Veterinary Medicines Directorate

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Post Authorisation Assessments

Ampicare 250mg Hard Capsule

Vm 50146/4035

•	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.
•	26 October 2018	Changes to an existing pharmacovigilance system as described in the DDPS. 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.
•	24 October 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer Deletion of Ph. Eur. certificates of suitability for an active substance
•	24 March 2014	Change of distributor details.
•	06 February 2014	Submission of a new and updated TSE certificates from an already approved manufacturer of an excipient.
•	16 January 2014	Submission of a new TSE certificate from a new manufacturer of an excipient.
•	13 March 2012	Change of ink used on packaging.
•	03 October 2011	Change in manufacturing process of the finished product. Change in batch size of the finished product.
•	12 January 2011	Change in test method for a finished product test.
•	20 August 2009	Submission of two updated Ph. Eur. Certificates of Suitability for two already approved manufacturers of the active substance.
•	04 August 2009	Update of TSE certificate.
•	17 July 2009	Renewal.
•	20 February 2008	Change in legal category from POM to POM-V Changes to bring the SPC and Product Literature in line with new legislation and change in legal category from POM to POM-V.
•	03 July 2006	Introducing new specifications for two new ink suppliers.
•	05 April 2006	Updated TSE certificates submitted for excipients.
•	28 October 2005	Renewal.
•	22 September 2005	Change in manufacturer of active substance.