



Post Authorisation Assessments

Terramycin Aerosol Spray 3.92% w/w Cutaneous Spray Vm 42058/5175

20 January 2026	Addition of a site responsible for testing for a finished product.
17 December 2025	Alignment of the product information with version 3 of the National QRD templates.
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 Pharmacopoeia 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.