Veterinary Medicines Directorate

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Post Authorisation Assessments

Bovilis Bovipast RSP: Vm 01708/5069

•	14 April 2021	Changes to the labelling and package leaflet.
•	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.
•	17 July 2020	Change in the composition (excipients) of the finished product. Change in the manufacturing process of the finished product.
•	15 May 2019	Replacement of a site where batch control/testing takes place.
•	25 January 2019	Change in the specification limits of the finished product. Changes in the summary of product characteristics (SPC) and package leaflet to implement the outcome of a PSUR assessment.
•	17 October 2018	Change in RMS from UK to IE.
•	15 October 2018	Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Change in the manufacturer of the active. Replacement of a site where testing takes place. Changes in the manufacturing process of the active substance. Addition of a manufacturing site of the finished product.
•	12 November 2015	The addition of an alternative sterility test method for the finished product. Replacing of a preservative.
•	17 August 2012	Grouped variation to: change a sterility test, change a control test, remove a control test, delete an identity test, delete a microbiological test, remove an identity test, and to change the sterilisation process of excipients.
•	30 March 2012	Change in the name and address of the manufacturer of the active substance.
•	30 March 2012	Change in the name and address of the manufacturer of the finished product.
•	06 September 2011	Changes in the test procedure for the finished product.
•	08 April 2011	Changes in the test procedure for the finished product.
•	03 February 2010	To introduce an alternative incubation temperature for BRSV propagation.
•	03 February 2010	Alternative use of a serum-free medium for MDBK cells.
•	03 February 2010	Introduction of and end of shelf-life date for an excipient.

•	17 December 2009	Minor change to finished product test procedure.
•	17 December 2009	Minor change to finished product test procedure.
•	09 October 2009	Renewal procedure.
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•	01 October 2009	Minor change to finished product test procedure.
•	01 September 2009	Change of Marketing Authorisation Holder name and address.
•	03 December 2008	To update the description of the production process.
•	20 February 2008	Deletion of a manufacturing site.
•	13 June 2007	To include compatibility between viral markers.