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|  | issue(s) |

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| Applicant | Marketing authorisation holder (if different from applicant) |
| Exact name of the pharmaceutical product | |

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| Existing marketing authorisation/  Marketing authorisation No | Application for marketing authorisation submitted | Marketing authorisation not requested  \*\*) | Marketing authorisation not required  \*\*) | BASG GZ |
| Importing country | | | | |
| a) The marketing authorisation holder/applicant is manufacturer of the dosage form \*\*\*) | | | | |
| b) The marketing authorisation holder/applicant is only involved in labelling and/or packaging \*\*\*) | | | | |
| c) The marketing authorisation holder/applicant is not involved in manufacture of the dosage form/ packing/labelling \*\*\*) | | | | |
| d) The marketing authorisation holder/applicant is manufacturer of the dosage form and further  manufacturing sites for the finished dosage form may be involved \*\*\*) | | | | |
| e) The marketing authorisation holder/applicant is involved in manufacturing of the dosage form together with further manufacturing sites \*\*\*) | | | | |
| For categories b, c, d and e: please state name and address of the manufacturer(s) of the  dosage form\*\*\*) | | | | |
| In the CPP only active substances should  be stated | | In the CPP active substances and excipients should be  stated | | |
| The medicinal product is actually on the  market in Austria | | The medicinal product is actually **not** on the market in  Austria | | |
| If the applicant is different from the marketing authorisation holder: Declaration of consent is enclosed. | | | | |

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| Remarks \*\*\*\*) |

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| Additional data concerning the pharmaceutical product are enclosed | Place, date, contact person, phone/ext. and signature\*) |

*\*) Submission by E-mail (preferred) or as paper, in no case by both ways! In case of submission by E-Mail signature is not required.*

*\*\*) Submission of composition is required!*

*\*\*\*) Data confirming the statements (module 3.2.P.3.1 or other equivalent documents) are required unless there is a documentation according to eCTD!*

*\*\*\*\*) information about special requests (eg, appendix to the CPP, personal collection of the CPP)*