Veterinary Medicines Directorate

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Post Authorisation Assessments

Cronyxin Injection, 5% w/v Solution for Injection

Vm 50146/4011

•	18 September 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	10 November 2023	Deletion of a manufacturer of the active substance authorised via Ph. Eur. CEP. Submission of an updated Ph. Eur. CEP for a manufacturer of the active substance. Submission of an updated Ph. Eur. CEP for a manufacturer of the active substance.
•	11 October 2023	Replacement of a secondary packaging site of the finished product.
•	11 October 2023	Minor change in the manufacturing process of the finished product. Replacement of a manufacturing site responsible for batch control and batch release of the finished product. Replacement of a manufacturing site responsible for all of the manufacturing process of the finished product.
•	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.
•	29 June 2020	Changes to a test procedure for the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form. Replacement of an excipient with a comparable excipient.
•	03 March 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	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
•	10 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.

•	15 January 2015	Deletion of a Ph. Eur. certificate of suitability. Replacement of a Ph. Eur. certificate of suitability with a new manufacturer.
•	06 May 2015	Submission of an updated certificate of suitability.
•	09 July 2013	Approval of previously unseen mock ups
•	15 February 2012	Change of immediate packaging container type Change in batch size Change of in-process specifications of the finished product Change of finished product specification Submission of an updated Ph. Eur. Certificate of Suitability Addition of a manufacturer responsible for batch release
•	11 April 2011	Addition of a manufacturer of an active substance
•	23 December 2010	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	27 November 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	17 November 2008	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	13 November 2008	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	28 August 2008	Corrections to the SPC and Product Literature
•	13 February 2006	Renewal
•	14 December 2005	Addition of new user warnings to the SPC and Product Literature
•	04 November 2004	Change to the SPC to bring in line with new legislation
•	16 May 2003	Addition of a manufacturer of the dosage form
•	16 August 2002	Addition of a manufacturer of the active substance
•	07 November 2001	Change of manufacturer of the dosage form
•	24 July 2001	Renewal
•	13 April 1999	Change of type of sterile container
•	23 October 1998	Change of finished product specification
•	24 September 1997	Change of manufacturing site of the dosage form