Veterinary Medicines Directorate

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Post Authorisation Assessments

Bravoxin 10 Suspension for Injection for Cattle and Sheep

Vm 01708/4585

•	01 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	17 January 2019	Replacement of a manufacturer responsible for batch release of the finished product. Addition of a manufacturer responsible for batch release of the finished product.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	21 February 2018	Change in the RMS from UK to DE.
•	26 January 2017	Changes in test procedure for the finished product. Changes in the manufacturing process of the active substance. Changes in the manufacturing process of the active substance.
•	16 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	04 December 2014	Update to the DDPS.
•	23 May 2014	Renewal procedure – UK as RMS
•	15 May 2014	Change in the name and address of the manufacturing authorisation holder.
•	16 August 2013	Change of starting material. Removal of Target animal batch safety test. Changes in manufacturing process of active substance. Changes of in-process control tests.
•	20 December 2011	To increase font size for all packaging and reduce text on labels to improve legibility.
•	20 December 2011	To add a new distributor in Northern Ireland.
•	20 December 2011	To transfer the MA holder from Schering-Plough Ltd. to Intervet UK Ltd.
•	04 August 2011	To change the name of the MAH in Portugal.
•	08 April 2011	Introduction of a new Pharmacovigilance system.
•	30 November 2010	To adjust the end of the shelf life specification of thiomersal.
•	28 October 2010	To change the supplier of the starting material to comply with Ph.Eur.
•	08 July 2010	To submit a new Ph. Eur certificate of suitability.
•	14 August 2009	To change the Marketing Authorisation Holder in France.

•	17 March 2009	To change the legal category.