

EVER Valinject GmbH  
Oberburgau 3  
4866 Unterach am Attersee  
Austria

29.05.2018

To the National Agencies in the following countries:  
Croatia, Hungary, France, Slovenia, Portugal

**Subject: Response to Questions Day 30**  
**Application for Marketing Authorisation of**  
**Dexmedetomidine EVER Pharma 100 micrograms/ml concentrate for solution for infusion**  
**DK/H/2619/001/E/001**

**CESP number: 712613**

Dear Madams and Sirs,

We are pleased to submit our Response to Questions (Day 30) for our Application for a Mutual Recognition Procedure which details are as follows:

**Name of the medicinal product(s) (in the RMS):** Dexmedetomidine EVER Pharma  
**Pharmaceutical form(s) and strength(s):** Concentrate for solution for infusion (100 micrograms/ml)  
**INN/active substance(s):** Dexmedetomidine Hydrochloride  
**ATC Code(s):** N05CM18

**Legal Basis of the Application(s):**

*When appropriate, please indicate:*

- |   |   |  |
|---|---|--|
| - Use of European Reference Medicinal Product                               | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No            |
| - If the strength(s) of the Reference MP differs between RMS/CMS            | <input type="checkbox"/> Yes            | <input checked="" type="checkbox"/> No |
| - If the pharmaceutical form(s) of the Reference MP differs between RMS/CMS | <input type="checkbox"/> Yes            | <input checked="" type="checkbox"/> No |
| - If the indication(s) of the Reference MP differs between RMS/CMS          | <input type="checkbox"/> Yes            | <input checked="" type="checkbox"/> No |

You will find enclosed the submission dossier as specified hereafter:

- eCTD format, Sequence number: 0018
- We confirm that all future submissions for this specific product will be submitted in this same format.
- The eCTD has passed the applicant's internal technical validation (all P/F criteria passed and all BP criteria have been fulfilled up to our best knowledge) using eCTDmanager, Extedo, Version 4 – SP8 (4.0.8.058).

We confirm that the electronic submission has been checked with an up-to-date and state-of-the-art virus checker.

- The relevant fees have been paid.

List of Changes made in the application:

- In M1.2 the confirmation of the International Trade Mark EVER Pharma has been added to account for the changes desired by the CMS SI.
- In M1.Responses to Questions a commitment letter has been included stating the three commitments made:
  - o Variation of the PIL to account for the changes desired by the CMS SI
  - o Variation of the SmPC to account for the changes desired by the CMS SI
  - o Variation of the RMP to account for the changes desired by the CMS HU

We, EVER Valinject GmbH, hereby certify that the dossier submitted to the RMS and CMS(s) are fully identical.

- There are, however, some different **national** documents (<cover letter><application form><specific national requirements>) that are submitted to the relevant RMS/CMS only, **outside** the eCTD dossier
- There are, however, some different **national** documents (<cover letter><application form><specific national requirements>) that are submitted to the relevant RMS/CMS only, **within** the eCTD dossier

Yours sincerely,

Regulatory Affairs

Phone:

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