

EVER Valinject GmbH
Oberburgau 3
4866 Unterach am Attersee
Austria

07.05.2018

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

**Subject: Submission to Questions during Validation of Application Dossier(s) for Marketing Authorisation of
Dexmedetomidine EVER Pharma 100 micrograms/ml concentrate for solution for infusion
DK/H/2619/001/E/001**

CESP number: 699522

Dear Sirs,

We are pleased to submit our Application Dossier(s) 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: 0017
- 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.
- The Risk Management Plan in module 1.8.2 is similar to the one <submitted><approved> in the procedure DK/H/2619/001/DC.

List of Changes made in the application:

- In M1.2 the eAF has been updated to account for the changes desired by the CMSs SI and HR.
- In M1.2 Annex 5.19 has been amended on request of the CMS HR.
- In M1.2 the missing 5.4 PoA for Mirjam Lutz of Ever Valinject has been added.
- In M1.5.2 the Annex 1 and Annex 2 have been replaced by the correct versions. In particular, as the reference medicinal product has been changed during the validation phase of the DCP from the Polish to the Czech MA the Annexes 1 and 2 are now depicting the Czech SmPC and comment of the Czech authority, respectively.

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

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Yours sincerely,

Regulatory Affairs

Phone:

Email address: @everpharma.com

Email address for technical validation issues: @everpharma.com