Veterinary Medicines Directorate

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

Post Authorisation Assessments

Scalibor Protectorband 0.76 g medicated Collar for Small and Medium Sized Dogs

Vm 01708/3011

•	04 March 2024	Deletion of a test procedure for an excipient. Deletion of a non-significant specification parameter of an excipient.
•	21 July 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
•	20 February 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
•	16 March 2022	Minor changes to an approved test procedure of the finished product.
•	05 October 2020	Change in the specification limits of an excipient.
•	01 October 2020	Changes to the labelling and package leaflet.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	22 April 2020	Updates to the SPC following a Repeat Use procedure.
•	16 January 2020	Change in the name and address of the manufacturer of the finished product. Change in the name of the manufacturer of the finished product.
•	16 January 2020	Minor changes to an approved test procedure of the finished product.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	07 March 2018	Change in the name of a manufacturer of the active substance. Change in the name of an ASMF holder.
•	05 January 2017	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH.
•	28 September 2016	Update to layout and branding style of Mock-ups.
•	06 September 2016	Change in the name of the supplier of a starting material used in the manufacture of the active substance. Addition of two manufacturers of an intermediate used in the manufacturing process of the active substance.
•	22 July 2015	Deletion of non-significant in-process tests applied during the manufacture of the finished product.

•	07 May 2015	Change in the name of the manufacturer of the active substance.
•	01 April 2015	Changes to section 4.6 of the SPC.
•	28 November 2014	Update to the DDPS.
•	05 February 2014	Update to SPC and packaging with changes agreed in repeat use procedure.
•	20 November 2013	Repeat use procedure.
•	21 August 2013	Deletion of an active substance manufacturing site.
•	14 February 2013	Changes to the manufacturing process for the active substance.
•	13 November 2012	Submission of an updated ERA.
•	18 July 2012	Change in the specification of an excipient.
•	15 June 2011	Addition of a secondary packaging site.
•	04 May 2010	Change of legal category from POM-V to NFA-VPS.
•	19 April 2010	Changes made to the product literature.
•	31 March 2010	Increase batch size of the finished product.
•	26 March 2010	Renewal.
•	09 June 2009	Addition of a finished product manufacturer responsible for batch release and quality control.
•	09 June 2009	Addition of a manufacturer responsible for primary and secondary packaging.
•	05 December 2008	Change in batch size.
•	03 March 2006	Addition of a new therapeutic indication.
•	16 August 2005	Addition of an active substance manufacturing site.
•	07 September 2004	Renewal.
•	11 April 2004	Change of TSE format from Format 3 to Format 2.
•	18 February 2004	Updates to the SPC and product literature.
•	09 May 2003	Addition of a new site for packaging and batch release.