Veterinary Medicines Directorate

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Post Authorisation Assessments

Bovilis Bovivac S

Vm 01708/4415

•	08 October 2021	Changes in the manufacturing process of the active substance.
•	15 June 2021	Change in the manufacturing process of the finished product.
•	27 April 2021	Changes to the labelling and package leaflet.
•	27 January 2021	Change in the invented name of the veterinary medicinal product from Bovivac S to Bovilis Bovivac S in the UK only.
•	06 January 2021	Deletion of a non-significant specification parameter of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product. Addition of a site where batch control/testing takes place.
•	01 October	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	29 March 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	11 September 2018	Submission of a new Ph. Eur. TSE certificate of suitability for a starting material from a new approved manufacturer.
•	09 February 2018	Change in the RMS from UK to IE.
•	25 November 2015	Approval of revised mock-ups
•	03 May 2012	Change to in-process tests during the manufacture of the active substance.
•	30 March 2012	Change of name of a manufacturer of the finished product, including batch release.
•	17 August 2011	Change to starting materials for the manufacture of the active substance.
•	06 February 2009	Addition of a manufacturing site for part of the manufacturing process.
•	25 June 2008	Minor changes to the labelling.
•	15 August 2006	Renewal.
•	20 May 2005	Change of distributor.

•	29 August 2002	Change to shape of container.
•	29 August 2002	Addition of a manufacturer and change to the manufacturing site responsible for batch release site.
•	10 June 2002	Mutual recognition – UK as RMS.
•	07 June 2002	Increase of shelf life from 12 months to 24 months
•	21 January 2002	Change of supplier of an excipient.
•	03 September 2001	Change of distributor.
•	31 August 2000	Change to the manufacturing process of the active substance.
•	14 March 2000	Change to quality control procedures.
•	28 February 2000	Change of name and address of MAH from Hoechst Roussel Vet Ltd to Intervet UK Ltd.