**Application for variation – parallel imported medicinal product**



The completed variation application form must be sent to: [post@dmp.no](mailto:post@dmp.no)

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| **Information about the medicinal product** |
| Name of the product: |
| Pharmaceutical form and strength: |
| Marketing Authorisation Number (MT(PI)no.): |
| Exporting state: |
| Name of product in the exporting state: |

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| **Information about the variation** |
| Types of change(s):  *(tick one or more options and describe the change in a separate attachment)* |
| Name of the Marketing Authorisation Holder in the exporting state  Marketing Authorisation Number in the exporting state  Manufacturer  Updated package leaflet  Relabeling / repackaging  New package size(s)  Storage conditions / Shelf life  Appearance of the medicinal product  Composition  Name, and/or change in the address of the Marketing Authorisation Holder for parallel imported medicinal product  Transfer  Other: |
| If the variation involves a change in the product information, new drafts must be enclosed, tick off the following boxes:  New draft on package leaflet  New draft on labelling |

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| **Information about the Marketing Authorisation Holder for parallel import** | |
| Company Name: | |
| Address: | |
| Phone: | |
| E-mail: | |
| Contact person: | |
| Date: | Signature by applicant: |