

**De :** <@-h.eudra.org>  
**À :** @-h.eudra.org; @-h.eudra.org; @-h.eudra.org; @-h.eudra.org; Fr-h  
**CC :** @everpharma.com  
**Date :** 25/05/2018 12:12  
**Objet :** DK/H/2619/001/E/001 - Dexmedetomidine Ever Pha - - Day 30  
**Pièces jointes :** header.txt

Dear Colleagues,

has one additional comment:

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.

Kind regards,

Coordination Department National Institute  
of Pharmacy

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