



Post Authorisation Assessments

Cobactan 4.5% Powder and Solvent for Solution for Injection for Horse and Cattle

•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	05 January 2017	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH
•	28 November 2014	Update to the DDPS.
•	26 October 2012	Changes to an existing pharmacovigilance system as described in the DDPS.
•	28 March 2012	Changes in Summary of Product Characteristics (SPC), labelling or package leaflet following a referral procedure
•	14 December 2011	Renewal procedure – Germany as RMS.
•	03 November 2011	To add an additional site for part of manufacture and to delete a further site.
•	27 November 2009	Minor change to the manufacturing process of the active substance.
•	04 November 2009	Minor change to test procedure for active substance.
•	16 July 2009	To amend the specification limits of the assay disodium hydrogenphosphate (as anhydrous salt)
•	18 June 2008	To change the name of the product in UK and Ireland.