Veterinary Medicines Directorate

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Post Authorisation Assessments

Bovilis Bovivac S Suspension for Injection for Cattle

Vm 06376/3018

26 May 2026	Increase in the maximum batch size for S. typhimurium and S. dublin antigens. Addition of alternative primary packaging components. Change to the in-process control test for total cell count for S. typhimurium and S. dublin. Alternative in-process control test for sterility to align with Ph. Eur. requirements for S. typhimurium and S. dublin. Change to the in-process control test for formaldehyde for S. typhimurium and S. dublin. Change to the finished product control test for potency and replacement of finished product control SOPs. Replacement of finished product control tests for aluminium and thiomersal content determination. Increase in the maximum finished product batch size. Update of the country of origin for the animal materials used in the culture media of S. typhimurium and S. dublin. Updates to the finished product manufacturing process. Update to the antigen production process for S. typhimurium and S. dublin. Replacement of reference sera used for the S. dublin potency test. Addition of MSD AH Danube Biotech GmbH, Krems, Austria as antigen production site for S. Typhimurium and S. Dublin. Addition of MSD AH Danube Biotech GmbH, Krems, Austria as blending and filling site for the finished product.
March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
11 August 2025	To remove the obsolete in-process control test for specific gravity for S. Typhimurium and S. Dublin.
08 January 2025	Change in legal entity of MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands
21 May 2024	Alignment of the SPC/QRD text with the newest EU version 9.0 QRD template and GB National SPC/QRD template.
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.