Veterinary Medicines Directorate

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Post Authorisation Assessments

Bovidec Suspension for Injection

•	14 April 2021	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	02 March 2020	Submission of a new Ph. Eur. certificate of suitability for starting material (used in manufacturing process of active) from an already approved manufacturer.
•	22 October 2019	Changes in the manufacturing process of the active substance.
•	20 June 2019	Approval of mock-ups.
•	10 December 2018	Introduction of a new pharmacovigilance system.
•	22 November 2018	Change of MAH, from Elanco Europe Ltd., Lilly House, Priestley Road, Basingstoke, RG24 9NL, United Kingdom to Benchmark Animal Health Ltd., Benchmark House, 8 Smithy Wood Drive, Chapeltown, Sheffield, South Yorkshire, S35 10N, United Kingdom
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	06 December 2016	Minor change to an approved test procedure for an excipient.
•	13 January 2016	Change of Marketing Authorisation Holder from Novartis Animal Health UK Ltd to Elanco Europe Ltd. Change in distributor details.
•	16 August 2013	Updates made to the product literature not connected with the SPC.
•	24 May 2013	Change of manufacturing site for the finished product, including quality control, primary and secondary packaging.
•	07 November 2012	Change of MA holder address, change of name and address for the finished product manufacturer, change of name for the manufacturer responsible for batch release and change of name of the manufacturer of the active substance.
•	22 August 2012	Updates to Section 4.2 of the SPC.
•	25 September 2008	Change to limits during the manufacturing process.
•	29 August 2008	Change to update the legal category from POM to POM-V and changes to bring the SPC and Product Literature in line with new legislation.
•	16 February 2006	Minor changes to the manufacturing process for the active substance.
•	21 December 2005	Renewal.
•	14 December 2005	Change to in-process controls applied during the manufacture of the finished product
•	17 March 2005	Change in the manufacturing process of the active

		substance.
•	19 May 2004	Addition of a supplier of an excipient.
•	30 September 2003	Minor changes to the SPC.
•	28 May 2003	Change of method for a test on the finished product.
•	05 February 2003	Change to a test procedure and change of site for part of the manufacturing process.
•	04 November 2002	Addition of a 200 ml glass vial pack size.
•	07 March 2002	Updates to Section 4 and 5 of the SPC.
•	25 May 2001	Renewal.
•	30 April 2001	Change in name of manufacturing site of the finished product.
•	05 March 2001	Updates made to Section 5.1 of the SPC.
•	28 December 2000	Change of MA holder from Vericore Ltd to Novartis Animal Vaccines Ltd.
•	24 July 2000	Addition of a safety warning to the SPC.
•	17 February 2000	Change to the method of manufacture.
•	25 May 1999	Change of MA holder address.
•	07 April 1999	Change to the safety warnings on the SPC.
•	19 January 1999	Extension of shelf life.
•	07 July 1998	Change to therapeutic indications and extension of duration of immunity.
•	17 March 1998	Changes to safety warnings.
•	03 February 1998	Changes to safety warnings.
•	09 September 1997	Change of shelf life.
•	02 August 1996	Change to the manufacturing process.