Application for Dual Pack Import Registration

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| *FOR HPRA USE ONLY* |
| CRN:       |

For details of the requirements, please see the ‘Guide to Parallel Imports of Human Medicines’.

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| 1. Name and address of the proposed registration holder:

     Wholesale authorisation number:       Country where wholesale authorisation was issued:       | Name and address of the applicant, if different:      |
| 1. (Invented)Name:

Active substance(s):      Type of Product:Chemical      Biological      Biotechnological      Blood Product      Vaccine      Other (please specify)       | Pharmaceutical form(s) and strength(s):      Irish marketing authorisation number(s):      Country of import:      Country of import marketing authorisation number(s):       |
| 1. Name and address of manufacturer carrying out overlabelling:

     Manufacturer’s authorisation number:       |
| 1. Confirmation that a dual pack exists for both markets.

**[ ]** Yes **[ ]** NoConfirmation of whether the specific mechanism (see section 2.3.1 of the Guide to Parallel Imports of Human Medicines) applies to this application. **[ ]** Yes **[ ]** Not applicable*If yes, a copy of the notification should be attached.**Determination of whether the specific mechanism is applicable is the responsibility of the applicant. The HPRA is not responsible for such determination.* Confirmation that the product contains both the marketing authorisation number of the country of import and the Irish marketing authorisation number. **[ ]** Yes **[ ]** NoConfirmation that the details below are identical for both markets.Outer and inner packaging **[ ]** Yes **[ ]** NoPackage Leaflet **[ ]** Yes **[ ]** NoSummary of Product Characteristics\* **[ ]** Yes **[ ]** No **[ ]** N/A*(\*Where the SmPC is contained within the pack)*Shelf life (as detailed in the SmPC) **[ ]** Yes **[ ]** NoNote: If the answer is No to any of the above items, do not proceed any further. Please refer to the Guide to Parallel Imports for Human Medicines for further information. |
| 1. Batch specific checks

 Confirmation that the product(s) will be distributed in accordance with the EU Guidelines on good distribution practice, that detailed distribution records will be kept which will facilitate, in the event of a potential recall, the identification of each customer that has received units of the relevant batch(es) and that all batches will be checked for compliance by the Responsible Person (prior to marketing). This compliance check will include checks against the Irish authorised labels and package leaflet for the product(s) concerned. **[ ]** Yes **[ ]** No Confirmation that there are written procedures in place describing all aspects of the checking and distribution of DPR products (e.g. checks of the application form, batch-specific checks, on-going DPR product compliance monitoring against current marketplace packs, etc.). **[ ]** Yes **[ ]** No |
| 1. Contact Person - Recalls

Name:      Status (job title):      Address:      24-hour telephone number (or mobile no.):      Email address:      Fax number:       | 1. Contact Person – Urgent Safety Issues

 Name:       Status (job title):       Address:       24-hour telephone number (or mobile no.):       Email address:       Fax number:       |
| 1. I hereby apply for a Dual Pack Import Registration in accordance with the information given above. I declare that: (*all boxes in this section must be ticked)*

**[ ]** The information given on this application form is correct.**[ ]** I accept that should the authorisations on which this registration is based be suspended, revoked or withdrawn for reasons of quality, safety or efficacy, this registration will cease to be valid and a recall of the product may be required to be executed by the registration holder.[ ]  The MA holder of the product on the Irish market has been given one month’s notification of the intention to import the product in advance of submitting this application, and a copy of that letter is attached with this application form.A written objection from the MA holder to the intention to parallel import was received and is attached.**[ ]** Yes **[ ]** No[ ]  Where it has been indicated the specific mechanism is applicable, confirmation that one-month prior notification of the intended import or marketing of the product in Ireland has been given to the holder/holder’s beneficiary of a medicinal product patent or supplementary protection certificate. A copy of the notification is attached with this application form. [ ]  I confirm that the label, carton, package leaflet and shelf life for the product being imported under the DPR scheme have been checked against the product currently placed on the Irish market by the marketing authorisation holder and that these have been found to be identical. Copies of the packaging materials that have been verified are attached (packaging material for the product currently placed on the Irish market and that which is to be imported).[ ]  I attach a copy of the overlabel showing its intended position on the outer carton.**[ ]** Fees have been/will be paid. *If fees have been paid, attach proof of payment.*[ ]  I will co-operate fully with the HPRA if requested.Signature of applicant: Date:      Print/type name:      Capacity in which signed:      Telephone number:       Fax number:      Email address:       |

Send to:

Receipts and Validation, Health Products Regulatory Authority, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02 XP77.

Tel: +353 1 676 4971

Email: submissions@hpra.ie