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

The completed variation application form must be sent to: 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:  |