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 ☑ Yes ☐ No
- If the strength(s) of the Reference MP differs between RMS/CMS ☐ Yes ☑ No
- If the pharmaceutical form(s) of the Reference MP differs between RMS/CMS ☐ Yes ☑ No
- If the indication(s) of the Reference MP differs between RMS/CMS ☑ Yes ☐ 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).
- 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:
  - Variation of the PIL to account for the changes desired by the CMS SI
  - Variation of the SmPC to account for the changes desired by the CMS SI
  - Variation of the RMP to account for the changes desired by the CMS HU

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

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.

Yours sincerely,

Regulatory Affairs
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Email address for technical validation issues: @everpharma.com