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)** |
| 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 European  reference 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** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| CTD module | 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)** | | | | | |
|  | | **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”)*** |
| 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**