April 2024

CMDh/442/2022, Rev 3

[The MAH should use this template for their request to prepare an updated Assessment Report in accordance with article 28.2 in Directive 2001/83/EC. The filled in template should be sent to the RMS in Word format. The RMS will then use the document in the preparation of their updated Assessment Report.]

**Request for MRP/RUP**

[If this document is used for the Updated AR, the RMS should change the title to “Updated Assessment Report for Repeat Use Procedure”]

OVERVIEW OF PROCEDURES

**<Invented Name in RMS>**

**<(Active Substance)>**

**<AB/H/nnnn/{nnn}/MR** [if known by the applicant]**>**

**<AB/H/****nnnn/****{nnn}/E/     >**

**Applicant:**

**Date:** [Date of RMS AR to be filled in by RMS]

**ADMINISTRATIVE INFORMATION**

[The administrative information table should be filled in by the applicant. The RMS will validate the information before the updated AR is circulated to CMS.]

|  |  |
| --- | --- |
| **Requested MS to act as RMS** |       |
| Procedure type  | [ ]  MRP [ ]  RUP |
| Anticipated submission date in (the new) CMS |       |
| EU procedure number(s) [if known by the applicant] |       |
| Marketing authorisation number(s) in RMS |       |
| Name of the product in the RMS |       |
| Name of the active substance (INN name) |       |
| Pharmacotherapeutic group (ATC code) |       |
| Pharmaceutical form(s) |       |
| Strength(s) |       |
| Legal basis of marketing authorisation | [ ]  Art. 8(3)[ ]  Art. 10(1)[ ]  Art. 10(3)[ ]  Art. 10(4)[ ]  Art. 10a[ ]  Art. 10b[ ]  Art. 10c[ ]  Art. 16a |
| Is the product a duplicate?If yes, please state the name and MA/identification number/procedure number of the associated duplicate license(s). | [ ]  Yes [ ]  No      |
|  |  |
| CMS for the current MRP/RUP[It should be indicated per strength if different CMSs are proposed]  |       |
| Proposed future MAH in (the new) CMS(s)[It should be indicated per CMS if different MAHs are proposed]Note: If any of the above mentioned MAH(s) are not covered by the already approved sPhVS(s) the corresponding sPhVS(s) should be submitted to the RMS together with this request  |       |
|  |
| Abridged applications only:Will a European reference medicinal product (ERP) be used for any of the proposed CMS?If yes, please state the CMS where ERP will be used and information about the ERP (name, pharmaceutical form, strength, member state, MA/identification number). | [ ]  Yes [ ]  No      |
|  |
| **Manufacturers** |  |
| Names and full addresses of all approved manufacturer(s) responsible for batch release in the EEA |  |
| Names and full addresses of all approved manufacturer(s) of the medicinal products *specify the activities for each manufacturer (e.g. manufacture of tablets, primary packaging, secondary packaging, batch control testing* |  |
| Names and full addresses of all approved manufacturers of the active substance |  |
| Names and full addresses of all approved ASMF holders (if different from manufacturer of active substance) | *If not applicable, please state N/A* |
| Names and full addresses of all approved CEP holders (if different from manufacturer of active substance) | *If not applicable, please state N/A* |
| Names and full addresses of contract companies used for clinical trials (CRO(s)) | *Please specify the duties performed according to contract (e.g. clinical study, bio-analysis, statistical analysis)**If not applicable, please state N/A* |
| **Contact Information**  |  |
| Marketing authorisation holder’s name and full address in RMS | Company:      Contact:      Phone:      E-mail:       |
| MAH contact person for this request*If relevant, attach letter of authorisation for communication/signing on behalf of the applicant* | Company:      Contact:      Phone:      E-mail:       |
| RMS Contact Person [To be filled in by RMS] | Name:      Phone:      E-mail:       |

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# **Status of the marketing authorisation**

[The entire section “Status of the marketing authorisation” should be filled in by the applicant. The RMS will delete the section when they prepare the updated AR]

**It is confirmed that the dossier complies with the current legislation/EU guidelines:**

[ ]  Yes [ ]  No

**Are there any ongoing regulatory procedures (if yes, explain in Appendix 1)?**

[ ]  Yes [ ]  No

**Are there any planned regulatory procedures foreseen until the anticipated MRP/RUP submission date in (the new) CMS(s) (if yes, explain in Appendix 1)?**

[ ]  Yes [ ]  No

**Active Substance**

Active Substance Master File(s) (ASMF)?

