December 2018

CMDh/387/2018

CMS Validation Checklist for Human Medicinal Products in **MRP**

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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 |  |
| RMS Assessment Report received | Yes ☐No ☐ |

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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 |
| Existing MA in the MS: | Yes [ ] No[ ] National MA-No.: Comments:   |
| **Is this application in accordance with the** Guideline 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)** |
| ■ Use of European Reference Product (ERP)? Yes [ ] No[ ] **If yes:**  Minimum information (Annex II) on ERP provided? Yes [ ] No [ ] ■ Medicinal product authorised in the Union/Member State where the application is made or Europeanreference medicinal product:* RefMP based on art. 8(3), 10a, 10b or 10c? Yes [ ] No[ ]
* RefMP authorized in accordance with *Acquis Communautaire*? Yes [ ] No[ ]

*Comments*:◼ 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** [ ] Not applicable [ ] *Comments*:  |
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| **MODULE 1** |
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| CTDmodule | Appl.Form | Annex |  | Yes | No | No,requested | N/A | Comments |
|  | 1.2.2 |  | Any MP designated as Orphan MP for condition relating to indication proposed in this application? | [ ]  | [ ]  |  |  |  |
|  | If yes, does the orphan MP have a MA in EU? | [ ]  | [ ]  |  |   |  |
| If yes, is the MP considered as “similar” to any of the authorised orphan MP? | [ ]  | [ ]  |  |   |  |
| If ticked **yes:**Module 1.7.1 and 1.7.2 completed? | [ ]  |  | [ ]  |  |  |
| If ticked **no**:Module 1.7.1 completed? | [ ]  |  | [ ]  |   |  |

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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 | [ ]  | [ ]  | [ ]  |  |
| 5.11 | If ASMF: Confirmation from the manufacturer of the active substance | [ ]  | [ ]  | [ ]  |  |

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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. |

**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 MR procedure**

**3. Additional information for the applicant**