Veterinary Medicines Directorate

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Post Authorisation Assessments

Resflor 300/16.5 mg/ml Solution for Injection for Cattle

Vm 01708/5081

•	10 October 2023	Implementation of safety amendments regarding avian scavengers in the product information. One-off alignment of the product information with version 9.0* of the QRD templates.
•	05 October 2023	Change(s) in the Summary of Product Characteristics (SPC), labelling or package leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 20.
•	07 June 2023	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	09 February 2023	Tightening of specification limits for the active substance.
•	27 January 2022	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	18 August 2021	Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product.
•	15 December 2020	Minor changes to an approved test procedure of the finished product.
•	27 November 2020	Update to product information following a Periodic Safety Update Report (PSUR).
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	29 December 2017	Change in address of the Active Substance Master File holder. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the

		active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.
•	02 August 2017	Minor changes to an approved test procedure of the finished product. Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers.
•	29 June 2016	Change in the manufacturer of a starting material used in the manufacturing process.
•	10 April 2015	Submission of an updated Ph. Eur. Certificate of Suitability.
•	06 March 2015	Change in the batch size of the active substance. Tightening of specification limits of the active substance.
•	20 November 2014	Change in test procedure for the active substance. Change in the re-test period of the active substance. To introduce a second manufacturing process.
•	31 July 2014	Change in supplier of a packaging component. Change in part of the primary packaging not in contact with the finished product. Change in a specification limit of the finished product.
•	31 July 2014	Deletion of a manufacturing site for the active substance.
•	04 November 2013	Change to the therapeutic indication.
•	11 June 2013	Changes to the manufacturing process for the active substance.
•	17 May 2013	Change in manufacturer of the active substance. Change in re-test period of active from 24 to 36 months.
•	13 May 2013	Change to the storage conditions of the finished product, from 'Do not store above 30^{o}C' to, 'Do not store above 25^{o}C'.
•	23 April 2013	Change to in-process limits applied during the manufacture of the finished product.
•	29 October 2012	Submission of a new certificate of suitability for the active substance.
•	20 September 2012	Deletion of a manufacturing site.
•	20 June 2012	Changes to sections 4.3 and 4.5 of the SPC.
•	13 June 2012	Addition of a manufacture of the active substance.
•	23 January 2012	Deletion of a manufacturing site.
•	25 October 2011	Change in legal entity.
•	02 September 2011	To change a test procedure for the active substance. To update the specification limits of the active substance.
•	14 June 2011	Change in the test procedure for the finished product.
•	16 May 2011	Renewal Marketing Authorisation.
•	14 March 2011	Change to the name of the MAH in Portugal only.
•	04 February 2011	Change in the name of the manufacturer of the finished product, also responsible for batch release.
•	20 May 2009	To add a manufacturer of the active substance.
•	14 April 2009	To add a manufacturer of the active substance.

•	28 September 2007	To change the finished product test procedure.
•	06 August 2007	To amend the SPC following a repeat use mutual recognition procedure.
•	03 August 2007	Repeat Use Comm.