect the tree structure. For more information about the tree structure and how each document should be titled, see "6.2. Tree structure of the application".

5.1 Application

Application form
The template can be found on the website of the FAMHP.

Comparison form
Various elements (including composition, appearance, etc.) need to be compared between the medicinal product that you wish to parallel import and the Belgian reference medicinal product.

The template can be found on the website of the FAMHP.

5.2 Generic Documents

Declaration of conformity for the PIL of the parallel imported medicinal product and the PIL of the reference medicinal product
A document wherein the applicant declares that the patient information leaflet for the parallel imported medicinal product, in the three Belgian national languages, is identical to the patient information leaflet of the reference medicinal product, except for the differences from the medicinal product from the country of origin. This document must also specify the version of the patient information leaflet of the reference medicinal product.

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

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

The original state of the medicinal product has not been changed directly or indirectly
- The medicinal product has been imported from (country of origin) without changes
- The primary packaging has not been affected in a way that it could influence the stability of the medicinal product
- 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 the packaging[1] (under GMP conditions).
- Outer 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 ...).*

- Primary packaging (country of origin) contains the same information as the reference medicinal product in the three national languages
- 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 Order of 14 December 2006, where applicable

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

Specific mechanism *(if applicable)*
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, Bulgaria and Croatia.

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

Concretely, this means that if a medicinal product is to be parallel imported from Croatia to an "old" member state 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 medicinal product due to breach of patent rights.

The specific mechanism is stipulated in Article 27 of the RO 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 to application. This document must be added to the file as proof.

5.3 PIA

Draft of the authorisation for parallel import (PIA)
The template can be found on the website of the FAMHP.

Fill in pages 1, 2 and 3. With the exception of points 5 and 8, in case of a new application.

In case the name of the medicinal product from the country of origin is not written in the Latin alphabet, the English name of the medicinal product must be added between brackets.

5.4 Enterprises

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

GMP-certificate
A GMP certificate is a certificate issued after an inspection by the competent authorities. A GMP certificate is valid for three years from the date of inspection. The validity of the GMP certificates is checked during validation and must be valid at the time of granting the PIA.

The GMP certificates of both the packager and the person responsible for batch certification must be submitted.

You have the option to add a copy of the GMP certificate to the submitted file or to add the certificate number to the application form.

MIA
A MIA for medicinal products is issued by the competent authorities. This authorisation is valid from the date of issue. The validity of the MIA is checked during validation and must be valid at the time of granting the PIA.

The MIAs of both the packager(s) and the person(s) responsible for batch certification must be submitted.

You have the option to add a copy of the MIA to the submitted file or to add the authorisation number to the application form.

WDA/GDP-certificate of the parallel importer
This is an authorisation issued by the competent authorities. It determines that a company is authorised for distributing medicinal products in conformity with the GDP of the European Commission or with other provisions that offer equivalent guarantees.

The validity of the GDP and/or WDA certificate is checked during validation and must be valid at the time of granting the PIA.

The WDA of both the parallel import authorisation holder and the distributor of the parallel imported medicinal product must be submitted.

You have the option to add a copy of the GDP and/or WDA certificate to the submitted file or to add the authorisation number to the application form.

5.5 Leaflets

Patient information leaflet of the medicinal product from the country of origin
Provide the most recent PIL (as enclosed to the medicinal product from the country of origin that you want to parallel import) of the medicinal product from the country of origin.

Translation of the patient information leaflet from the country of origin
A translation of QRD sections 3,5 and 6 of the PIL from the country of origin, in one of the three national languages (Dutch, French or German).

In case that the package leaflet of the concerning batch does not correspond with the latest version of the published PIL on the website of the competent authority, a translation of both versions must be provided.

Declaration of conformity for the translation of the patient information leaflet from the country of origin
This declaration indicates that the translation of the PIL is consistent with the latest approved patient information leaflet from the country of origin.

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

Revised patient information leaflet for parallel import
The requirements for the revised patient information leaflet for parallel import are stipulated in Article 8 of the RO PI.

The revised PIL for the parallel imported medicinal product is based on the PIL of the reference medicinal product in Belgium, to which changes specific to the medicinal product from the country of origin must be applied, as well as specific additions. The revised PIL for the parallel imported medicine must be provided in the three national languages.

The PIL of the parallel imported medicinal product must begin with following information:

"The medicinal product in this package is authorised as a parallel imported medicinal product. Parallel import is the marketing in Belgium of a medicinal product for which a marketing authorisation [or registration] has been granted in another Member State of the European Union or in a country that is part of the European Economic Area and which is identical or virtually identical to a reference medicinal product that is or has been authorised in Belgium. A parallel import licence is granted when certain legal requirements are met."

