Veterinary Medicines Directorate

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Post Authorisation Assessments

Linco-Spectin Premix for Medicated Feed

•	27 April 2016	Submission of an updated certificate of suitability.
•	13 November 2014	Submission of a new and an updated Ph. Eur. Certificate of Suitability.
•	01 July 2014	Deletion of a manufacturer of the active substance.
•	08 August 2013	Transfer of Marketing Authorisation Holder (including a change in Distributor). Change of name of the manufacturer of the finished product. Addition of a site for batch release of the finished product excluding batch control/testing.
•	20 November 2012	Variation to update the Certificate of Suitability for the Active Substance.
•	11 May 2011	Change in the shelf life limits of the finished product.
•	15 December 2009	Submission of a new European Pharmacopeia Certificate of Suitability from an additional supplied of the Active Substance. Deletion of an API supplier. Addition of an Active Substance Manufacturer.
•	09 December 2009	Variation to submit an update European Pharmacopeia Certificate of Suitability.
•	02 June 2009	Variation concerning the addition of a new site for QA Testing.
•	09 October 2007	Variation to change the Active Substance Manufacturer.
•	26 September 2007	Variation concerning the addition of a manufacturing, stability testing, and storage site.
•	20 June 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	14 June 2006	Renewal.
•	27 June 2005	Addition of a Distributor.
•	18 February 2005	Change in the name of the Manufacturer, Assembler, and Distributor.
•	09 December 2004	Change in the name and address of an Active Substance Manufacturer.
•	26 November 2004	Change in the name and address of the Marketing Authorisation Holder.
•	29 August 2003	Variation concerning the addition of a Distributor.
•	22 August 2002	Variation for an additional indication to the SPC and package labelling.
•	08 July 2002	Renewal.
•	14 December 2001	Change in the name of the Marketing Authorisation Holder and Assembler/Importer of Dosage Form.

•	13 November 2001	Extension of product shelf life.
•	24 September 1999	Change in the Manufacturer of Dosage Form.
•	24 September 1999	Change in the name and address of the Marketing Authorisation Holder.