July 2022

CMDh/369/2017, Rev.3

CMS Validation Checklist for Human Medicinal Products in DCP

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| **THIS APPLICATION WAS CHECKED BY**  |
| CMS |  |
| Date |  |
| Contact/unit responsible for validation: |  |
| Telephone: |  |
| E-mail: |  |
|  |  |

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| **IDENTIFICATION** |
| Date of receipt |  |
| Name of the medicinal product in the CMS |  |
| Procedure number |  |
| National reference number (if applicable) |  |
| Proposed MAH in CMS |  |
| Active Substance |  |
| Procedure number duplicates |  |

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| **Required signatures** |
| Original/scanned signature on Application form Comments:  | Yes [ ] No[ ] N/A [ ]  |
| Original/scanned signature on Cover letter Comments: | Yes [ ] No[ ] N/A [ ]  |

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| 1. **Extension Application**
 |
| Yes [ ] No[ ]  |
| In case of EA: Reason: | [ ]  qualitative change in active substance not defined as a new active substance[ ]  change of bioavailability[ ]  change of pharmacokinetics[ ]  change or addition of a new strength / potency[ ]  change or addition of a new pharmaceutical form[ ]  change or addition of a new route of administration |
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| Existing MA in the MS: | Yes **[ ]** No **[ ]** Comments:  |

 | National MA-No.:  |
| Is this application in accordance with theGuideline on the Categorisation of Extension Applications (EA) versus Variation Applications (V) | Yes [ ] No[ ]  Comments: |

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| 1. **LEGAL BASIS OF THE APPLICATION** **(DIRECTIVE 2001/83/EC)**
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| Please duplicate this section if applicable[ ]  Article 8(3) application [ ]  Article 10(1) Generic application[ ]  Article 10(3) Hybrid application [ ]  Article 10(4) Similar Biological application[ ]  Article 10a Well-Established Use application[ ]  Article 10b Fixed Combination application[ ]  Article 10c Informed Consent application[ ]  Article 16a Traditional Use registration for herbal medicinal products**Is the use of this legal basis acceptable?** Yes [ ] No[ ] Comments: |
| **Where applicable: Reference Medicinal Product (RefMP)**Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product (ERP):■ Use of European Reference Product (ERP) Yes [ ] No[ ] **If yes:**  Minimum information (Annex II) on ERP been provided? Yes [ ] No [ ] ■ RefMP based on art. 8(3), 10a, 10b or 10c? Yes [ ] No[ ] ■ RefMP authorized in accordance with *Acquis Communautaire*? Yes [ ] No[ ] ◼ In case of article 10(3): Difference(s) compared to the reference medicinal product:[ ]  changes in the active substance(s)[ ]  changes in therapeutic indications [ ]  change in pharmaceutical form[ ]  change in strength (quantitative change to the active substance(s))[ ]  change in route of administration[ ]  bioequivalence cannot be demonstrated through bioavailability studies■ The RefMP in the EEA, the RefMP in the CMS and MP used for the demonstration of the BE belong to the same GMA? Yes [ ] No[ ] *Comments*:  |

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| 1. **ANNEXED DOCUMENTS (where appropriate)**

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|  | **Yes** | **No** | **N.A.** | **Comments** |
| 5.1 | Proof of payment | [ ]  | [ ]  | [ ]  |  |
| 5.3 | Proof of establishment of the applicant/MAH in the EEA. | [ ]  | [ ]  | [ ]  |  |
| 5.4 | Letter of authorisation for communication on behalf of the applicant/MAH during the procedure | [ ]  | [ ]  | [ ]  |  |
| 5.4 | Letter of authorisation for communication on behalf of the applicant/MAH after the procedure | [ ]  | [ ]  | [ ]  |  |
| 5.10 | Letter(s) of access to Active Substance Master File(s) (Drug Master File(s)) *Cf. “In case ASMF is used”* \* | [ ]  | [ ]  | [ ]  |  |
| or copy of Ph. Eur. Certificate(s) of suitability | [ ]  | [ ]  | [ ]  |  |

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| **In case ASMF is used** |
| ASMF received in CMS: Yes [ ] No[ ] Comments: |

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| 1. **Specific NATIONAL REQUIREMENTS *(cf. “Additional Data requested for New Applications in the MRP and DCP”)***
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| Yes [ ] No[ ]  |
| Comments: |

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| **Status of the application** |
| [ ]  The application is considered valid.[ ]  The application is considered valid and the procedure can start, but the issues in section 2 below need to be addressed before day 30.[ ]  The application is considered invalid and the procedure cannot start before the issue in section 1 below have been addressed. |

***Specify below whether the above identified validation issues prevent the procedure from starting or not (NO NEW ISSUES TO BE INTRODUCED HERE)***

1. **CMS validation issue(s) preventing the procedure from starting**
2. **CMS validation issue(s) not preventing the procedure from starting but which have to be addressed by day 30 of the DCP**
3. **Additional information for the applicant**