# Reference Member State
# End of Procedure

## 1. This document is sent by:

| | |
|---|---|
| RMS | DK |
| Contact point project team leader (name/E-mail/phone) | ☎<br>💻 |
| Date/Day of procedure | 20 June, 2018 / Day 58 |

## 2. This document concerns:

| | |
|---|---|
| Name of the product in the RMS | Dexmedetomidine Ever Pharma |
| Name of the active substance | Dexmedetomidine |
| Applicant | EVER Valinject GmbH, Austria |
| Procedure number | DK/H/2619/001/E/001 |

## 3. Conclusions

Based on the final positions of the CMS(s) and the discussions thereafter it is concluded that all Concerned Member States are in agreement with the RMS X

There is disagreement between the conclusions of the RMS and the CMS(s). Therefore, the matter is forwarded to the Co-ordination Group ☐

## 4. Attached documents

Please find attached:

the approved SmPC X

the approved PL X

the approved labelling X

proposed changes to SmPC, PL and labelling* X

list of commitments X

the approved specifications X

* *please refer to commitment*

## 5. Renewal Date/ PSUR-cycle/Conditions to Marketing Authorisation pursuant to Article 21a or 22 of Directive 2001/83/EC

### Renewal

The common renewal date is 01-06-2022.

### Risk management plan (RMP)

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

### PSUR

The present application for Dexmedetomidine Ever Pharma containing dexmedetomidine hydrochloride is authorised under Article 10(3) of Directive 2001/83/EC (hybrid) (New indication) and therefore, **per default submission of PSURs are required.**

Active substance is listed in the published EURD list

X 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.

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

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

## 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 5 days after the procedure is closed.