

EVER Valinject GmbH
Oberburgau 3
4866 Unterach am Attersee
Austria

30.05.2018

To the Danish Medicines Agency
Medicines Licensing

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

Subject: Commitment letter to the Marketing Authorisation of
Dexmedetomidine EVER Pharma 100 micrograms/ml concentrate for solution for infusion
DK/H/2619/001/E/001

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

The marketing authorisation relating to the above product is subject to the following commitments.

The marketing authorisation holder EVER Valinject GmbH agrees to the following commitments resulting from the above procedure and confirms that the commitments will be fulfilled through the submission of the stated data within the specified timeframe.

The list of agreed commitments				
No.	Commitment identification	Action need to be taken to fulfil the commitment *	Deadline	Requested by MS
1.	Package leaflet	Variation submission	1 month after approval of procedure	
2.	Summary of product characteristics	Variation submission	1 month after approval of procedure	
3.	Update of RMP	Variation submission	3 month after approval of procedure	

**(e.g. variation submission, study submission, supplementary data submission)*

The marketing authorisation holder EVER Valinject GmbH confirms that if they are unable to fulfil the commitment or to provide the necessary data within the specified timeframe, they will consult with the RMS.

Yours sincerely,

Regulatory Affairs

Phone:

Email address:

Email address for technical validation issues: