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| **Application for approval to carry out parallel trade of a veterinary medicinal product (VMP)[[1]](#footnote-1)** |
| Administrative InformationApplicant: Wholesale distributor intending to carry out parallel trade in the destination Member State Company name:  Address:  City:  Postcode:  Country:  Contact Person:  Phone number:  Email:  Authorisation number to perform wholesale distribution (article 99 of Regulation (EU) 2019/6) as registered in the Manufacturing and Wholesale distribution database:  OMS LOC ID: Wholesale distributor for the source Member State (copy the section if more than one wholesale distributor is used) Company name:  Address:  City:  Postcode:  Country:  Contact Person:  Phone number:  Email:  Authorisation number to perform wholesale distribution (article 99 of Regulation (EU) 2019/6) as registered in the Manufacturing and Wholesale distribution database:  OMS LOC ID: |
| Parallel traded VMP applied forProposed name for the parallel traded VMPin the destination Member State:Proposed pack sizes of the parallel traded VMP in the destination Member State:Country acting as source member state for the parallel traded VMP: |
| Confirmation We as the wholesale distributor intending to carry out parallel trade in the destination Member State hereby confirms that:  the marketing authorisation holder in the destination Member State has been notified in accordance with article 102.6 (b) Regulation (EU) 2019/6.  a written declaration that the marketing authorisation holder in the destination Member State has been notified in accordance with article 102.6 (b), and a copy of the notification, is attached as an annex to the application form in accordance with article 102.6 (c) Regulation (EU) 2019/6.  the marketing authorisation holder and the National Competent Authority (NCA) of the source Member State have been notified according to article 102.5 Regulation (EU) 2019/6.  Copies of any declarations and notifications made by the applicant are submitted as annexes to the application form where relevant, see section 6.  Applicant:  Name:  Title:  Phone number:  Email: |

# Details of the veterinary medicinal product in the source Member State and in the destination Member State

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|  | VMP in the source Member State (to be parallel traded) | VMP already authorised in the destination Member State |
| Name of the VMP: |  |  |
| UPD Product identifier: |  |  |
| UPD Permanent Identification number: |  |  |
| Active substance(s): |  |  |
| Strength: |  |  |
| Pharmaceutical form: |  |  |
| Package sizes: |  |  |
| Target specie(s): |  |  |
| Procedure Number (if MRP/DCP/SRP): |  |  |
| Marketing Authorisation Number: |  |  |
| Name and address of the Marketing Authorisation Holder: |  |  |
| Name and address of the manufacturer of the finished product (all type of products): |  |  |
| Name and address of the manufacturer of the active substance of the medicinal product (only for immunologicals/biologicals) |  |  |

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| Review and analysis of the common origin shared by the VMPs The veterinary medicinal product in the source Member State is authorised through the same mutual recognition, decentralised- or subsequent recognition procedure as the veterinary medicinal product already authorised in the destination Member State, or has been subject to an SPC harmonisation procedure, thus the requirements for the common origin is fulfilled.  **When the above statement does not apply, please fill out the rest of this section.**  **The wholesale distributor intending to carry out the parallel trade in the destination Member State should confirm that the VMP obtained from the source Member State and the VMP already authorised in the destination Member State have:**  the same qualitative and quantitative composition in terms of active substances and excipients;  the same pharmaceutical form;  the same clinical information\* and, if applicable, withdrawal period;  *\*”clinical information” in this context should cover the information detailed in Article 35.1 (c) as much as possible. For products for which the SPC has not yet been harmonised, “clinical information” should cover at least target species, withdrawal period and indication/claim*  both products have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation. |
| Relabelling /RepackagingInformation regarding the relabelling/repackaging procedure Nature of the relabelling/repackaging:  Relabelling outer packaging  Relabelling immediate packaging  New outer packaging  Full details regarding the relabelling/repackaging procedure (also any devices included in the packaging): Company(ies) performing the relabelling/repackaging of the product Company name:  Address:  City:  Postcode:  Country:  Contact Person:  Phone number:  Email:  Manufacturing activities performed :  Authorisation number to perform manufacturing activities (article 88 of Regulation (EU) 2019/6) as registered in the Manufacturing and Wholesale distribution database:  OMS LOC ID: Company(ies) performing the batch release of the relabelled/repacked product Company name:  Address:  City:  Postcode:  Country:  Contact Person:  Phone number:  Email:  Authorisation number to perform manufacturing activities (article 88 of Regulation (EU) 2019/6) as registered in the Manufacturing and Wholesale distribution database:  OMS LOC ID: |
| Pharmacovigilance We, as the wholesale distributor intending to carry out the parallel trade in the destination Member State, confirm that:  appropriate measures have been taken to ensure that the wholesale distributor in the source Member State will keep us informed of any pharmacovigilance issues in accordance with article 102.6 (a) Regulation (EU) 2019/6;  suspected adverse events will be collected and reported to the marketing authorisation holder of the parallel traded veterinary medicinal product in accordance with article 102.6 (e) Regulation (EU) 2019/6. |
| Post-licencing maintenance We, as the wholesale distributor intending to carry out the parallel trade in the destination Member State, confirms that we will:  receive relevant information from the wholesale distributor in the source Member State to keep the NCA in the destination Member State informed of any variations with relevance for the parallel trade licence, applied to the VMP in the source Member State;  inform the NCA in the destination Member State of any variations applied to the authorised VMPs with relevance for the parallel trade licence by submitting a notification/changes application, including amendments of the product information of the parallel traded VMP if applicable/needed.  inform/submit notification or change application to the NCA in the destination Member State regarding of any changes with relevance for the parallel trade licence (e.g change of pack size of parallel traded products/ change of re-packager etc) |
| Documents, annexes and samples enclosed with the applicationProduct information (some Member States do not require all documentation listed below. Please be advised to verify the national requirements applicable in the intended destination Member State) An authorised translation of the approved package leaflet for the veterinary medicinal product in the source Member State, presented in the national language of the destination Member State  A comparison of the translation of the approved package leaflet for the veterinary medicinal product in the source Member State with the corresponding package leaflet for the veterinary medicinal product already authorised in the destination Member State  Proposed labelling for the immediate and outer packaging  Proposed package leaflet  Proposed SPC Annexes a written declaration that the marketing authorisation holder in the destination Member State has been notified in accordance with article 102.6 (b) Regulation (EU) 2019/6, together with a copy of the notification, in accordance with article 102.6 (c) Regulation (EU) 2019/6.  copies of valid manufacturing authorisations for the company(ies) performing the relabelling/repackaging of the VMP and the company(ies) performing the batch release of the relabelled/repacked product, and any technical agreements (if relevant) or reference to the EudraGMDP database.  a copy of the wholesale distribution authorisation of the wholesale distributor intending to carry out the parallel trade in the destination Member State or reference to the EudraGMDP database.  a copy of the wholesale distribution authorisation of the wholesale distributor in the source Member State or reference to the EudraGMDP database. Samples if required (see national requirements stated on the [CMDv website](https://www.hma.eu/fileadmin/dateien/Veterinary_medicines/CMDv_Website/Procedural_guidance/General_info_on_applications/GUI-030_Product_samples_for_visual_lab_control_NCAs.pdf)) Samples are submitted together with the application as required by the NCA in the destination Member State.  No samples are submitted together with the application as this is not required by the NCA in the destination Member State. |

1. VMP refers to « veterinary medicinal product » in the whole document [↑](#footnote-ref-1)