November 2021  
CMDh/434/2021, Rev.0

**Reference Member State**

**End of Procedure MRP/RUP**

### 1. This document is sent by:

|  |  |
| --- | --- |
| RMS |  |
| Contact point project team leader (name/E-mail/phone) | 🕿 |
| Date of approval/Day of procedure |  |

### 2. This document concerns:

|  |  |
| --- | --- |
| Name of the product in the RMS |  |
| Name of the active substance |  |
| Applicant |  |
| Procedure number |  |
| Concerned Member States involved in this procedure |  |

### 3. Conclusions

Based on the final positions of the Concerned Member States, it is concluded that all CMS recognise the RMS marketing authorisation.

### 4. Attached documents

The approved SmPC

The approved PL

The approved labelling

The approved specifications

*(If amended during the MRP. Not applicable for RUP)*

*Only applicable for repeat-use*

<The SmPC<, PL> and labelling are identical to the documents circulated together with the assessment report at the start of the procedure.>

< The PL has been updated with the trade names in all concerned member states.>

### 5. Renewal Date /RMP /PSUR-cycle /List of recommendations /Conditions to Marketing Authorisation /Orphan market exclusivity

**Renewal**

<The marketing authorisation has not yet been granted with unlimited validity. The common renewal date is <*DD Month YYYY* >.>

OR

<A renewal with unlimited validity has previously been granted. Common renewal date: <*DD Month YYYY*>:

All new CMS(s) confirmed that they accept the unlimited validity of the renewal granted by the RMS.

An additional renewal after the end of this <Repeat Use> <MR> procedure is required. The new common renewal date is <*DD Month YYYY* > (five years after the end of procedure date of the MRP/ RUP). A shortened renewal is applicable if agreed by all CMS before submission.

**Risk management plan (RMP)**

In case of changes during MRP or if not yet submitted to the CMDh-secretariat, the applicant is requested to send the list of safety concerns included in the approved RMP to CMDh secretariat, e-mail address: [H-CMDhSecretariat@ema.europa.eu](mailto:H-CMDhSecretariat@ema.europa.eu) by using the form published by CMDh (<http://www.hma.eu/464.html>)”

**PSUR**

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 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.

**List of recommendations not falling under Article 21a/22/ 22a of Directive 2001/83/EC**

N/A

The following post-approval commitments **not** falling under Article 21a or 22 have been made during the procedure:

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| **Description** | **Due date** |
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<See also attached “Commitment letter.>

**Conditions to Marketing Authorisation pursuant to Article 21a, 22 or 22a of Directive 2001/83/EC**

There are no conditions pursuant to Article 21a, 22 or 22a of Directive 2001/83/EC

The following conditions pursuant to Article 21a or 22a of Directive 2001/83/EC have been agreed: (initial conditions (as included in MRP/RUP AR) and, if any, additional conditions agreed during MRP)

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| **Description** | **Due date** |
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This concerns a marketing authorisation under exceptional circumstances in accordance with Article 22 of Directive 2001/83/EC. The specific obligations agreed upon are

|  |  |
| --- | --- |
| **Description** | **Due date** |
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**Information relating to orphan market exclusivity by end of procedure**

<There <is a> <are> positive designation<s> for a condition relating to the indication proposed in this application. Prior to granting a national MA, MSs should check whether an orphan medicinal product has been granted a MA resulting from these designation<s> and check for possible conflict with market exclusivity.

<N/A>

**6. National phase**

Applicants are reminded to submit the national translations taking into consideration the recommendations of the Best Practice on the submission of high quality national translations no later than 7 calendar days after the procedure is closed.

**7. Compliance statement referred to in Article 28(3) of the Regulation (EC) No 1901/2006**

*Where the measures in a PIP contain no study initiated before the entry into force of the Paediatric Regulation (i.e. 26 January 2007)*

The development of this product has complied with all measures in the agreed paediatric investigation plan <reference number>. All studies were conducted after the entry into force of Regulation (EC) No. 1901/2006.

*Where the measures in a PIP contain some studies initiated before the entry into force of the Paediatric Regulation*

The development of this product has complied with all measures in the agreed paediatric investigation plan <reference number>. For the purpose of the application of Article 45(3) of Regulation (EC) No. 1901/2006, significant studies in the agreed paediatric investigation plan were completed after the entry into force of that Regulation.>

N/A