Veterinary Medicines Directorate

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Post Authorisation Assessments

Dectospot 10 mg/ml Spot-on Solution for Cattle and Sheep

Vm 50146/4023

•	04 March 2024	Change to the in-process controls applied during the manufacture of the finished product.
•	24 November 2023	Minor changes to the dimensions of the immediate packaging.
•	16 November 2023	Change to the in-process controls applied during the manufacture of the finished product.
•	05 September 2023	Change in part of the primary packaging material not in contact with the finished product.
•	15 November 2022	Replacement of a quality control testing site for the finished product.
•	14 April 2022	Tightening of specification limits of the immediate packaging of the finished product.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 February 2020	National Renewal.
•	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.
•	05 March 2019	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	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.
•	23 July 2018	Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product.
•	25 April 2018	Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years.
•	05 September 2016	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product.
•	01 August 2016	Variation to include dial-a-dose applicator in promotional

		pack.
•	25 May 2016	Change in pack size of the finished product.
•	26 January 2016	Change in dimensions of the container or closure (immediate packaging). Addition of a new specification parameter of the immediate packaging of the finished product.
•	19 August 2015	Change of MAH, from Triveritas Lrd to Cross Vetpharm Group Ltd. Introduction of a new pharmacovigilance system. Approval of mock-ups.