



Post Authorisation Assessments

Dexafort Suspension for Injection

Vm 06376/4086

27 February 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
20 August 2025	One-off alignment of the product information with version 3 of the QRD templates.
05 August 2025	Change to comply with an update of the relevant monograph of the Ph. Eur.
10 December 2024	Change in legal entity from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes MK7 7AJ to Intervet International B.V., Wim de Korverstraat 35, 5831 AN, Boxmeer, Netherlands.
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.