Post Authorisation Assessments

Oxytetrin 20 LA 200 mg/ml Solution for Injection

•	09 January 2015	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance.
•	04 July 2012	Minor change in the manufacturing process of the finished product.
•	11 April 2012	Change in the maximum injection site volume in pigs and reduction of withdrawal period to be 40 days.
•	28 March 2012	Change in the name of the veterinary medicinal product from Oxytetrin 20 LA 20% w/v Solution for Injection to Oxytetrin 20 LA 200 mg/ml Solution for Injection.
•	04 August 2011	Submission of an EDQM certificate of suitability from a new manufacturer of the active substance.
•	07 July 2010	Change of MAH from Schering-Plough Ltd to Intervet UK Ltd.
•	03 June 2010	Changes to the withdrawal periods for cattle and pigs.
•	30 March 2010	Change in specification limits for the finished product.
•	15 January 2009	Changes to the SPC and product literature to bring them into line with new legislation.
•	15 January 2009	Change in legal category from POM to POM-V.
•	26 November 2008	Change to contra-indications on the SPC.
•	21 August 2008	Replacement of a manufacturing site for the active substance.
•	12 March 2008	Increase in the withdrawal period in sheep.
•	08 March 2007	Change in test procedure of the finished product.
•	22 January 2007	Renewal.
•	13 October 2006	Addition of a manufacturer of the active substance.
•	01 July 2003	Change to manufacturing formulation.
•	24 May 2002	Addition of a manufacturer and assembler of the finished product.
•	12 January 1998	Change in the name/address of the MAH.
•	12 January 1998	Change to withdrawal periods.