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CC : "" <@dkma.dk>
Date : 12/06/2018 09:38
Objet : RUP - Revised SmPC Day 50 - DK/H/2619/001/E/001 - Dexmedetomidine - DK - RMS updated AR - Day 48
Pièces jointes : Dex SPC_v1_ev1_1.2_cl_RUP d48.docx; Dex SPC_v1_ev1_1.2_tr_RUP d48.docx; common-responses-commitment.pdf

Dear colleagues,

The applicant has provided revised SmPC (working document) to align with RMS's Day 48 AR. Please find the new draft attached inclusive a copy of the commitment.

Day 50 RMS comments: The outstanding day 48 concern raised by RMS is considered solved.

CMS's are kindly requested to provide Day 55 comments/ final positions prior/by 17 June at the latest and update CTS accordingly, thank you.

Remaining time table:
Day 55: 17.5 - final CMS com (Sunday)
Day 60: 22.6 - EoP (Friday)

Additional comment from the applicant:

Note that there is a minor mistake in the updated RMS AR, page 2; the authorisation holder in RMS is EVER Valinject GmbH not EVER Neuro Pharma:

[cid:image003.jpg@01D40231.28FAB8C0]

Official responses: After EoP, a final response seq. will be provided to all member states.

Kind regards,

Regulatorisk Projektleder
Regulatory Project Leader
T (dir.)
T (m.)

Lægemiddelstyrelsen
Lægemiddelgodkendelse
Danish Medicines Agency
Medicines Licensing
T

[LMST_auto_stor]<<http://lmst.dk/>>

Fra:
Sendt: 8. juni 2018 12:37
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Emne: DK/H/2619/001/E/001 - Dexmedetomidine - DK - RMS updated AR - Day 48

Dear colleagues,

Please find attached RMS's Day 48 - Updated assessment report for the am RUP procedure.

There are minor outstanding concerns to be solved prior a final conclusion. CMS's are kindly requested to provide final comments/positions by 17 June at the latest and update CTS accordingly, thank you.

Remaining time table:
Day 55: 17.5 - final CMS com
Day 60: 22.6 - EoP

Kind regards,

Regulatorisk Projektleder
Regulatory Project Leader
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