# **Application for a Parallel Import Marketing Authorisation**

# **for a medicinal product for HUMAN use**

Could you please **type** the requested information, **sign** the form and add it to the electronic submission of the dossier.

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| 1. Procedure Application for a marketing Authorisation of Parallel Import  Renewal of a Marketing Authorisation of Parallel Import  Variation of a Marketing Authorisation of Parallel Import |

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| 2. Administrative Data2.1. Parallel Import Authorisation Holder (Parallel Importer) Name:  Address:      Contact Person:  Phone number:  email:  Authorisation number:  2.2. Contact Person for Information  Name:  Phone number:  Email:  2.3. Applicant, if different from the Parallel Importer  Name:  Address:      Contact Person:  Phone number:  Email: |

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| 3. Details of the Medicinal Product for Human Use 3.1. Information about the product to be imported  Name:  Pharmaceutical form and strength:  Active substance(s):    Name and address of the Marketing Authorisation Holder:  Marketing Authorisation Number:  Member State of Origin :  AT BG\* CY CZ\* DE DK EE\* EL ES FI FR HU\* IE  IS IT LI LT\* LU LV\* MT NL NO PL\* PT RO SE  SI\* SK\* UK  HR\*  Name and address authorised manufacturer(s) responsible for batch release in the EEA in accordance with Article 40 and article 51 of Directive 2001/83/EC:  \* With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria, Croatia or Romania the parallel importer would needs to check whether the “specific mechanism” applies:  The specific mechanism is applicable. I have given the patent holder one month’s advance notification, with copy annexed.  The specific mechanism does not apply to the present application.  3.2. Information about the product in Belgium which the applicant refers to as the reference product  Name:  Pharmaceutical form and strength:  Active substance(s):    Name and address of the Marketing Authorisation Holder:  Marketing Authorisation Number:  3.3. Information about the marketing authorisation for parallel import  Parallel Import Marketing Authorisation Number[[1]](#footnote-1):  Expiry date of the current authorisation\*  Procedure Number\*:  Manufacturer(s) for repackaging (name and address):  Manufacturer(s) responsible for the batch-certification (name and address): |
| **4. In case of Variation of a Marketing Authorisation for Parallel Import**  4.1. Variation type:  Variation conform art 7 § 2 of RD of 19.04.2001  Variation conform art 7 § 3 of RD of 19.04.2001  Variation not conform art 7 §2 or §3 of RD of 19.04.2001  4.2. Description of the variation:  *Precise scope and background for the change (include a description and background of all the proposed changes; add this information also in the tabulated overview present-proposed)*:     |  |  | | --- | --- | | *Present* | *Proposed* | |  |  | |

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| 5. DocumentS / Samples TO BE ADDED TO THIS APPLICATION Proof of payment  Draft marketing authorisation for parallel import, using the template  Copy of Belgian reference product’s leaflet (Dutch, French, German)  Copy of the imported medicinal product’s leaflet  Authorised translation of the imported medicinal product’s leaflet in one of the national languages  A declaration that the translation is conform the leaflet of the imported medicinal product  A declaration of conformity: a declaration that the leaflet for the public is identical to the leaflet included in the package of the Belgian reference product  A draft of the annexes (Dutch, French, German): contains additional information concerning the parallel imported product (these documents needs to be added to the leaflet included in the package of the parallel imported product for the Belgian Market)  Samples of the imported medicinal product for human use for the Belgian Market (outer and inner packagings)  send by postal package *(tick box in case only the samples are sent via postal services)*  Mock-up of the imported medicinal product to be placed on the Belgian market (outer and inner packagings) + pictures (added to the electronic submission)  Samples of the imported medicinal product for human use in its original package (outer and inner packagings) + pictures (added to the electronic submission)  send by postal package *(tick box in case only the samples are sent via postal services)*  Samples of the Belgian reference product (outer and inner packagings) + pictures (added to the electronic submission)  send by postal package *(tick box in case only the samples are sent via postal services)*  Statement (in case of the implementation of the safety features in line with the Falsified Medicines Directive 2011/62/EU of the European Parliament and of the Council) (see document national Q&A FMD for PI) – if applicable  A motivation that the used anti-tampering device is equally effective as the anti-tampering device used for the Belgian reference product (see document national Q&A FMD for PI) – if applicable  A declaration of integrity that the imported product hasn’t been modified directly or indirectly  Contracts between the Parallel Importer and the repackagers  Manufacturing and Importation Authorisation (= MIA) = scan of the signed, official document: the dossier needs to contain the MIA of all the repackagers  Good Manufacturing Practice certificat (= GMP certificat) = scan of the signed, official document: the dossier needs to contain the GMP of all the repackagers  Good Distribution Practice certificat (= GDP certificat) = scan of the signed, official document: the dossier needs to contain the GDP of all the distributors  A notification (NOT): A copy of the letter notifying the marketing authorization holder of the reference product about the parallel import and sent one month prior to submitting the application, *if specific mechanism is applicable*  Delegation of Power, if the applicant is different from the parallel importer |
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**Name person responsible submission application:**

**Signature + date:**

1. \*in case of variation or renewal [↑](#footnote-ref-1)