HorStem

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued / amended on	Product Information affected [2]	Summary [3]
EMEA/V/C/004265/REC/011	Post marketing surveillance study (part of risk management plan put in place at the time of initial authorisation)	09/11/2023		Annex II	The Marketing Authorisation Holder (MAH) presented the results of a post marketing surveillance study (PMSS) in order to further substantiate the safety and efficacy of HorStem. The obligation put on the MAH to improve and validate the potency assay was fulfilled and evaluated by CVMP prior to the first batch release. In the PMSS, only the batches of HorStem that were tested with the improved potency assay were used. For the collection of data from the PMSS, veterinarians were requested to fill in a questionnaire for each patient receiving HorStem. A total of 144 questionnaires were sent to veterinarians, from which 70 questionnaires were considered valid for safety evaluation and 51 questionnaires for efficacy evaluation. The results of the PMSS were based on a relatively low number of animals but nevertheless some conclusions could be reached. With regards to the safety of HorStem, CVMP concluded that all suspected adverse events reported in the PMSS were already known and described adequately in the product information (the SPC and package leaflet). The

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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					efficacy findings were not inconsistent with the efficacy data evaluated during the initial marketing authorisation application. In summary, the data presented in the PMSS did not change the positive benefit-risk evaluation of HorStem. Going forwards, as part of the standard pharmacovigilance requirements, any new safety or efficacy issue for HorStem must be reported to the EMA by the marketing authorisation holder for assessment of the continued positive benefit-risk balance.
IB/0002	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	13/10/2021		SPC	The Agency accepted the variation to extend the shelf life of the finished product from 14 days to 21 days.
IAIN/0001/G	This was an application for a group of variations: A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.1 - Administrative change - Change in the name and/or address of the MAH A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	26/07/2021		SPC, Annex II, Labelling and PL	The Agency accepted the variation to change the name of the marketing authorisation holder, and the name of the manufacturer responsible for the active substance and finished product.