# **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):       |  |  | | --- | --- | | *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 packaging  Provide 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)