Application for a Parallel Traded Veterinary Product Authorisation



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|  | Administrative details of the wholesale distributor in the destination Member State  Name and address of the wholesale distributor intending to carry out parallel trade in Ireland:  OMS LOC ID: | |
|  | Administrative details of the wholesale distributor in the source Member State  Name and address of the wholesale distributor in the source Member State:  Source Member State country:  OMS LOC ID: | |
|  | Parallel traded product details  Proposed name of product to be marketed in Ireland:  Proposed pack size product to be marketed in Ireland: | |
|  | Wholesale distributor confirmations in accordance with Article 102 of Regulation (EU) 2019/6  a written declaration that the marketing authorisation holder in the destination Member State has been notified is attached as an annex to this application  the marketing authorisation holder and the National Competent Authority (NCA) of the source Member State has been notified | |
|  | Confirmation of common origin  The proposed parallel traded product is authorised via the same mutual recognition or decentralised procedure in both the source and destination Member States, thereby fulfilling the requirement to establish common origin.  Insert MR/DC procedure number:  Or  The proposed parallel traded product is not authorised via the same mutual recognition or decentralised procedure in both the source and destination Member States.  Evidence is provided in the application that the products 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 been harmonised yet, ‘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. | |
|  | Re-labelling/re-packaging details  Manufacturer(s) responsible for re-labelling/re-packaging of the product:  Name and address:  OMS LOC ID:  Details of operations carried out:  Re-labelling – outer packaging  Re-labelling – immediate packaging  New outer packaging  Batch release of the relabelled/repackaged product  Provide full details regarding the relabelling/repackaging procedure (also any devices included in the packaging): | |
|  | The wholesale distributor intending to carry out the parallel trade in the destination Member State confirms that  the NCA in the destination Member State will be kept informed of any variations applied to the VMP in the source Member State;  relevant information from the wholesale distributor in the source Member State will be received in order to be able to fulfil the obligation to maintain the parallel trade authorisation in the destination Member State (e.g. informing the NCA in the destination Member State of any variations with relevance for the parallel trade authorisation, and submit variation applications if needed). | |
|  | Pharmacovigilance confirmations  The wholesale distributor intending to carry out parallel trade in the destination Member State confirms that, as per Article 102 of Regulation (EU) 2019/6:  appropriate measures have been taken to ensure that the wholesale distributor in the source Member State will inform them of any pharmacovigilance issues  suspected adverse events will be collected and reported to the marketing authorisation holder of the parallel traded veterinary medicinal product | |
|  | Documents appended to this application  *Provide the documents in the order given below, clearly identified and separated from each other.*  Signed application form Product information An authorised translation of the approved package leaflet for the veterinary medicinal product in the source 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  For products to be parallel traded that are not authorised via the same mutual recognition or decentralised procedure in both the source and destination Member State, appropriate documentation to confirm common origin as detailed in section 5 above  Annexes  copy of the notification made to the NCA in the source Member State  written declaration that the marketing authorisation holder in the destination Member State has been notified together with a copy of the notification  copy of a valid manufacturing authorisation for the company performing the relabelling/repackaging of the VMP, and any technical agreements (if relevant) or reference to the EudraGMDP database  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  copy of the wholesale distribution authorisation of the wholesale distributor in the source Member State or reference to the EudraGMDP database  Samples  Samples are included for each pack size | |
|  | I hereby apply for a parallel trade licence:  Signature of applicant:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: | |
| Print/type name:  Capacity in which signed: | Telephone no.:  Email address: |