**Reference Member State**

**End of Renewal Procedure**

**1. This document is sent by**

|  |  |
| --- | --- |
| RMS |  |
| Contact point project team leader  Phone  E-mail address | 🕿       🖳 |
| Date/Day of procedure |  |

**2. Product related information**

|  |  |
| --- | --- |
| Name of the product in the RMS |  |
| Name of the active substance |  |
| MAH |  |
| Procedure number |  |
| Common renewal date |  |

**3. Recommendation**

**a)** The product is:

Renewable

Not Renewable

**b)** Validity of renewal:

The renewal can be granted with unlimited validity

One additional five-year renewal is required

*<for standard renewal>*

**c)** SmPC, PL or labelling:

Renewal of the product was agreed via the standard renewal procedure and no changes to the product information were made during the procedure. In accordance with Article 23 Directive 2001/83/EC the MAH is reminded of the obligation to keep the product information up to date with the current scientific knowledge, including the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26, and/or the CMDh webpage.

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

N/A – Renewal of the product was agreed via the standard renewal procedure; thus, the conditions have not been reviewed.

**4. Attached documents**

The product information has not been updated during the renewal procedure. No product information is attached.

*<For expanded renewal>*

**c)** Variation to amend SmPC, PL or labelling:

During the renewal procedure it was agreed that the MAH will submit a variation to amend the SmPC, PL or labelling

Yes

No

**d)** PSUR:

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.
* For medicinal products that do not fall within the categories waived of the obligation to submit routine PSURs by the revised pharmacovigilance legislation, the MAH should follow the DLP according to the EURD list.

The frequency of PSUR submission should be revised to <xxx>. The next PSUR should therefore cover the period from <dd.mm.yyyy> to <dd.mm.yyyy> and be submitted within <70> <90> days of the data lock point. The list of European Union reference dates (EURD list) is updated accordingly.

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

There are no **conditions** to the Marketing Authorisation.

The following conditions to the Marketing Authorisation have been lifted as a result of the renewal assessment:

The following previously agreed conditions to the Marketing Authorisation remain valid and are still outstanding:

The following **new conditions** to the Marketing Authorisation have been agreed as a result of the renewal assessment:

**f)**In the case of approval of a new or updated RMP during the renewal procedure

The MAH 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 by using the form published by CMDh (http://www.hma.eu/464.html).

**4. Attached documents**

The product information has not been updated during the renewal procedure.

The product information has been updated during the renewal procedure. Please find attached the following documents (both clean and track-change versions):

Approved SmPC

Approved PL

Approved labelling

The MAH is reminded to submit national translations of the SmPC, PL and labelling and mock-ups (if applicable) to the RMS and CMSs taking into consideration the recommendations of the Best Practice on the submission of high quality national translations no later than 7 days after the procedure is closed.