October 2020

CMDh/339/2015 Rev.2

**Update Assessment Report for**

**Repeat Use Procedure**

OVERVIEW OF PROCEDURES

**<Invented Name>**

**<(Active Substance)>**

**AB/H/****nnnn/****{nnn}/E/**

**Applicant:**

**Date:**

 **ADMINISTRATIVE INFORMATION**

|  |  |
| --- | --- |
| Name of the product in the Reference Member State |       |
| Name of the active substance (INN name) |       |
| Pharmaco-therapeutic group (ATC code) |       |
| Pharmaceutical form(s) and strength(s) |       |
| Reference number(s) for the Mutual Recognition Procedure |       |
| Reference Member State |       |
| Member States concerned in earlier procedure(s) |       |
| Member States concerned in current procedure |       |
| Legal basis of marketing authorisation |       |
| Marketing authorisation holder’s name and address in RMS |       |
| Names and addresses of all approved manufacturer(s) responsible for batch release in the EEA |  |
| Names and addresses of all approved manufacturer(s) of the medicinal products | *please specify the activities for each manufacturer (e.g. manufacture of tablets, primary packaging, secondary packaging, batch control testing)* |
| Names and addresses of all approved manufacturers of the active substance | *If not applicable, please state N/A* |
| Names and addresses of all approved ASMF holders (if different from manufacturer of active substance) | *If not applicable, please state N/A* |
| Names and addresses of all approved CEP holders (if different from manufacturer of active substance) | *If not applicable, please state N/A* |
| Names and 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* |
| Marketing Authorisation number(s) in RMS |       |
| RMS Contact Person | Name      Tel:      Email:       |

**Overview of applications submitted after the end of the** **<Mutual Recognition Procedure><Decentralised Procedure>**

# **I Initial** **<MRP><DCP>**

Procedure number :

**Timetable**

Start procedure :

Day <90>/<210> :

CMDh referral procedure Y/N :

Day 60 of CMDh procedure :

**CMS**

Before start :

Withdrawal during procedure :

Reason withdrawal :

**Renewal**

<Common Renewal date :      >

*In case a renewal has already been granted*

<Common Renewal date : A renewal with unlimited validity was granted in <Month YYYY>, common renewal date: <DD Month YYYY>. In case the new CMSs require an additional renewal it is proposed to have a shortened renewal 5 years after the end of this repeat use MRP>

Number of reports attached :

# **II Repeat use Procedure****(s)**

*If not applicable, please state N/A*

Procedure number :

**Timetable**

Start procedure :

Day 90 :

CMDh referral procedure Y/N :

Day 60 of CMDh procedure :

**CMS**

Before start :

Withdrawal during procedure :

Reason withdrawal :

# **III Variation****(s)**

For type IA and IB variations, reference is made to CTS. Only type II variations are listed.

<There have been no type II variations submitted/approved.>

<Procedure number :

Variation scope :

End of the procedure date :

Outcome :

Number of reports attached :

Procedure number :

Variation scope :

End of the procedure date :

Outcome :

Number of reports attached :      >

# **IV Renewal****(s)**

*If not applicable, please state N/A*

Procedure number :

End of the procedure date :

Outcome : The renewal was granted <with unlimited validity><for a period of <X> years. The next renewal is due for:      >

Number of reports attached :

# **V PSUR(s)**

<The following PSURs have been assessed:

PSUSA procedure number :

Outcome :

PSUSA procedure number :

Outcome :      >

*If applicable (when a PSUR worksharing or a PSUR was assessed outside a PSUSA procedure):*

<Period PSUR :

Number of reports attached :      >

<No PSURs have been assessed>

*Use the below statement in case a substance is 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.

*For MAA with a substance not listed in the published EURD list, please use one of the below statements.*

<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>.

# **VI Conditions for marketing authorization**

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

*If not applicable, please state N/A*

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**

*If not applicable, please state N/A*

*All conditions and specific obligations in the RMS and current CMSs falling under Article 21a, 22a or 22 should be discussed and included. It should also be discussed when the product is subject to additional monitoring in the RMS and current CMSs and therefore requires a black symbol in their product information.*

*If considered appropriate, the following conditions should be mentioned/discussed:*

*-Risk minimisation measures including educational material*

*-Post-authorisation safety or efficacy studies*

*-PSUR cycle*

*-Approval under exceptional circumstances with annual reassessment*

*-Product subject to additional monitoring.*

*The following wording based on annex II for centrally authorised products (QRD template human product information) can be used:*

* **<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** |
| --- | --- |
|  |  |
|  |  |
|  |  |

# **VII Art 61(3) Notification(s)**

For art 61(3) Notifications reference is made to CTS.

# **VIII Assessment of similarity with authorised orphan medicinal product(s) under market exclusivity**

**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.*

*The following text can be used for this subsection*

**<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.>

# **IX Product information**

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

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

# **X Additional information**