- "Imported by: <name and address of the holder of the PIA>"
- "Imported from <country of origin>"
- Name of the medicinal product in the country of origin <name – strength – pharmaceutical form>
  In case the name of the medicinal product is not written in the Latin alphabet, the English name of the medicinal product must be added between brackets.
- "Marketing authorisation holder of the imported medicinal product: <name and address MAH in the country of origin>"
- Name of the Belgian reference medicinal product <name – strength – pharmaceutical form>

Section "2. When should you not use this medicinal product, or when should you take extra care?".

- If there are differences in the excipients between the parallel imported medicinal product and the reference medicinal product in Belgium, and these are excipients consistent with the guideline for excipients with known effect and the annex "Excipients as information for the patient information leaflet
- Add a proper warning to this section if necessary

Section "5. How to store this medicinal product?"
- Mention the storage conditions of the PI medicinal product, i.e. the storage conditions as in the country of origin

Section "6. Content of the package and other information"
- Mention the composition of the parallel-imported medicinal product, i.e. the composition as in the country of origin
- Mention the pack sizes and a description of the imported medicinal product as it is authorized in Belgium.
- Replace the BE authorisation number with the parallel import authorisation number. If necessary, per strength.
- The following information must also be added:
    - Manufacturer of the imported medicinal product (batch releaser)
    - Marketing authorisation holder of the reference medicinal product

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

5.6 Content and packaging

5.6.1 Generic documents

Declaration safety features (statement FMD)
In order to make sure a PIA is in line with the European directive regarding falsified medicines or FMD, you must submit a declaration of safety features that indicates the extent to which the readability of the 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 statement must be dated and signed by the responsible person.

ATD efficacy
This document contains a substantiated motivation proving that the ATD used is as effective as the ATD used for the Belgian reference medicinal product.

Blister cutting
Blister cutting or the physical cutting of blister packs into smaller units to adapt the packaging for the Belgian market is allowed, if certain conditions are met.

Following documents and information need to be provided in case you want to perform blister cutting:
- Information on the re-packaging site
- Full description of the re-packaging process for the concerned blister pack size, including a description of any product to be discarded
- Confirmation of the cutting scheme of the blister
- Description of the cutting device/guillotine that will be used (photograph and technical description)
- Technical description of the leak test (method and limits), including the sampling plan/frequency during batch processing to assure blister tightness of both the process validation and the routine re-packaging batches
- Description of any other in-process controls that routinely will be executed

5.6.2 Pictures & Mock-up

The labelling requirements are fully applicable to the parallel imported medicinal product. These requirements may be revised if necessary.

However, additional requirements are applicable to parallel imported medicinal products. Following information should be added to the packaging:
- "Imported by: <name and address of the holder of the PIA>"

- Name of the medicinal product in the country of origin <name – strength – pharmaceutical form>
  In case the name of the medicinal product is not written in the Latin alphabet, the English name of the medicinal product must be added between brackets.
- "Marketing authorisation holder of the imported medicinal product: <name and address MAH in the country of origin>"
- Name of the Belgian reference medicinal product <name – strength – pharmaceutical form>

Pictures
Colour pictures or scans of the outer packaging, inner packaging and content of the packaging need to be provided of the medicinal product from the country of origin, the reference medicinal product and the parallel imported medicinal product. To enable a qualitative comparison, the images of the reference medicinal product and the parallel imported product must be displayed side by side.

The pictures and scans must be in colour and must give a clear representation of the medicinal products. All sides of the packaging must be visible.

The content of the package refers to: tablets or capsules, but also any other item contained in the package (e.g. applicators, syringes, patient cards, etc.). Images of the content of the package must be displayed on graph paper in order to ensure a qualitative comparison.

Mock-up
A mock-up, including the Braille, of the outer and inner packaging of the parallel imported medicinal product must to be uploaded.

5.6.3 RMA

If the reference medicinal product in Belgium is accompanied by educational or informational material, programmes or services (Additional Risk Minimisation Measures (RMA), e.g. patient card, DHCP letter, brochures, etc. as published on the website and saved under the 'RMA' button), then these RMAs need to be added to your application for PI.

RMA's intended for healthcare professionals need to be submitted in French and Dutch. RMA's intended for patients need to be submitted in the three national languages (FR, NL, DE). The RMA's need to contain all necessary warnings and need to be uploaded in word version.

