Veterinary Medicines Directorate

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Post Authorisation Assessments

Deccox 6% w/w Premix for Medicated Feeding Stuff for Sheep and Cattle

Vm 42058/4032

•	01 July 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	08 April 2021	Deletion of manufacturing site for a manufacturer responsible for batch release. Deletion of manufacturing site for a site where batch control takes place.
•	24 November 2020	Increase in batch size from 1020 kg to 1520 kg of the finished product.
•	13 August 2020	Replacement of a site where batch control/testing takes place.
•	10 June 2020	Change in testing frequency of specification parameters for an intermediate in the manufacturing process of the active substance.
•	09 March 2020	Addition of a test procedure for the finished product.
•	12 November 2019	Change in the address of the marketing authorisation holder from Zoetis UK Limited 5th Floor, 6 St. Andrew Street London EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building Springfield Drive Leatherhead Surrey, KT22 7LP.
•	11 July 2019	Change in the SPC, labelling or package leaflet due to new data.
•	08 May 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	23 April 2018	Change in RMS from UK to ES.
•	05 April 2018	Update to the SPC following the implementation of the new template.
•	January 2018	To update section 6.2 of the SPC to V 8.1 of QRD template.
•	06 July 2016	Changes in the manufacturing process of the active substance
•	01 April 2015	Change in test procedure for the finished product.
•	03 December 2014	Minor changes to the manufacturing process of the active substance. Increase to the batch sizes used in the manufacturing process of the active substance.
•	13 November 2013	Renewal.

•	16 August 2013	Change of distributor and MAH from Pfizer Limited to Zoetis UK Limited.
•	28 November 2011	Batch control.
•	21 November 2011	Batch control
•	10 August 2011	Change of MAH from Alpharma Animal Health BVBA to Pfizer Ltd.
•	10 June 2009	To change the batch size of the active ingredient including changes to the in-process controls and specification.
•	14 August 2008	Mutual recognition procedure.
•	28 December 2006	Changes to bring the SPC and product literature in line with new regulations.
•	10 May 2006	Change of address of the MAH.
•	09 September 2005	Change in a test procedure for the active substance.
•	07 September 2005	Change to the specification for the active substance.
•	03 December 2004	Change of product name from Decoquinate to Deccox.
•	22 October 2004	Change of marketing authorisation holder (MAH) name and address from Alpharma As to Alpharma Animal Health BVBA.