[ ]  Yes [ ]  No

Currently approved version\*:

If applicable, please indicate the national ASMF number in the RMS:

If applicable, please indicate the EU ASMF WS number:

Certificate(s) of Suitability (CEP)

[ ]  Yes [ ]  No

Currently approved version\*:

\**If superseded by a new version, a variation has to be filed prior to the MRP/RUP.*

**GMP Status**

[ ]  It is confirmed that valid documentation (manufacturing authorisations, GMP certificates, QP statements) for all the approved manufacturers is enclosed in the current dossier.

[ ]  It is confirmed that valid documentation (manufacturing authorisations, GMP certificates, QP statements) for all the approved manufacturers is available and will be enclosed when the application is submitted to the CMS(s).

**Legal Status**

Is non-prescription proposed in any of the new CMS?

[ ]  Yes [ ]  No

If yes, “Justification for Non-Prescription Classification” should be submitted to the RMS together with this request, please see section X.

**Reference Medicinal Products / Bioequivalence Study(-ies) / CROs**

Reference medicinal product for the RMS:

Reference medicinal product used for bioequivalence study:

Bioequivalence study(ies):

Contract research organisations CROs:

It is confirmed that the study(ies) is in compliance with current guidelines

[ ]  Yes [ ]  No

In case of non-compliance, please explain:

**Product information**

The approved versions of the product information can be found in the following eCTD sequences:

SmPC: sequence

Labelling: sequence

PL: sequence

**Risk Management Plan RMP**

It is confirmed that the RMP is in line with GVP Module V:

[ ]  Yes [ ]  No

*If the RMP isn’t in the current template the MAH should make a commitment to submit a variation within 3 months after end of MRP/RUP.*

**Orphan similarity**

Have one or more marketing authorisations been granted for an orphan medicinal product for the proposed indication(s) since the initial application or previous MRP/RUP?

[ ]  Yes [ ]  No

*If yes, module 1.7.1. and 1.7.2, as relevant, should be submitted to the RMS together with this request. Applicants are reminded that there is a specific template to use for their preparation of Module 1.7.1, see <<https://www.hma.eu/human-medicines/cmdh/templates/applications-for-ma.html>>. The completed template should be submitted in PDF format in Module 1.7.1 and in Word format in the “working documents” folder.*

**Medical devices**

Does the dossier refer to one or more medical devices within the meaning of Article 2(1) of Regulation (EU) 2017/745 or one or more accessories to a medical device within the meaning of Article 2(2) of Regulation (EU) 2017/745?

[ ]  Yes [ ]  No

If yes:

Has conformity of device or device part with general safety and performance requirements of Annex I to Regulation 2017/745 been demonstrated by providing a manufacturer’s EU declaration of conformity, an EU certificate issued by a Notified Body or a Notified Body opinion?

[ ]  Yes

[ ]  Not applicable, as the medicinal product is a Drug-Device Combination (DDC) approved in RMS before 26 May 2021 and there has been no major changes to the design or intended purpose of the device (part), and no new device, since that date.

[ ]  No

*If no, a variation application should be submitted to add a declaration of conformity, certificate of conformity or notified body opinion prior to the commencement of the MRP/RUP.*

# **Overview of procedures**

# **Initial procedure (MRP or DCP)**

[Section I should be filled in by the applicant. The RMS will validate the information before the updated AR is circulated to CMS.]

*If not applicable (in case of an initial MRP request), please state N/A*

Procedure number:

Start of procedure date:

End of Procedure date:

CMDh Referral procedure: [ ]  Yes [ ]  No

CHMP Referral procedure: [ ]  Yes [ ]  No

**CMS**

Before start of the initial procedure:

Withdrawal during the initial procedure:

Reason withdrawal:

Number of reports attached [to be filled in by RMS]:

# **Repeat Use Procedures**

[Section II should be filled in by the applicant. The RMS will validate the information before the updated AR is circulated to CMS.]

