Veterinary Medicines Directorate

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Post Authorisation Assessments

Rimadyl Small Animal Solution for Injection 50 mg/ml

Vm 42058/4123

•	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.