Veterinary Medicines Directorate

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Post Authorisation Assessments

Osphos 51 mg/ml Solution for Injection for Horses

Vm 10434/4086

•	09 November 2023	Substantial changes in an updated version of an ASMF.
•	19 August 2022	Change in the address of a manufacturer of the active substance where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier. Addition of an external test laboratory for the active substance.
•	06 May 2022	Minor changes to an approved test procedure of the finished product.
•	11 February 2021	Renewal – UK as CMS.
•	06 July 2020	Update to the Active Substance Master file (ASMF).
•	22 November 2019	Change to the manufacturing process of the finished product.
•	27 June 2019	Change to in-process tests applied during the manufacture of the finished product.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	01 August 2018	Change in the RMS from UK to IE.
•	20 December 2017	Replacement of a manufacturer responsible for batch release including batch control/testing. Minor change in the manufacturing process of an immediate release solid oral dosage form Addition of a manufacturing site of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product
•	05 December 2017	Change in the manufacturer used in the manufacture of the active substance where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
•	23 November 2017	Addition of warnings to sections 4.5, 4.6 and 4.8 of the SPC.
•	17 November 2016	To increase the shelf life of the finished product from 2 years to 3 years.