The RMA's of the parallel imported medicinal product must contain following information:
- "Imported by: <name and address of the holder of the PIA>"
- "Imported from <country of origin>"
- "Marketing authorisation holder of the imported medicinal product: <name and address MAH in the country of origin>"
- "Marketing authorisation holder of the reference medicinal product: <name and address MAH of the reference medicinal product>"
- Name of the Belgian reference medicinal product <name – strength – pharmaceutical form> (in case this would be different from the name of the parallel imported medicinal product)

All logos, images and photographs must be present in colour. The logos can be found on the FAGG website.

More detailed information on the content of the RMAs can be found in the RMA guideline.

6. Procedure for submitting an application

6.1 Electronic submission of an application

The application for a parallel import licence is submitted electronically to the FAMHP. You must submit your application via parallelimport@fagg.be using Eudralink. It is important to respect the tree structure and that the leaflet is added to your Eudralink as a zip file. More information about the tree structure can be found under "6.2 Tree structure of the application".

The subject line of the email must be worded as following: <Type of application> <name of medicinal product – strength – pharmaceutical form> <(country of origin)>.

All the necessary forms and templates for completing the application are available on the FAMHP website.

6.2 Tree structure of the application

The documents that need to be submitted for an application vary depending on the type of application or type of change. In case of a variation, Annex I clarifies which document(s) must be submitted for each type of variation. Consequently, it can be possible that certain documents do not need to be submitted and that certain (sub)folders are empty.

The tree structure specifies the naming of the folders and the documents. Always use the proposed names. In case of a variation: please provide a current and proposed version (both annotated and clean, e.g. draft_PIA_proposed_annotated) of the concerned document(s).

Make sure that the manufacturers names are not too long as this causes errors when uploading your file into our database. Please limit the full name of the document to a maximum of thirty characters.

Name primary folder
Name folder
Name subfolder
Naming document(s)

<name - strength - pharmaceutical form > (country of origin) of the imported medicinal product

01 Application

- Application_form
- Comparison_form

02 Generic documents

- DOC
- DOI
- Specific_mechanism
- Power of Attorney (POA)

03 PIA

- Draft PIA

04 Enterprises

- Contract <name company>
- GMP certificate <name company>
- MIA <name company>
- WDA and/or GDP <name company>

05 Leaflets

01 Product in country of origin

- PIL_product_country_of_origin
- Translation
- Conformity_translation

02 PI product

- 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 Content and packaging

01 Generic documents

- Statement_FMD
- Motivation_ATD
- PAC
- Blister_cutting

02 Product in country of origin

- Pictures_content_packaging
- Pictures_primary_packaging
- Pictures_secondary_packaging

03 Reference product BE

- Pictures_content_packaging
- Pictures_primary_packaging
- Pictures_secondary_packaging

04 PI product

- Pictures_content_packaging
- Pictures_primary_packaging
- Pictures_secondary_packaging
- Pictures_comparison_content_packaging (PI - reference product)
- Pictures_comparison_primary_packaging (PI - reference product)
- Pictures_comparison_secondary_packaging (PI - reference product)
- Mock-up_primary_packaging
- Mock-up_secondary_packaging

05 RMA

- RMA_NL
- RMA_FR
- RMA_DE
- DHCP_NL
- DHCP_FR
- …
- RMP_NL
- RMP_FR
- …

6.3 Physical samples

6.3.1 Request of physical samples

<u>New application</u>
Physical samples of the reference medicinal product and of the PI medicinal product (as marketed in BE) will be requested during evaluation, when the primary or secondary packaging is relabelled.

To save time, it is recommended to send the samples at the time of application.

<u>Variations</u>
Physical samples will be requested if the variation has impact on the medicinal product itself, the content of the package, relabelling,… (e.g. blister cutting, repackaging, etc.), including its safe and proper use. Annex I indicates for which types of variations samples will be requested during evaluation.

However, (other) samples can be requested during the evaluation of your application. At the request of the FAMHP, it may be necessary to provide a sample of the medicinal product from the country of origin.

A sample refers to:

- The primary packaging
- The secondary (and tertiary) packaging
- The content of the packaging (e.g. applicator, syringes, tablets, etc.)
- All other items that are part of the product and packaging (e.g. patient card, RMA's, etc.)

6.3.2 Sending physical samples by post

Samples must be sent by post. You must enclose a covering letter with a clear inventory of the contents of the package. The covering letter and the accompanying samples must be bound together with a rubber band. Samples cannot be loose in the package. If know, add the procedure number to the accompanying letter and attach a copy of the application form.

