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.

☒ 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:

- **Lorenz eValidator - Version 5.9.**

☒ 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 dispatch list is appended (to RMS only).
☒ The dispatch list will be forwarded to the RMS as soon as the application has been submitted to all CMS.

☒ We, Mylan S.A.S., hereby certify that the dossier submitted to the RMS and CMS(s) are fully identical.

☒ There are, however, some different **national** documents (specific national requirements) that are submitted to the relevant RMS/CMS only, **outside** the eCTD dossier.

☒ There are, however, some different **national** documents (specific national requirements) that are submitted to the relevant RMS/CMS only, **within** the eCTD dossier.

Yours sincerely,


Person in charge of the dossier:

*Senior Manager*
*EMEA Institutional Regulatory Affairs*
*tel:*
*e-mail:*

*Manager*
*EMEA Institutional Regulatory Affairs*
*tel:*
*e-mail:*


Email address for technical validation issues:

*Mylan S.A.S. (only) certifies the accuracy of the English version of the application form and cover letter. Thus, any mistake in the translated cover letter or application form cannot engage Mylan S.A.S.*

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**APPENDIX**

**Detailed RMS and CMS address list and enclosed documentation**

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

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