EVER Valinject GmbH
Oberburgau 3
4866 Unterach am Attersee
Austria

12.03.2018

ANSM
DMFR – PGF-AMM-930 (this is the code for MA hybrid / generic applications)
143-147, Bd Anatole France
F-93285 Saint-Denis cedex
France

Subject: Submission 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: 661848

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	☒ 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: 0015

☒ 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 approved in the procedure DK/H/2619/001/DC.

The local PV person, located in France, is:

Tel:
Fax:
e-mail:

The local exploitant is:

☒ 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