Veterinary Medicines Directorate

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Post Authorisation Assessments

Bimotrim Co Injection Solution for Injection

Vm 50146/4027

•	July 2021	Submission of a new certificate of suitability for an active substance.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	24 July 2019	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	25 October 2018	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of MAH, from Bimeda Chemicals Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
•	01 August 2017	Change in the specification parameters of an excipient
•	24 August 2012	Change of specification of an excipient to comply with Ph. Eur.
•	13 April 2011	Change in manufacturing process of the finished product
•	01 December 2010	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	10 November 2010	Replacement of manufacturer of the active substance
•	02 August 2010	Renewal
•	02 April 2009	Amendment of batch size
•	31 July 2008	Minor changes to SPC and Product Literature
•	13 June 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation Change of distributor address
•	16 March 2005	Renewal
•	04 November 2004	Changes to the SPC and Product Literature to bring in line with new legislation
•	22 May 2003	Addition of a manufacturer of the dosage form
•	28 November 2002	Addition of manufacturer of the active substance
•	25 September 2001	Change of manufacturing site of dosage form
•	12 March 1998	Renewal
•	17 July 1995	Change of manufacturer
•	17 May 1995	Extension to add Horses (not intended for human consumption) to the target species