Application for a Variation to a Parallel Import Licence

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

*For details of the requirements, please see the Guide to Parallel Imports – Human Medicines. (For addition of a source country, use the form Application for Addition of a Source Country to a Parallel Import Licence.)*

All sections must be completed in full

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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:       | Active substance(s):      Strength(s):       |
| 3.

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| **Variation number** | **Change description** | **Conditions to be fulfilled** | **Documentation to be supplied** | **Fee code classification** |
| **IA** | **IB** |
| 1  | Change in source country authorisation number and/or source country national code (changes to a number of source country authorisation numbers and/or source country national codes for a single parallel import licence can be made under one Type IA variation)  |  | 1 and/or 8\* | [ ]  |  |
| 2 | Change in source country authorisation holder’s name/address |  | 1 and/or 2 | [ ]  |  |
| 3 | Change in parallel import licence holder’s name/address |  | 3, 4 | [ ]  |  |
| 4 | Change in PA number of the Irish-market product  |  |  | [ ]  |  |
| 5 | Deletion of a source country |  | 4 | [ ]  |  |
| 6 | Change in the name of the active substance | 1 | 2, 4 | [ ]  | [ ]  |
| 7 | Change in the product name | 2, 3 | 4, 5 | [ ]  | [ ]  |
| 8 | Amendment to the details of the manufacturer of the product in the source country  |  |  |  |  |
| 1. Replacement/addition of a manufacturer
 | 4 | 2, 4 | [ ]  | [ ]  |
| 1. Deletion of a manufacturer
 |  | 2, 4 | [ ]  |  |
| 1. Change in the name/address of a manufacturer where the actual site remains unchanged
 |  | 2, 4 | [ ]  |  |

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| **Variation number** | **Change description** | **Conditions to be fulfilled** | **Documentation to be supplied** | **Fee code classification** |
| **IA** | **IB** |
| 9 | Amendment to the details of the re-packager/assembler of the product |  |  |  |  |
| 1. Replacement/addition of a re-packager/assembler
 | 5 | 4, 6 | [ ]  | [ ]  |
| 1. Deletion of a re-packager/assembler
 |  | 4 | [ ]  |  |
| 1. Change in the name/address of the re-packager/assembler where the actual site remains unchanged
 |  | 4, 6 | [ ]  |  |
| 10 | Change in product composition as stated in the SmPC, labelling or package leaflet |  | 2, 4 |  | [ ]  |
| 11 | Change in product description (score-lines, colour, shape etc.) | 6 | 4, 7 | [ ]  | [ ]  |
| 12 | Change to the method of sale and supply or to method of promotion (following an approved change to the Irish reference product) |  | 4,5 |  | [ ]   |
| 13 | Deletion or addition of a pack size where the pack size to be added is within the currently approved range for the PPA |  | 4 | [ ]  |  |
| 14 | Amend to add a new pack size (if outside the currently approved range for the PPA) |  | 4, 5 |  | [ ]  |
| 15 | Replacement or addition of a new pack presentation (including re-boxing) |  | 1, 4, 5 |  | [ ]  |
| 16 | Amendment of the SmPC, labels and/or leaflet in line with the reference product or EU Commission decision |  | 4 |  | [ ]  |
| 17 | Amendment of the labels and/or leaflet in line with the reference product where the SmPC is not affected. |  | 4 |  | [ ]  |
| 18 | Other (please specify):       |  |  |  | [ ]  |

Conditions1. The proposed new name of the active substance must be in line with the Irish reference product.
2. The name is changing to the currently approved name of the Irish reference product.
3. The approved over-label already obscures the source country product name on both immediate and outer packaging. If the product is already re-boxed, the only change to the outer packaging is to the name on the re-box.
4. The proposed new manufacturer is listed in the current package leaflet for the reference product.
5. The new site must have a valid manufacturing authorisation/GMP certificate confirming that the site is authorised for secondary packaging.
6. The change relates to the product markings only.

Documentation1. Scan of source country packaging showing the change
2. Scan of source country package leaflet showing the change.
3. A formal document from a relevant official body (e.g. Chamber of Commerce) in which the new name or new address is mentioned.
4. Revised product information (SmPC, package leaflet, labelling and Braille as applicable).
5. Justification for the change.
6. Manufacturer’s authorisation for the re-packager/assembler.
7. A scan/sample of the product with the differences clearly visible.
8. A declaration that the source country regulatory website has been checked and a change in the authorisation number of the medicinal product has been noted1).

1) Only applicable to products sourced from Member States where marketing authorisation numbers are not printed on the outer label of medicinal products. |
| 4. Background *(Please give brief background explanation for the proposed change to the product import licence)* Specify the precise present and proposed details, using additional pages if necessary. If the change affects the SmPC, labelling or package leaflet, the changed words should be indicated by underline, strikethrough or highlight, and a clean version should be attached. Colour mock-ups must be provided where the change affects the labelling or leaflets.

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| **Present** | **Proposed** |
|                      |                      |

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| 1. I hereby apply to vary 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 declare that all changes have been identified and that there are no other changes in the amended documentation.

I declare that fees have been/will be paid. *If fees have been paid, attach proof of payment.*

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| Signature of applicant: Print/type name:      Telephone number:      E-mail address:       | Date:      Capacity in which signed:      Fax number:       |

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Send to:

Receipts and Validation, Health Products Regulatory Authority, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02 XP77 E-mail: submissions@hpra.ie Tel.: +353 1 676 4971