Veterinary Medicines Directorate

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Post Authorisation Assessments

Amoxycare, 250 mg, Hard Capsules

Vm 50146/4009

•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	25 July 2019	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
•	07 June 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance.
•	11 June 2014	Submission of a new and updated Ph. Eur. Certificate of Suitability.
•	24 March 2014	Change to the distributor address.
•	06 February 2014	Updated certificates of suitability.
•	13 March 2012	Change in specifications of packaging.
•	03 October 2011	Change in batch size of the finished product. Change in manufacturing process of the finished product.
•	12 January 2011	Change in test procedure for the finished product.
•	20 August 2009	Submission of 2 updated Ph. Eur. Certificates of Suitability.
•	05 August 2009	Submission of 2 updated Ph. Eur. Certificates of Suitability.
•	04 August 2009	Submission of updated TSE certificates.
•	20 February 2008	Changes to the SPC/Product literature to bring in line with new legislation. Change in legal category from POM to POM-V.
•	03 July 2006	Change in specifications of packaging.
•	24 March 2006	Renewal.