Send the package to:

FAGG
DG POST vergunning - afdeling Vergunning voor het in handel brengen (variaties en hernieuwingen) - cel Administratieve ondersteuning – parallel import
Galileelaan 5/03
1210 BRUSSEL

6.4 Payment

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.

Annex I

Classification of variations

For each type of change, the documents required at least to complete the change request are specified. These documents must be added to your electronic file. The classification code needs to be filled in on the application form.

This classification is for guidance only. Other documents and/or information may be requested at any stage of the procedure if deemed necessary to carry out a qualitative evaluation. If deemed necessary, additional documents and/or information can be added by the applicant.

A. Variations to the MA of the medicinal product in country of origin

A.1 Change in pack size, the storage conditions and/or period, the composition of the excipients, the appearance of the medicinal product itself or any change that may have an impact on its (almost) identical nature in relation to the reference medicinal product

- Application form
- Comparison form
- Draft PIA
- Patient information leaflet of the PI medicinal product
- Colour images of the packaging and content
- Mock-up of the packaging

A.2 Administrative change of the batch releaser, name of the medicinal product or the name and/or address of the MAH/registration holder

- Application form
- Comparison form
- Draft PIA
- Patient information leaflet of the PI medicinal product
- Colour images of the packaging and content
- Mock-up of the packaging

A.3 Change in the appearance of the packaging

- Application form
- Comparison form
- Colour images of the packaging and content
- Mock-up of the packaging

A.4 Changes in the content of the packaging

- Application form
- Comparison form
- Draft PIA (if applicable)
- Patient information leaflet of the PI medicinal product
- Colour images of the packaging and content
- Mock-up of the packaging
- If applicable; samples of:
    - The reference medicinal product
    - The PI medicinal product

B. Variations to the MA of the reference medicinal product

B.1 Change in the composition of the excipients, the dosage form or content of the packaging

- Application form
- Comparison form
- Colour images of the packaging and content
- Mock-up of the packaging

B.2 Withdrawal of the MA of the reference medicinal product, at request of the MAH

- Application form
- Comparison form
- Draft PIA
- Patient information leaflet of the PI medicinal product
- Declaration of conformity
- Colour images of the packaging and content
- Mock-up of the packaging
- Samples of:
    - The (new) reference medicinal product
    - The PI medicinal product

B.3 Changes in the RMA's

- Application form
- Comparison form
- RMA's

B.4 Changes in the patient information leaflet

- Application form
- Comparison form
- Draft PIA (if applicable)
- Patient information leaflet of the PI medicinal product
- Declaration of conformity

B.5 Changes in the packaging

- Application form
- Comparison form
- Draft PIA (if applicable)
- Colour images of the packaging and content
- Mock-up of the packaging

C. Change(s) to the PIA

C.1 Deleting, adding or changing a pack size

- Application form
- Comparison form
- Draft PIA
- Patient information leaflet of the PI medicinal product
- Declaration of conformity
- Mock-up van de verpakking

C2. Repackaging because of safety features

- Application form
- Comparison form
- Draft PIA
- Patient information leaflet of the PI medicinal product
- Declaration of conformity
- Colour images of the packaging and content
- Mock-up of the packaging
- Samples of:
    - The reference medicinal product
    - The PI medicinal product

C3. Administrative change of the name of the medicinal product, the name/address of the holder of the PIA or the addition/deletion of a legal entity

- Application form
- Comparison form
- Draft PIA
- Patient information leaflet of the PI medicinal product
- Declaration of conformity
- Colour images of the packaging and content
- Mock-up of the packaging

D. Overview table

Below you can find a summary table listing the documents to be submitted for each type of variation.

	AF	CF	Draft PIA	PIL + DOC	Pict. + M-U	Sample	RMA
A1	X	X	X	X	X		
A2	X	X	X	X	X		
A3	X	X			X		
A4	X	X	X	X	X	X	
B1	X	X			X		
B2	X	X	X	X	X	X	
B3	X	X					X
B4	X	X	X	X			
B5	X	X	X		X		
C1	X	X	X	X			
C2	X	X	X	X	X	X	
C3	X	X	X	X	X		

Abbreviations: application form (AF), comparison form (CF), parallel import authorisation (PIA), patient information leaflet (PIL), Declaration of Conformity (DOC), mock-up (M-U)

Legend:

X	Yes
	No
X	Not by Default