Application for Addition of a Source Country to a Parallel Import Licence

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

For details of the requirements, refer to the Guide to Parallel Imports of Human Medicines.

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| 1 | Name and address of the parallel import licence holder: | Name and address of the applicant, if different: |
| 2 | PPA Number:  Brand name of product:  Pharmaceutical form: | Active substance(s):  Strength(s): |
| 3 | Manufacturer(s) responsible for re-labelling/re-packaging of the product:  Name:  Address:  Details of operations carried out:  Re-labelling  Re-packaging to change the number of blister strips in one outer carton  Inserting a new leaflet  Re-packaging the product,  in a new container or  in a new outer carton  Replacement of the unique identifier (2D barcode and human readable)  Other *(please specify)*:  Information on any other manufacturer should be given in the text box below in the format: name, address and operations carried out. | |
| 4 | *Complete only when the original product on the Irish market has more than one method of sale and/or more than one method of promotion.* | |
| Method of sale or supply:  General sale  Retail sale through pharmacies only  Prescription only | Method of sales promotion:  Direct to the public  To the professions  To the professions as a prescription-only medicine |
| 5 | Basis on which applicant makes a presumption of therapeutic equivalence between the Irish and imported product:  I agree to the Health Products Regulatory Authority contacting the marketing authorisation holder in order to confirm therapeutic equivalence between the imported and Irish product, if this is deemed necessary by the HPRA:  Yes No | |
| 6 | Confirmation 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.* | |
| 7 | **Documents appended to this application**: *tick as appropriate*  Cover letter  Application form  SmPC *(based on authorised SmPC issued by the HPRA only)*  Proposed labelling for immediate container and outer packaging *(colour mock-ups)*  Proposed package leaflet *(colour mock-up)*  Package leaflet in country from which the product is to be imported  Braille declaration  Manufacturer’s authorisation(s) *(only to be submitted for manufacturers outside Ireland)*  Wholesaler’s authorisation(s) *(only to be submitted for wholesalers outside Ireland)*  Copy of specific mechanism notification, if applicable (see section 6)  Documents should be submitted as per the *Guide to Electronic Submissions – Human Medicines*. | |
| 8 | I hereby apply for an additional source country to be added to the parallel import licence.  I declare that fees have been/will be paid. *If fees have been paid, attach proof of payment.*  I declare that the MA holder of the product on the Irish market will be notified of the intention to import the product no later than one month before importation, and such notification will be given in respect of each Member State from which product is sourced. | |
| 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](mailto:submissions@hpra.ie)

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| COMPARATIVE PRODUCT DETAILS | IRELAND | MEMBER STATE OR EEA COUNTRY  *Insert name:* | HPRA USE ONLY |
| Marketing Authorisation number and national code1), if applicable | PA |  |  |
| Name and address of the Marketing Authorisation Holder | Name:  Address: | Name:  Address: |  |
| Name of product, strength and pharmaceutical form |  |  |  |
| Name of active substance |  |  |  |
| Line list of excipients2) |  |  |  |
| Storage conditions on label of product as marketed |  |  |  |
| Container type(s) and pack size(s) |  |  |  |
| Name and address of manufacturer, as declared in the package leaflet |  |  |  |

1) Applicable when the national code, not the marketing authorisation number, is stated on the outer label of the imported medicinal product.

2) List excipients in the Irish reference product and parallel-imported product in the same order, one excipient per line. Refer to the Guide to Parallel Imports for Human Medicines on the ‘Publications and Forms’ section of [www.hpra.ie](http://www.hpra.ie) for further details.