De :
À :
CC :
Date : 29/06/2022 13:28
Objet : DE/H/6991/001/DC - Trientine Waymade 200mg - Day 195 FR no comments

Dear colleagues, dear ap^plicant,

Please note that France fully endorses D180 AR and has no further comments regarding the above mentionned procedure.

Kind regards,

Evaluateur coordonnateur scientifique et réglementaire
Pôle AMM2 - Direction des autorisations (DA)
Tel :
ANSM - Agence nationale de sécurité du médicament et des produits de santé
143/147 bd Anatole France - 93285 Saint-Denis

>>> @bfarm.de> 23/06/2022 16:18 >>>
Dear Colleagues,
Dear Applicant,

Please find attached the Day 180 DAR for the above mentioned DC procedure. These documents are also provided in CTS for download.

From RMS´s point of view the procedure is recomended for approval,therefore we kindly ask the CMS to send us your final positions till 05 July 2022 (Day 195). If you have none final positions/ D195 comments, please be so kind and note this in CTS.

RMS note: According to theCMDh
(https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/CMDh_pressreleases/2022/CMDh_press_release_-_February_2022.pdf) decision (February 2022) it is required that applicants submit their responses in the DCP with astandardised template
(https://www.hma.eu/human-medicines/cmdh/templates/assessment-reports/dcp-ar/comments.html) .Thenew procedure for applicant‘s responses
(
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Applicant_Response/CMDh_091_2003_Rev.9_2022_01_clean_-_Applicants_response_document_in_MRP_DCP_for_MAAs.pdf) is effective from April 1, 2022.

Important notice:
In line with the CMDh guidances the applicant should keep data synchronisation between module 3 and module 1.2. In this respect, the applicant should submit as part of the response document an updated application form, each time the information is modified.
Only manufacturing sites that are included in Module 1.2 can be considered for issuing the MA decision.
Here it should be noted that a brief description of functions performed for each manufacturer(s) concerned is available in the dropdown field based on a controlled dictionary.
The applicant is requested to ensure that the correct functions are assigned separately for each manufacturer in line with Module 3.
For details, please refer to the User guide for the electronic application form for a Marketing Authorisation published by the CMDh.

With kind regards/ Mit freundlichen Grüßen
On behalf of BfArM / Im Auftrag

Due to the current IT security policy of BfArM, all emails containing older MS Office doc, xls and ppt file formats will be rejected. Please make sure to attach the current MS Office file formats docx, xlsx, pptx only. Many Thanks.
Aufgrund der aktuellen IT-Sicherheitspolitik des BfArM werden alle E-Mails mit doc, xls und ppt Dateianhängen zurückgewiesen. Bitte stellen Sie sicher, dass Sie nur noch die aktuellen MS-Office-Formate docx, xlsx, pptx als Anhang verwenden. Vielen Dank.

Regulatory Affairs/ Verfahrensmanagement
Licensing Division 2/ Abteilung Zulassung 2
Federal Institute for Drugs and Medical Devices/ Bundesinstitut für Arzneimittel und Medizinprodukte

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