Veterinary Medicines Directorate

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Post Authorisation Assessments

Alamycin Aerosol 3.58% w/w Cutaneous Spray, Solution

Vm 02000/4053

•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, BT35 6QQ, Co. Down, Northern Ireland.
•	14 June 2022	Deletion of a manufacturer of the active substance.
•	05 May 2022	Deletion of manufacturing site for an active substance. Deletion of manufacturing site for an active substance.
•	06 December 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Introduction of a re-test period of the active substance.
•	02 November 2021	Minor change in the manufacturing process of an immediate release solid oral solutions. Changes to a test procedure for the finished product.
•	31 March 2021	Change in shape or dimensions of the container or closure (immediate packaging).
•	12 December 2019	Update to the method of product administration.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	02 July 2018	Deletion of a non-significant specification parameter of the finished product. Deletion of a non-significant specification parameter of the finished product. Deletion of a non-significant specification parameter of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product.
•	21 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	28 February 2018	Deletion of a non-significant specification parameter of the finished product.
•	05 January 2016	Submission of a new Ph. Eur. certificate of suitability.
•	10 December 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance.
•	11 April 2012	Change in distributor address.
•	28 December 2011	Submission of a new/updated Ph. Eur. Certificate of

		Suitability for an active substance.
•	09 February 2011	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance.
•	05 December 2008	Renewal.
•	23 October 2008	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance.
•	27 February 2008	Update to SPC and labels to keep in line with new legislation.
•	07 February 2007	Change of legal category from POM to POM-V.
•	02 November 2005	Change in packaging materials.
•	19 November 2004	Renewal.
•	16 July 2004	Addition of a manufacturer of dosage form.
•	15 October 1999	Change in manufacturer of active substance.
•	15 October 1999	Renewal.
•	09 September 1998	Change in manufacturing site of dosage form.
•	27 January 1998	Change in outer packaging (non-sterile containers).
•	30 June 1997	Change in manufacturer of active substance.
•	10 March 1997	Extension for use in cattle and pigs.
•	07 March 1997	Change in manufacturer of active substance.