Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Flukiver Bovis 50 mg/ml Solution for Injection for Cattle

•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	08 October 2015	Renewal – Ireland as RMS.
•	24 November 2014	Assessment of additional stability data for proposed re-test period.
•	16 October 2014	Submission of a new certificate of suitability.
•	11 June 2014	Submission of an updated certificate of suitability.
•	25 April 2014	Changes to an existing pharmacovigilance system.
•	06 March 2013	Change in the SPC and product literature in line with Commission Decision regarding Article 35 referral on flukicides.
•	26 February 2013	To change the distributor from Janssen-Cilag Ltd to Eli-Lilly & Company Limited.
•	09 January 2013	Submission of an updated certificate of suitability.
•	02 November 2011	To change the manufacturing site, for production, primary and secondary packaging, batch control and release. Minor modifications to manufacturing process, and change in batch size. Minor modifications to in-process control tests.
•	26 May 2011	To change the QPPV.