## 1. DETAILS OF THE MEDICINAL PRODUCT

1.1 Name of the medicinal product

1.3 Pharmaceutical form

1.4 Active substance(s)

1.5 Country of acquisition

1.6 Pack size(s) and type (s)

1.7 MA number

## 2. NAME AND ADDRESS OF THE PARALLEL IMPORT LICENSE HOLDER

2.1 Name

2.2 Street Address

2.3 Postal box

2.4 Postal code and city

2.5 Country

2.6 Telephone details

2.7 Email

## 3. NAME AND ADDRESS OF THE CONTACT PERSON

**3.1 Name**

**3.2 Street Address**

**3.3 Postal box**

**3.4 Postal code and city**

**3.5 Country**

**3.6 Telephone details**

**3.7 Email**

| | | Fee code classification | | |
|---|---|---|---|---|
| | **Change description** | **IA** | **IB** | **II** |
| 1. | Change in marketing authorisation number in the country of acquisition. | ☐ | | |
| 2. | Change of marketing authorisation holder in in the country of acquisition. | ☐ | | |
| 3. | Change in the name/address of the marketing authorisation holder in in the country of acquisition. | ☐ | | |
| 4. | Deletion of the country of acquisition. | ☐ | | |
| 5. | Change in the product name in the country of acquisition. | ☐ | | |
| 6. | Change in the product name of the directly imported product | ☐ | | |
| 7. | Change in the name of the active substance | | ☐ | |
| 8. | Replacement or addition of manufacturer of the product in the country of acquisition. | ☐ | | |
| 9. | Deletion of a manufacturer of the product in the country of acquisition. | ☐ | | |
| 10. | Change of the name and/or address of the manufacturer of the product in the country of acquisition where the actual manufacturing site remains unchanged. | ☐ | | |
| 11. | Change of re-packager information if there is no change in the site but change in the name or address | ☐ | | |
| 12. | Addition of a new re-packager | ☐ | | |
| 13. | Deletion of a re-packager | ☐ | | |
| 14. | Change in the declaration of repacking | ☐ | | |
| 15. | Significant change in the product composition in the country of acquisition. | | ☐ | |

| | | | | |
|---|---|---|---|---|
| 16. | Minor change in the composition in the country of acquisition. | ☐ | | |
| 17. | Change in the shelf life and/or the storage conditions in the country of acquisition. | ☐ | | |
| 18. | Change in the shelf life and/or the storage conditions in the directly imported product | ☐ | | |
| 19. | Addition of sentence to the outer package that indicates the difference between the directly imported product and the parallel imported product (for example, difference in the tablet markings or score- lines). | ☐ | | |
| 20. | Change in the product description (including tablet markings and score- lines) in the country of acquisition | ☐ | | |
| 21. | Change in the product description (including tablet markings and score- lines) of the directly imported product. | ☐ | | |
| 22. | Addition of a new pack size (within the currently approved range by the direct importer). | ☐ | | |
| 23. | Addition of a new pack size (outside the currently approved range by the direct importer). | | ☐ | |
| 24. | Replacement or/and addition of packaging type | ☐ | | |
| 25. | Change or addition of condition to the marketing authorisation. | | | ☐ |
| 26. | Change of legal status of the medicinal product | | | ☐ |
| 27. | Other ( please specify): | ☐ | ☐ | ☐ |

Finnish Medicines Agency reserves the right to request an unforeseen variation to be updated to a type II variation if the proposed changes are considered to be significant.

Specify the precise present and proposed details, using additional pages if necessary. If the change affects the Package Leaflet the changed words should be indicated by underline, highlighted or strikethrough and clean version should be attached. Color mock-ups for each pack size and type need to be provided where the change affects inner and/or outer labeling.

| PRESENT | PROPOSED |
| --- | --- |
| | |

| OTHER CONCERNS |
| --- |
| |

***The following product information proposals are provided:***

- ☐ Summary of Product Characteristics
- ☐ Package leaflet
- ☐ Mock-ups
- ☐ Declaration of repacking
- ☐ Copy of the original Package Leaflet, Outer/Inner labelling or Summary of Product Characteristics of the country of acquisition.
- ☐ Other

I hereby apply to vary the parallel import license. I confirm that no changes have been made to the product particulars other than those approved by Finnish Medicines Agency. I declare that all changes have been identified and that there are no other changes in the amended documentation.

Signature of applicant:

Date:

Print/type name:

Send to:
FIMEA, Rinnakkaistuonti, PL 55, 00301 Helsinki E-mail: parallelimport@fimea.fi