Veterinary Medicines Directorate

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Post Authorisation Assessments

Toxovax

Vm 06376/4102

•	16 October 2024	Change in legal entity of MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to Intervet International B.V., Wim de Körverstraat, 35, 5831 AN Boxmeer, The Netherlands.
•	20 September 2023	Addition of alternative sterilisation method of the immediate packaging of the finished product.
•	13 January 2023	Addition of an alternative test procedure for the finished product.
•	12 November 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation. Addition of a secondary packaging site of the finished product. Joint labelling variation to create separate GB only packaging and joint IE/NI packaging.
•	23 April 2021	Change in the address of a manufacturer used in the manufacture of the active substance.
•	22 April 2021	Change in the address of the manufacturer of the finished product.
•	10 September 2020	Change in the name of the manufacturer of the finished product.
•	02 June 2020	Change in the name of the MAH, from Intervet UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	02 April 2019	Deletion of a packaging site.
•	02 September 2016	Submission of updated Ph. Eur. TSE Certificate of Suitability for a starting material from already approved manufacturers. Deletion of certificate of suitability.
•	26 April 2016	Submission of a new Ph. Eur. TSE certificate of suitability for an excipient from an already approved manufacturer
•	05 December 2013	Variation to change the name and/or address of the manufacturer of the finished product (for all steps including QC testing).
•	17 September 2013	Variation to make minor additions to the SPC and to bring the SPC in line with the latest authorised QRD template. Submission of mock-ups for approval prior to marketing.
•	01 July 2013	Change in the manufacturing process of the finished product.

•	03 February 2011	Addition of a manufacturer responsible for all steps in the manufacturing process of the finished product.
•	08 April 2010	Addition of an active substance manufacturer responsible for manufacture of the dosage form, filling, and assembly.
•	03 July 2008	Renewal.
•	28 April 2008	Variation to align the SPC between the UK and IE.
•	25 May 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	19 October 2005	Review of Marketing Authorisation.