Veterinary Medicines Directorate

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Post Authorisation Assessments

Dexafort Suspension for Injection

Vm 01708/4324

•	10 March 2023	Change in test procedure for active substance- other changes to a test procedure for active substance.
•	16 November 2022	Updated certificate of suitability from an already approved manufacturer.
•	23 March 2022	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a PSUR.
•	20 January 2022	Minor changes to an approved test procedure of the finished product. Replacement to a test procedure for the finished product. Replacement of an excipient with a comparable excipient.
•	31 March 2021	Amendment to specification for particle size.
•	02 December 2020	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
•	24 April 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	02 November 2016	Reduction of the shelf life of the finished product as packaged for sale from 3 to 2 years. Change in storage conditions of the finished product. Changes to SPC and labelling to implement the outcome of a procedure concerning PSUR.
•	19 January 2016	Deletion of a manufacturing site.
•	30 September 2015	Approval of mock-ups.
•	01 May 2015	Submission of an updated Ph. Eur. Certificate of Suitability.
•	27 January 2015	Change to part of the packaging material not in contact with the finished product formulation. Changes to the manufacturing process. Addition of a new batch control/testing site. Change in the composition (excipients) of the finished product. Addition of a new manufacturing site.
•	27 October 2014	Change to the name of the active substance manufacturer.
•	26 September 2013	Change of shelf life to 36 months.
•	20 October 2009	Change of withdrawal period for meat from cattle from 48 days to 63 days.
•	02 June 2009	Update to Part II of the dossier.
•	11 June 2008	Change of legal category from POM to POM-V. Changes to the SPC and Product Literature to bring in

		line with new legislation. Submission of a new Ph. Eur. Certificate of Suitability for the active substance. Change of manufacturer of the active substance.
•	21 August 2007	Change of name of a manufacturer of the active substance.
•	23 February 2006	Renewal.
•	01 July 2005	Change of distributor.
•	28 August 2003	Renewal.
•	10 October 2001	Change of formulation.
•	27 July 2001	Change of distributor.
•	05 June 2000	Update to licence particulars.