**Application for marketing authorisation - parallel imported medicinal product**

The completed form must be sent to: post@dmp.no.

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| **1. General information about the medicinal product in Norway** |
| 1.1.Name under which the medicinal product is to be supplied in Norway:       |
| 1.2. Pharmaceutical form:       |
| 1.3. Strength:       |
| 1.4. Package sizes:        |

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| **2. Information about the Holder of the Marketing Authorisation for parallel imported medicinal product in Norway** |
| 2.1. Company name:       |
| 2.2. Address, PO Box, City:       |
| 2.3. Country:      |
| 2.4. Invoice address:       |
| 2.5. E-mail:       | 2.6. Phone:       |

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| 3. Person authorised for communication on behalf of the applicant |
| 3.1. Name:       |  |
| 3.2. Address:       |
| 3.3. E-mail:       | 3.4. Phone:       |

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| **4.** **Information about the medicinal product in the exporting state** |
| 4.1 Exporting state*:*       |
| 4.2 Name of the product:       |
| 4.3 Pharmaceutical form:       |
| 4.4 Strength*:*       |
| 4.5Marketing Authorisation Number in the exporting state:       |
| 4.6 Name and address of the Marketing Authorisation Holder in the exporting state; <name>, <city>, <country>:       |
| 4.7 Responsible for batch release name and address:       |
| 4.8 Legemiddelforskriften (Pharmaceutical regulations) §4-8 b requires a specific claim of notification in order to parallel import patent protected medicines from some countries in EU. See Patentforskriften (Patent regulations) av 20. desember 1996 nr. 1162 § 109a.[ ]  Yes, notification has been submitted at least 1 month before this application is being sent. Documentation is enclosed.[ ]  No, notification has not been submitted because the medicinal product is not underlied patent protection in the exporting state. |

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| 5. Information about the directly imported product |
| 5.1 Name of the product:       |
| 5.2 Pharmaceutical form:       |
| 5.3 Strenght:       |
| 5.4 Marketing Authorisation Number:      | 5.5 Legal status:       |
| 5.6 Name and address of the Marketing Authorisation Holder; <name>, <city>, <country>:      |

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| 6. Information about the relabelling/repackaging procedure |
| 6.1A detailed description of the relabelling/repackaging procedure:       |
| 6.2 Package size(s), please clarify if legal status is CF.Legal status F:      Legal status C:       |
| 6.3 ­Company name:       |
| 6.4. Address:       |
| [ ]  Verification of manufacturing licence is attached |

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| 7. Describe the differences between the directly and the parallel imported product |
| 7.1 Describe the main differences in labelling, packaging,colour, break-mark, apperarance and size:       |

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| **8. Attachment** |
| [ ]  Scan and/or foto of packaging, outer ,immediate, blister,strips, small immediate and the medicinal product[ ]  Drafts of label on the immediate container of the product[ ]  Drafts of label on the outer container or carton[ ]  Draft of package leaflet |

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| **9. Signature by applicant (Responsible person)** |
| Date:       | Signature by applicant:       |