Application for Renewal of a Parallel Import Licence

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

*For details of the requirements, please see the Guide to Parallel Import Licence*

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| 1. Name and address of the parallel import licence holder: | Name and address of the applicant, if different: |
| 1. PPA Number:   Name of product:  Pharmaceutical form: | Date of expiry of the current authorisation:  Active substance(s):  Strength(s): |
| 1. For each approved source country, fill in the date on which importation was first authorised: | |
| Austria  Belgium  Bulgaria  Czech Republic  Denmark  Estonia  Finland  France  Germany  Greece  Hungary  Italy | Lithuania  Luxembourg  Netherlands  Poland  Portugal  Romania  Slovenia  Slovakia  Spain  Sweden  United Kingdom  EEA Country *(Name)* |
| Please specify if you wish to delete any approved source country:  Please specify if the product, from any approved source country, is currently marketed.  Yes  No | |

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| 1. List of approved manufacturers responsible for re-labelling or re-packaging   Company name:  Address:  Country:  Telephone:       Telefax:       E-mail:  *Further approved assemblers can be detailed in the text field below, in the same format as shown above*. | | |
| 1. SmPC, labelling and/or package leaflet   *If revised product information (SmPC, labelling and/or package leaflet) is proposed to take account of new guidelines, specify the precise present and proposed wording, underlining or highlighting the changed words. Alternatively, such listing may be provided as a separate document attached to the application form* | | |
|  | PRESENT | PROPOSED |
|  |  |  |
| 1. Documents and samples appended to this application:   Cover letter  Application form  SmPC  Labelling *(mock-ups)*  Package leaflet *(colour mock-ups)*  Package leaflet in each source country from which the product is imported  Chronological list of all approved or pending Type IA/IB and Type II variations since grant of the authorisation or last renewal, giving the Case Reference Number, date of submission, date of approval (if approved) and brief description of the change.  Updated manufacturer’s authorisation(s) *(only to be submitted for manufacturers outside Ireland)*  Updated wholesaler’s authorisation(s) *(only to be submitted for wholesalers outside Ireland)*  Documents should be submitted as per the *Guide to Electronic Submissions – Human Medicines.*  **Samples**  Currently-marketed samples are included from each country of importation  Samples are included of any product re-packaged in a new container or outer carton | | |

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| 1. I hereby apply for renewal of the parallel import licence.   I confirm that no changes have been made to the product particulars other than those approved by the Health Products Regulatory Authority.  I confirm that the clinical particulars in the SmPC and package leaflet are in accordance with the currently-marketed SmPC and package leaflet of the originator product.  **Quality** **defects**  I declare that any suspected or confirmed quality defect, which could impact upon the safe and appropriate use of the medicinal product, has been satisfactorily addressed, and that any such defect, which could have resulted in a recall or in the abnormal restriction on the supply of the product, has been notified to the competent authority in the Member State where the manufacturer is located. I also declare that, in cases where the affected batch was marketed in Ireland, the HPRA Compliance Department was notified of the defect in a timely manner also. | |
| Signature of applicant:  Print/type name:  Telephone number:  E-mail address: | Date:  Capacity in which signed:  Fax number: |

Send to: Receipt and Validations, Health Products Regulatory Authority, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2.

Tel. No. 00353 1 676 4971; Fax No. 00353 1 676 7836

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| COMPARATIVE PRODUCT DETAILS | IRELAND | MEMBER STATE OR EEA COUNTRY  *Insert name* | HPRA USE ONLY |
| Marketing Authorisation number | 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 excipients\* |  |  |  |
| 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 |  |  |  |

\*List excipients in the Irish reference product and parallel-imported product in the same order, one excipient per line. See *Guide to Parallel Import Licence* for further details.