Veterinary Medicines Directorate

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Post Authorisation Assessments

Terramycin Aerosol Spray 3.92% w/w Cutaneous Spray

Vm 60021/3022

•	15 November 2024	Change of Legal Entity for UK(NI) from Zoetis UK Limited to Zoetis Belgium S.A.
•	12 March 2024	Deletion of a manufacturing site for the finished product.
•	19 April 2023	Deletion of a manufacturer of the active substance.
•	30 November 2022	Extension of re-test period of an active substance.
•	08 August 2022	Updated certificate of suitability from an already approved manufacturer.
•	23 December 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	20 November 2019	Minor changes to the SPC/QRD text
•	05 November 2019	Change in the address of the marketing authorisation holder from Zoetis UK Limited 5th Floor, 6 St. Andrew Street London EC4A 3AE to Zoetis UK Limited 1st Floor, Birchwood Building Springfield Drive Leatherhead Surrey KT22 7LP.
•	18 June 2019	Introduction of a re-test period of the active substance.
•	19 December 2018	Introduction of a new site of manufacture. Deletion of a manufacturing site for an active substance. Addition of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	08 October 2018	Submission of an updated Ph. Eur. Certificate of Suitability. Changes to a test procedure for the active substance. Change in the specification parameters and/or limits of an active substance.
•	28 November 2013	Variation to transfer the Marketing Authorisation Holder and Distributor. Deletion of a redundant API manufacturing site.
•	24 May 2013	Submission of an updated European Pharmacopeia Certificate of Suitability for an active substance manufacturer.
•	07 March 2013	Variation to change an existing test procedure for the finished product.
•	27 April 2012	Submission of an updated European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
•	12 April 2012	Submission of an Updated European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
•	09 February 2010	Submission of a new European Pharmacopoeia

		Certificate of Suitability for an alternative active substance manufacturer.
•	09 February 2010	Addition of a site for part of the manufacturing process for the active substance.
•	09 February 2010	Change in the specification for the active substance.
•	19 August 2008	Renewal.
•	12 July 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	12 June 2007	Change in the name of a finished product manufacturer.
•	03 May 2006	Variation to make minor changes to the manufacturing process of the finished product.
•	03 May 2006	Addition of a dosage form assembler.
•	10 April 2006	Variation to change the test procedure for the finished product.
•	10 April 2006	Variation to change the batch release arrangements.
•	28 June 2005	Addition of a distributor.
•	04 March 2005	Renewal.
•	29 October 2004	Reduction in batch size and a minor change to the manufacturing process.
•	26 February 2004	Renewal.
•	11 December 2002	Change of analytical method.
•	09 December 2002	Variation to amend the fill weight of release specification.
•	09 December 2002	Variation for a minor change to the test procedure.
•	23 August 2002	Change in the manufacturing process of the active substance.
•	30 April 2002	Change in the manufacturing process of the active substance.
•	03 August 1995	Renewal.
•	03 August 1995	Addition of a manufacturer.
•	05 July 1995	Addition of an indication.
•	05 January 1995	Change to the manufacturer and formulation of the finished product.