# **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 InformationName:      Phone number:       Email:      2.3. Applicant, if different from the Parallel ImporterName:      Address:          Contact Person:      Phone number:       Email:       |

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| 3. Details of the Medicinal Product for Human Use3.1. Information about the product to be importedName:      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 productName:      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 importParallel 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 19.04.20014.2. 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)*:

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| *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)