*If not applicable (in case of no finalised Repeat use procedures), please state N/A*

Procedure number:

**Timetable**

Start procedure:

End of procedure:

CMDh referral procedure: [ ]  Yes [ ]  No

CHMP referral procedure: [ ]  Yes [ ]  No

**CMS**

Before start of repeat use procedure:

Withdrawal during repeat use procedure:

Reason withdrawal:

# **Variation****s / art. 61.3 notifications**

[Section III should be filled in by the applicant. The RMS will validate the information before the updated AR is circulated to CMS.]

*If not applicable, (e.g. in case of an initial MRP request), please state N/A*

<Only type II variations are listed.> <No type II variations have been submitted/approved.><For type IA and IB variations/Art. 61(3) notifications, reference is made to CTS.>

<Procedure number:

Variation scope:

End of procedure date:

Outcome: <Approved><Rejected><Withdrawn>

Number of variation reports attached [to be filled in by RMS]:

Procedure number:

Variation scope:

End of procedure date:

Outcome: <Approved><Rejected><Withdrawn>

Number of variation reports attached [to be filled in by RMS]:      >

# **Renewal****s**

[Section IV should be filled in by the applicant. The RMS will validate the information before the updated AR is circulated to CMS.]

Common Renewal date:

*In case a renewal has already been granted for the product:*

Procedure number:

End of procedure date:

Outcome: <A renewal with unlimited validity was granted in the RMS. In case the new CMSs require an additional renewal, it is proposed to have a standard renewal 5 years after the end of this procedure.><A renewal was granted with for a period of <X> years. The next renewal is due for      >

Number of renewal reports attached [to be filled in by RMS]:

# **PSURs**

[Section V should be filled in by the applicant. The RMS will validate the information before the updated AR is circulated to CMS.]

<No PSURs have been assessed outside a PSUSA procedure.>

<The following PSURs have been assessed outside a PSUSA procedure:

Period PSUR:

Number of PSUR reports attached [to be filled in by RMS]:      >

[Please select the appropriate section below and delete the one that does not apply.]

<Active substance is currently listed in the published EURD list

With regard to PSUR submission, the MAH should take the following into account:

* PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal. Marketing authorisation holders shall continuously check the European medicines web-portal for the DLP and frequency of submission of the next PSUR.
* For medicinal products authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC, no routine PSURs need to be submitted, unless otherwise specified in the EURD list.
* In case the active substance will be removed in the future from the EURD list because the MAs have been withdrawn in all but one MS, the MAH shall contact that MS and propose DLP and frequency for further PSUR submissions together with a justification.>

<Active substance is currently not listed in the published EURD list

<The MAH shall submit the first/next periodic safety update report for this product with a period of{xx} months/{xx} years (i. e. DLP of {xx} months after authorization) following authorisation. Further, MAHs shall continuously check the European medicines web-portal if the active substance has been included in the list of Union reference dates (EURD list). If yes, after publication in the EURD list the PSURs shall be submitted in accordance with the requirements set out in the EURD list.>

<The medicinal product is authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC. No routine PSURs need to be submitted unless it is stated as a condition in the marketing authorisation. Marketing authorisation holders shall continuously check the European medicines web-portal to see if the active substance has been included in the list of Union reference dates (EURD list). If yes, the PSURs shall be submitted in accordance with the requirements set out in the EURD list>.

# **Conditions for marketing authorisation**

[Section VI should be filled in by the applicant. The RMS will validate the information before the updated AR is circulated to CMS.]

*If not applicable, please state N/A*

**List of recommendations in the RMS and current CMSs not falling under Article 21a/22a/22 of Directive 2001/83/EC**

Description of commitment:

*If agreed:*

<Due date:

Status: <Fulfilled <on date {xx}> <during procedure {xx}> <Pending>

**List of conditions in the RMS and current CMSs pursuant to Article 21a/22a or specific obligations pursuant to article 22 of Directive 2001/83/EC**

* **<Additional risk minimisation measures (including educational material)>**

The educational material should contain the following key elements:

**<Obligation to conduct post-authorisation measures in accordance with Article 21a or 22a of Directive 2001/83>**

The MAH shall complete, within the stated timeframe, the below measures:

|  |  |
| --- | --- |
| **Description** | **Due date** |
|  |  |
|  |  |
|  |  |

* **<Specific obligation to complete post-authorisation measures for the marketing authorisation under exceptional circumstances in accordance with Article 22 of Directive 2001/83/EC>**

