# **Application for a parallel import marketing authorisation**

# **for a medicinal product for veterinary 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 Data**2.1. Parallel Import Authorisation Holder (Parallel Importer)**Name:      Address:          Contact Person:      Phone number:       email:      Authorisation number:      **2.2 Contact Person for Pharmacovigilance**Name:      Phone number:       Email:      **2.3. Contact Person for Information**Name:      Phone number:       Email:      **2.4. 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 Veterinary 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\*:       |

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| **4. In case of Variation of a Marketing Authorisation for Parallel Import****4.1. Variation type** [ ]  Variation Type IA [ ]  Variation Type IB [ ]  Variation Type II**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):

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| *Present* | *Proposed* |
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| **5. Renewal of a Marketing Authorisation for Parallel Import**Parallel Import Marketing Authorisation Number:      Expiry date of the current authorisation:       |

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| **6. Details of Relabelling/Repackaging****6.1. Relabeller/Repackager**Name:      Address:               Contact Person:      Phone number:       Fax number:      Email:      Date of last GMP Certificate:**6.2. Relabelling/Repackaging information**Nature of repackaging [ ]  Relabelling outer packaging [ ]  Overlabelling primary packaging [ ]  New outer packaging [ ]  New primary packagingProvide details:             |

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| **7.** **Batch certification**Name:      Address:               Contact Person:      Phone number:       Fax number:      Email:      Date of last GMP Certificate:       |

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| 8. Documents / Samples TO BE ADDED TO THIS APPLICATION**Generic documents**[ ]  Proof of payment[ ]  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 declaration of integrity that the imported product hasn’t been modified directly or indirectly[ ]  Delegation of Power, if the applicant is different from the parallel importer[ ]  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*[ ]  Table of comparison: imported product versus reference product**PIA**[ ]  Draft marketing authorisation for parallel import, using the template **Enterprises**[ ]  Contracts between the Parallel Importer and the repackagers[ ]  Good Manufacturing Practice certificat (= GMP certificat) = scan of the signed, official document, issued by the competent authority in the member state and not older than 3 years: the dossier needs to contain the GMP of all 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 Distribution Practice certificat (= GDP certificat) = scan of the signed, official document: the dossier needs to contain the GDP of all the distributors**Leaflet & labelling**[ ]  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[ ]  Proposed labelling for the primary/outer packaging following QRD-template (NL – FR – DE)[ ]  Proposed leaflet following QRD-template (NL – FR – DE)Samples[ ]  Samples of the imported medicinal product for veterinary 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)*[ ]  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*)* |
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**Name person responsible submission application:**

**Signature + date:**

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