Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Rimadyl Small Animal Solution for Injection 50 mg/ml

Vm 42058/5222

14 March 2026	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
28 July 2025	Submission of a updated Ph. Eur. TSE certificate of suitability for excipient used in the active substance.
13 December 2024	Deletion of a non-significant specification parameter for an excipient.
18 May 2024	Update to a Ph. Eur. TSE CEP for an already authorised active substance starting material.
September 2023	Submission of a updated Ph. Eur. TSE certificate of suitability for an excipient.
09 August 2023	Changes to the quality part of the dossier: Deletion of - a manufacturing site for an active substance. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter of an active substance.
01 March 2023	Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data have been assessed and accepted.
24 June 2021	Minor change in the manufacturing process of the finished product. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
07 January 2021	Deletion of a non-significant specification parameter of an excipient. Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a secondary packaging site of the finished product. Change in shape or dimensions of the container or closure (immediate packaging). Changes to a test procedure for the finished product. Addition to a test procedure for the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product- Applicable to AT, CY, CZ, DE, EL and SK. Change in the specification parameters of the finished product - Applicable to CY, CZ, EL and SK. Change to in-process tests or limits applied during the manufacture of the finished product.

	Addition of a new specification parameter to the specification with its corresponding test method of the finished product- Applicable to AT, CY, CZ, DE, EL and SK. Addition of a manufacturing site of the finished product.
27 August 2020	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.
02 July 2018	Change in the name of the manufacturer of the finished product.
23 June 2017	Change in the name of the manufacturer of the finished product.
6 April 2016	A change to the restricted part of the ASMF.
3 November 2015	Submission of an updated TSE certificate of suitability
29 April 2015	Addition of an active substance manufacturer.
30 August 2013	Change of MAH from Pfizer Ltd to Zoetis UK Limited, change of distributor, and change of name of batch release site.
22 September 2010	Change to finished product specifications.
18 August 2010	Replacement of a manufacturer and assembler of dosage form and addition of a site for quality control testing and batch release.
3 July 2010	Deletion of a manufacturer of the active substance.
15 April 2009	Update of specifications of the active substance in to Ph. Eur.
30 September 2008	Renewal.
25 October 2007	Changes to the SPC and product literature to bring them into line with new legislation.
25 October 2007	Change of legal category from POM to POM-V.
24 June 2005	Addition of a distributor.
14 May 2004	Renewal.
30 September 2003	Change in the name of the manufacturer of the active substance.
25 February 2002	Change to the Open part of the ASMF.
27 June 2001	Change to dosage on the SPC.
29 December 2000	Change to test method for the active substance.
31 March 2000	Deletion of horse as a target species.
11 February 2000	Change in the manufacturer of the active substance.
16 September 1999	Change to name of assembler of dosage form.
23 July 1999	Change affecting package leaflet.
23 July 1999	Change of manufacturing process of the active substance.