Post Authorisation Assessments

Cydectin 1% w/v Solution for Injection for Cattle

•	10 July 2015	Submission of a new Ph. Eur. Certificate of Suitability for the active substance.
•	05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
•	04 July 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
•	30 October 2013	Change to the name and address of a manufacturer responsible for the finished product and batch release. Change to the QPPV contact details.
•	24 October 2013	Change to the name of the MAH in Belgium, France and Luxembourg only.
•	12 August 2013	Change of the MAH and distributor, from Pfizer Limited to Zoetis UK Limited.
•	13 June 2012	Change to the DDPS.
•	14 November 2011	Removal of a specification parameter from the Finished Product Specification.
•	04 November 2011	Change to the name of the manufacturing site responsible for manufacture and batch release.
•	02 September 2011	Submission of new Ph. Eur. Certificate of Suitability for the active substance.
•	27 October 2010	Change of the MAH and distributor, from Fort Dodge Animal Health Ltd to Pfizer Limited.
•	19 August 2010	EU Renewal – UK as CMS.
•	09 February 2009	Variation to comply with Ph. Eur. To change the specifications of the active substance.
•	17 November 2005	Renewal.
•	05 December 2003	Change to extend the withdrawal period from 45 days to 65 days.
•	07 March 2003	Minor change in the production of active ingredient.
•	28 August 2001	Change to replace ingredients of animal origin to that of vegetable origin.
•	30 July 2001	Renewal.
•	02 October 2000	Renewal.
•	28 March 2000	Change to the name and address of the MAH.
•	23 December 1999	Change in manufacturer of the active substance.
•	20 April 1999	Change in legal category.
•	01 April 1998	Change to the name of a manufacturing site.
•	21 July 1997	Change to increase shelf life of the finished product, from 24 months to 36 months.
•	22 November 1996	Change to manufacturer of dosage form.
•	29 April 1996	Change to manufacture of active substance.
•	19 October 1995	Change to increase shelf life of the finished product, from 18 months to 24 months.
•	01 September 1995	Change to increase in-use shelf life.
•	28 February 1995	Formulation.
•	21 February 1995	Change to composition of product.

		Change to packaging.