<This being a marketing authorisation under exceptional circumstances and pursuant to Article 22 of Directive 2001/83/EC, the MAH shall complete, within the stated timeframe, the following measures:>

| **Description** | **Due date** |
| --- | --- |
|  |  |
|  |  |
|  |  |

# **Orphan similarity**

[The entire Section VII should be filled in by the RMS]

**Potential similarity with orphan medicinal products**

*The following text can be used for this subsection*

<According to the application form and a check of the Community Register of orphan medicinal products there is no medicinal product designated as an orphan medicinal product for a condition relating to the indication proposed in this application.>

OR

<According to the application form and a check of the Community Register of orphan medicinal products the following medicinal product(s) has/have been designated as orphan medicinal products, but not yet been granted a marketing authorisation in the EU: [specify EU Orphan Designation Number(s)].

The applicant should monitor these products during the entire procedure to check if a marketing authorisation has been granted. In case a marketing authorisation is granted, the applicant should <submit a> <update the> report on similarity (Module 1.7.1) and, if applicable, <submit> the data to support derogation from orphan market exclusivity (Module 1.7.2).>

AND/OR

<The applicant has provided a similarity report (Module 1.7.1) due to potential similarity with authorised orphan medicinal product(s) under market exclusivity. The detailed RMS assessment of similarity is presented in the attached RMS Similarity AR.

Conclusion

Having considered the arguments presented by the applicant and with reference to Article 8 of Regulation (EC) No 141/2000, <product name> is considered <similar><not similar> (as defined in Article 3 of Commission Regulation (EC) No. 847/2000) to <name of authorised orphan product>. <Therefore, with reference to Article 8 of Regulation (EC) No. 141/2000, the existence of any market exclusivity for <name of authorised orphan product> in the treatment of <orphan designation>, <prevents><does not prevent> the granting of the marketing authorisation of <name of product>. This finding is without prejudice to the outcome of the scientific assessment of the marketing authorisation application.>

***If applicable:***

*Complete the following paragraph only for submissions where the product was similar to an authorised orphan medicinal product(s) and claims for derogation(s) based on Art. 8.3 of Regulation (EC) No. 141/2000 was/were submitted (Module 1.7.2). Where applicable, a separate AR on the derogation(s) will have to be adopted and attached.*

**<Derogation(s) from market exclusivity**

The application contained a claim addressing the following derogation laid down in Article 8(3) of the Regulation (EC) No. 141/2000; <the holder of the marketing authorisation for the original orphan medicinal product has given his consent to the applicant> or < the holder of the marketing authorisation for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product> or <the applicant can establish in the application that the medicinal product, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise clinically superior.> Assessment of these claims is appended.>

# **Product information**

[The entire Section VIII should be filled in by the RMS]

The SmPC, PL and labelling attached as separate documents are the current approved versions.

[ ]  Yes [ ]  No

The name of the medicinal product should be identical in all MS as this is a generic application according to Art. 10(1) of the Directive 2001/83/EC with a centrally authorised reference product, cf. art. 3.3.c in Regulation 726/2004

[ ]  Yes [ ]  No

The name of the medicinal product in the new CMS should be added to the PL, section 6.

# **Additional information**

[Section IX can be filled in by the applicant as well as the RMS, as relevant]

# **List of documents to be submitted with MRP/RUP request**

[Section X should be filled in by the applicant. The applicant should also check the national website of the RMS for any national requirements. The entire Section X should be deleted by the RMS when they prepare the updated AR]

[ ]  Appendix 1 – Approved, pending and/or foreseen variations/renewal(s)/commitments.

[ ]  If applicable – information relating to Orphan Market Exclusivity (updated orphan similarity report/derogation report, Module 1.7.1/1.7.2).

[ ]  If applicable – The sPhVS (Module 1.8.1) for proposed future MAHs, if not covered by the already approved sPhVS(s).

[ ] If applicable (initial MRP only) - proposed translations in English of the SmPC, PL and labelling in current WORD-format, using [the QRD template for MRP/DCP](https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-templates-human).

[ ] If applicable **-** Justification for Non-Prescription Classification.

[ ]  If applicable - Letter of authorisation for communication/signing on behalf of the applicant.

[ ]  If applicable – any national requirements mentioned on the national website of the RMS regarding request for MRP/RUP have been adhered to.