Veterinary Medicines Directorate

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Post Authorisation Assessments

Bimectin 1% w/v Solution for Injection

Vm 50146/4002

•	18 March 2021	Replacement of a secondary packaging site of the finished product.
•	23 February 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	05 September 2019	Change in the name only of a quality control testing site. Change in the name and address of a manufacturer of the finished product, also responsible for batch release. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 October 2018	Change of MAH, from Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
•	10 April 2018	Deletion of a non-significant specification parameter of the finished product
•	22 December 2015	Submission of an updated certificate of suitability.
•	09 August 2012	Addition of a manufacturer of the active substance Submission of an updated Ph. Eur. Certificate of Suitability for an excipient.
•	01 March 2012	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance from an already approved manufacturer
•	17 February 2011	Renewal
•	09 December 2009	Increase in withdrawal period for cattle meat and offal from 35 to 49 days
•	10 September 2008	Updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	15 November 2007	Increase of shelf life from 24 months to 3 years
•	24 October 2007	Minor change to the manufacturing process
•	22 December 2006	Line extension to add sheep to target species
•	05 November 2005	Renewal
•	12 September 2003	Change in batch size of the finished product
•	17 August 2003	Addition of a secondary site of assembly