Veterinary Medicines Directorate

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Post Authorisation Assessments

Bimoxyl LA, 150 mg/ml Amoxicillin Suspension for Injection

Vm 50146/4010

•	14 September 2022	Change to batch release and quality control test sites. Replacement of a site responsible for secondary packaging. Change in a test procedure for the finished product. Change in the batch size of the finished product. Minor change in the manufacturing process of the finished product. Replacement of a manufacturing site. Introduction of new immediate packaging.
•	18 March 2021	Replacement of a secondary packaging site of the finished product.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	23 July 2019	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	24 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. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS
•	24 May 2016	Submission of an updated certificate of suitability.
•	19 November 2015	Changes to the withdrawal period of the finished product.
•	09 October 2014	Minor change in a test procedure for the finished product. Change from Manufacturer's Specification for an excipient, to pharmacopoeial reference in accordance with the Ph. Eur Monograph. Addition of in-process limits applied during the manufacture of the finished product. Minor change in the manufacturing process of the finished product.
•	19 November 2013	Submission of an updated certificate of suitability.
•	15 October 2012	Change of specification parameters of an excipient. Change of test method performed on an excipient.
•	05 January 2009	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance. Deletion of a manufacturing site of the active substance.
•	10 January 2008	Change of legal category from POM to POM-V. Changes to the SPC and Product Literature to bring in

		line with new legislation.
•	13 March 2007	Change of name of manufacturer of the finished product.
•	22 February 2007	Renewal. Change of withdrawal periods – from 11 to 13 days (Pig meat), from 72 to 156 hours (Cattle milk) and 25 days for meat from sheep.
•	24 October 2003	Change of manufacturing process. Change of glass type for container. Addition of a new manufacturing site of the finished product.
•	16 May 2003	Change of name of a manufacturer of the dosage form.
•	23 July 2001	Renewal.
•	28 June 2001	Addition of a manufacturer of the active substance
•	11 January 1998	Change of manufacturer of the active substance.
•	31 July 1997	Addition of Dogs to the target species.
•	04 March 1997	Renewal.
•	07 November 1996	Change of name and address of the MAH.