May 2023

CMDh/387/2018, Rev.2

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)** |
| ■ 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 provided? Yes [ ] No [ ]
* 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? | [ ]   |  | [ ]  |  | <The CMDh template “Module 1.7.1 Similarity report”, see [https://www.hma.eu/human-medicines/cmdh/templates/applications-for-ma.html](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hma.eu%2Fhuman-medicines%2Fcmdh%2Ftemplates%2Fapplications-for-ma.html&data=05%7C01%7CNicolas.Nyssen%40fagg-afmps.be%7Ce952ee9e46e14e01c10f08db41a946ab%7C66c008a4b56549a993c9c1e64cad2e11%7C1%7C0%7C638175967514426784%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=TPtgI3IG2Bt%2FVSdPHOXpw%2BcYstyrUOjqAQbRSWhtycE%3D&reserved=0), has not been used for Module 1.7.1. The applicant is requested to amend Module 1.7.1 according to this template. The completed template should be submitted in PDF format in Module 1.7.1 and in Word format in the “working documents” folder."> |
| If ticked **no**:Module 1.7.1 completed? | [ ]   |  | [ ]  |   | <The CMDh template “Module 1.7.1 Similarity report”, see [https://www.hma.eu/human-medicines/cmdh/templates/applications-for-ma.html](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hma.eu%2Fhuman-medicines%2Fcmdh%2Ftemplates%2Fapplications-for-ma.html&data=05%7C01%7CNicolas.Nyssen%40fagg-afmps.be%7Ce952ee9e46e14e01c10f08db41a946ab%7C66c008a4b56549a993c9c1e64cad2e11%7C1%7C0%7C638175967514426784%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=TPtgI3IG2Bt%2FVSdPHOXpw%2BcYstyrUOjqAQbRSWhtycE%3D&reserved=0), has not been used for Module 1.7.1. The applicant is requested to amend Module 1.7.1 according to this template. The completed template should be submitted in PDF format in Module 1.7.1 and in Word format in the “working documents” folder."> |

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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 10.[ ]  The application is considered invalid and the procedure cannot start before the issue(s) 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 10 of the MR procedure**

**3. Additional information for the applicant**