Veterinary Medicines Directorate

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Post Authorisation Assessments

Equip EHV1,4
Vm 42058/4060

•	05 July 2022	To replace the EHV-1 reference batch used in the EHV-1 finished product potency ELISA.
•	22 February 2022	Tightening of specification limits of an excipient. Addition of a manufacturer responsible for batch release of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Addition of a secondary packaging site of the finished product. Increase in batch size (from 15 to 150L to CCY: 15 to 150L LLN: 40 to 400L) of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Addition of a manufacturing site of the finished product.
•	15 June 2021	Submission of a new Ph. Eur. TSE certificate of suitability for a starting material from a new / already approved manufacturer. Addition of a new in-process test and limit applied during the manufacture of the active substance. Replacement of a test procedure for the finished product. Change of a test procedure for the finished product. Widening of the in-process test limits applied during the manufacture of the active substance. Changes in the manufacturing process of the active substance.
•	19 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	09 May 2017	Change in the specifications of appearance Addition of a new in-process test and limit applied during the manufacture of the active substance
•	06 April 2017	Addition of a new in-process test and limit applied during the manufacture of the active substance
•	09 March 2016	Change in the manufacturing process of the active substance.
•	02 February 2016	Update section 4.6 of the SPC
•	03 November 2015	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance.

		Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance.
•	23 October 2015	Change in name of manufacturer of the active substance. Change in name of manufacturer of the finished product.
•	20 October 2015	Change in name of manufacturer.
•	12 December 2014	Change in test procedure for the active substance. Change in the specification limits of an active substance. Change in the manufacturing process for the finished product.
•	24 July 2013	Change of MAH Change of Distributor Change of name of manufacturers of the active substance Change of name of manufacturers of the finished product
•	10 September 2012	Deletion of a test parameter applied during the manufacture of the active substance
•	12 June 2012	Addition of a manufacturer of a starting material used in the manufacture of the active substance
•	01 February 2012	Addition of manufacturing site for testing, labelling and packaging and batch release
•	23 November 2011	Change of name of product from ‘Duvaxyn EHV 1,4’ to ‘Equip EHV 1,4’
•	13 October 2011	Change of name of manufacturing site of QC testing, labelling and batch release
•	03 June 2011	Addition of a manufacturer of the active substance, filling and assemble, and blending Addition of a manufacturing site for QC testing, labelling and batch release
•	10 February 2011	Change of name of manufacturer of the active substance
•	16 June 2010	Change of MAH
•	26 March 2010	Extension
•	30 April 2009	Renewal
•	31 July 2008	Addition of 3 manufacturers of starting materials used in the manufacture of the active substance
•	27 February 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	07 September 2006	Addition of a new manufacturing site responsible for testing
•	05 April 2006	Renewal
•	16 December 2004	Change of reference vaccine batch
•	08 March 2004	Addition of a manufacturing site responsible for testing
•	07 January 2004	Change of specification of the finished product
•	19 October 2001	Minor change in manufacturing process of the active substance
•	18 September 2000	Renewal
•	20 August 1997	Change of MAH
•	22 January 1997	Change of shelf life from 12 months to 24 months
•	08 August 1996	Change to therapeutic indications

•	12 February 1996	Change of shelf life
•	07 July 1995	Change of shelf life
•	14 February 1995	Change to safety warnings