Mylan

Applicant: **Mylan S.A.S.**
117 Allée des Parcs
69800 Saint Priest
France

Wednesday, June 21, 2017

To the RMS and all CMS
(Please see Appendix for a detailed list of the address of RMS and CMS)

Subject: **Submission of an Application Dossier for Marketing Authorisation of Dexmedetomidine Mylan 100 µg/ml, concentrate for solution for infusion.**

- Marketing Authorisation Application Number: DE/H/5280/001/DC
- CESP Number: 507371

Dear Sirs,

We are pleased to submit our Application Dossier for a Decentralised Procedure which details are as follows:

Name of the medicinal product (in the RMS):	Dexmedetomidin Mylan 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung
Pharmaceutical form and strength:	Concentrate for solution for infusion – 100 µg/ml
INN/active substance:	Dexmedetomidine Hydrochloride
ATC Code:	N05CM18

Legal Basis of the Application: Article 10(1) generic application.

When appropriate, please indicate:

- Use of European Reference Medicinal Product: **Dexdor**
- 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: **0000**

☐ NeeS format
Submission number (if used):

Number of media units per application and number of copies are detailed in Appendix.

Mylan

APPENDIX

Detailed RMS and CMS address list and enclosed documentation

Member states	Agency address	Submission way
AT	**Austrian Medicines and Medical Devices Agency** Traisengasse 5 A-1200 Wien	CESP*
DE	**Federal Institute for Drugs and Medical Devices (BfArM)** Kurt-Georg Kiesinger-Allee 3 D-53175 Bonn	CESP*
DK	**Danish Health and Medicines Authority** Axel Heides Gade 1 DK-2300 Copenhagen	CESP*
FI	**Finnish Medicines Agency** P.O. Box 55 (Mannerheimintie 103b) FIN-00301 Helsinki	CESP*
FR	**Agence nationale de sécurité du médicament et des produits de santé (ANSM)** 143-147 bd Anatole France FR-93285 Saint-Denis Cedex	CESP*
IT	**Agenzia Italiana del Farmaco (AIFA)** Via del Tritone, 181 IT-00187 Roma	CESP*
NO	**The Norwegian Medicines Agency (NOMA)** Sven Oftedalsvei 8 N-0950 Oslo	CESP*
PL	**President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products** 181 C Aleje Jerozolimskie street PL-02-220 Warsaw	CESP*
SE	**Medical Products Agency** Dag Hammarskjölds väg 42 / Box 26 SE-751 03 Uppsala	CESP*

** In parallel to the submission through CESP, signed cover letter/AF and CD are sent depending on national requirements.*