Answers to D 30 comments
Dexmedetomidine EVER Pharma 100 micrograms/ml Concentrate for solution for Infusion

DK/H/2619/001/E/001

MODULE 1		
1. (CMS)	Annex 5.19: The proposed name Deksmedetomidin EVER Pharma 100 mikrogramov/ml koncentrat za raztopino za infundiranje is not acceptable for SI. The Applicant should submit Proof of establishment of trademark "EVER Pharma" or in case of proposing name composed of INN + MAH, MAH should be amended to be in line with MAH, stated in Annex 5.3/AF 2.4.1.	
	EVER Response: The applicant considers the product name Dexmedetomidine EVER Pharma to be appropriate as the Directive 2001/83/EC states in Art. 1 no. 20 that the name of the medicinal product may (i.a.) be "a common or scientific name accompanied by a trade mark". EVER Pharma is a registered trade mark. Thus, the same convention is applied for all medicinal products of EVER Valinject GmbH.	**Please refer to certificate on registered trade mark (eCTD 1.2)**
2. (CMS)	The list of safety concerns in the RMP submitted for this hybrid application is not aligned with the safety concerns in the latest RMP of the reference product. Please submit a variation within three month following the end of this RUP to update the RMP.	
	EVER Response: The applicant commits to submit a respective variation within the desired period.	**Please refer to commitment letter**

SmPC		
Amendments to the proposed SmPC are requested. Requested changes are incorporated into the SmPC with the regulatory assessor's comments in a boxed area within the text.		
1. (CMS)	4.4 Special warnings and precautions for use -Monitoring Based on the indications, [Nationally approved name] is intended for use in an intensive care setting, operating room and during diagnostic procedures (stylistic matter): -Subheading Elderly should be written as a new paragraph	
	EVER Response: - The applicant amended the respective section. - The applicant added the requested sub-heading.	**Please refer to SmPC (Annex), working documents and commitment letter**
2. (RMS)	Section 2: Sodium is listed in the Annex to the Guideline on the excipients in the label and package leaflet of medicinal product for human use and should therefore be included in section 2, e.g.: Excipient with known effect: Each ml of concentrate contains less than 1 mmol (approximately 3.5 mg) sodium. **Please refer to updated SmPC**	
	EVER Response: The text of section 2 was amended, and text passage on sodium was added as proposed by the RMS.	**Please refer to SmPC (Annex), working documents and commitment letter**

PIL		
1. (CMS)	<u>Section 2</u> Content of sodium should be in line with Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'	
	EVER Response: The PIL was updated to reflect the changes introduced in the SmPC.	**Please refer to PIL (Annex), working documents and commitment letter**
2. (CMS)	<u>Section 4</u> Frequency convention should be in line with last revision of QRD template	
	EVER Response: The PIL was updated to reflect the changes introduced in the SmPC.	**Please refer to PIL (Annex), working documents and commitment letter**