Veterinary Medicines Directorate

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Post Authorisation Assessments

Bimamix Oral Suspension for Calves

Vm 50146/4022

•	20 October 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	17 November 2022	Replacement of a quality testing site.
•	29 September 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	08 September 2020	Changes to the labelling and package leaflet.
•	18 August 2020	Change in the name of a manufacturer used in the manufacture of the active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	24 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 in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 December 2017	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in shape or dimensions of the container or closure (immediate packaging) Change in shape or dimensions of the container or closure (immediate packaging)
•	03 August 2017	Change in the specification limits of the finished product
•	03 August 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	04 May 2017	Minor change in the manufacturing process of the finished product.
•	29 November 2016	Minor change in the manufacturing process of the finished product.
•	25 January 2016	Addition of a measuring / administration device which is not an integrated part of the primary packaging.
•	01 November 2013	Change in the specification parameters and/or limits of an excipient.
•	01 March 2013	Submission of an updated Ph. Eur. certificate of suitability

		from an already approved manufacturer.
•	05 December 2012	Change in the specification parameters and/or limits of the finished product.
•	25 September 2012	Submission of an updated certificate of suitability.
•	19 July 2012	Submission of an updated certificate of suitability.
•	12 March 2012	Renewal Marketing Authorisation. UK as RMS.
•	29 September 2011	To add an additional manufacturer of the active substance.
•	17 August 2011	To change the shelf-life from three years to two years.
•	15 March 2011	To correct the input amount of the colourant, carmoisine from 0.0005%w/v to 0.005%w/v under 'Section 2. Composition' on the memorandum document.
•	03 August 2010	Submission of a new or updated European Pharmacopoeia certificate of suitability for an active substance or starting material/reagent/intermediate in the manufacturing process of the active substance
•	09 June 2009	To submit a new Certificate of Suitability from a new manufacturer for the active ingredient Neomycin Sulphate, and replacement of the current AIM
•	19 December 2008	Submission of a new or updated European Pharmacopoeia certificate of suitability for an active substance or starting material/reagent/intermediate in the manufacturing process of the active substance
•	18 November 2008	Submission of a new or updated European Pharmacopoeia certificate of suitability for an active substance or starting material/reagent/intermediate in the manufacturing process of the active substance