Veterinary Medicines Directorate

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Post Authorisation Assessments

Cobactan 2.5% w/v Suspension for Injection for Cattle and Pigs

•	04 June 2019	Change in the name of a manufacturer of the finished product
•	28 August 2018	Change in the specification limits of the finished product.
•	22 August 2018	Change in RMS from UK to DE.
•	28 January 2016	Change to importer, batch release arrangements and quality control testing of the finished product
•	04 April 2012	Update of the SPC and Product Literature
•	23 September 2011	Addition of a site for part of the manufacture of the active substance Deletion of a manufacturer of the active substance
•	24 August 2011	Change to specification of the finished product
•	04 May 2011	Change to the specification of the finished product
•	27 November 2009	Minor change in the manufacturing process of the active substance
•	26 November 2009	Change of MAH address in Portugal
•	28 September 2009	Changes in test procedure for the active substance
•	13 July 2009	Renewal
•	02 June 2009	Addition of a new site for batch testing
•	14 May 2009	Change of test procedure performed on the finished product
•	16 June 2008	Approval of previously unseen mock ups
•	22 June 2004	Change of manufacturer of intermediate used in the production of the active substance
•	22 June 2004	Repeat use procedure, UK as RMS
•	14 January 2004	Renewal
•	23 May 2003	Extension
•	23 March 2001	Repeat use procedure, UK as RMS
•	28 March 2000	Change of MAH
•	02 December 1999	Change of manufacturer of the active substance
•	28 May 1999	Renewal
•	17 September 1998	EU Decentralised procedure, UK as RMS
•	03 March 1998	Change in formulation
•	14 January 1998	Change in size of sterile containers Change of in-use shelf life
•	27 October 1997	Change to indications
•	31 January 1997	Change of MAH