Veterinary Medicines Directorate

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Post Authorisation Assessments

Eqvalan Duo, Oral Paste

Vm 08327/5003

•	16 November 2023	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
•	25 August 2023	Widening the average dose limits of the ejectable content specification.
•	26 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	24 August 2022	Submission of a new certificate of suitability from a new manufacturer.
•	16 August 2022	Change in address of manufacturer of the finished product.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	21 September 2020	Minor change in the manufacturing process of the finished product.
•	28 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	29 January 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	07 February 2019	Change in the name of the manufacturer of the finished product.
•	16 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	20 June 2018	Change in RMS from UK to FR.
•	01 March 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	30 August 2017	Change in the address of the marketing authorisation holder in BE, DK, FI, LU, NO, PT, ES & SE only.
•	06 April 2017	Change to part of the packaging material not in contact with the finished product formulation.
•	08 December 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
•	26 June 2015	Submission of an updated Ph. Eur. Certificate of Suitability.

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•	12 June 2014	Change of MAH address in Portugal only.
•	04 April 2014	Change of MAH address in Spain only.
•	16 January 2014	Change of the MAH address in Belgium.
•	18 January 2013	Addition of a supplier of packaging components or the finished product
•	13 September 2012	Minor changes to the manufacturing process of the finished product
•	03 August 2012	Deletion of a manufacturer of an active substance Submission of updated Ph. Eur. Certificates of Suitability for an active substance from already approved manufacturers
•	04 November 2011	Change of specification parameter for the finished product
•	26 July 2010	Addition of an indication against *Anoplocephala magna*
•	08 April 2010	Change of product name in Denmark only
•	29 January 2010	Renewal
•	21 January 2010	Addition of a 50 syringe pack size
•	29 December 2009	Submission of updated Ph. Eur. Certificates of Suitability for an active substance from an already approved manufacturer
•	20 November 2009	Replacement of a manufacturing site for all of the manufacturing process except batch release Minor change in manufacture of the finished product
•	04 November 2009	Change of batch size
•	03 February 2009	Deletion of a manufacturing site for packaging and control
•	07 August 2008	Change of specification of the finished product
•	03 January 2008	Addition of 2 manufacturers of the active substance
•	22 October 2007	Change of name of manufacturing site of the finished product
•	09 August 2006	Change of legal category from PML to POM-VPS
•	07 June 2006	Removal of safety warning regarding use in pregnant and lactating mares Decrease of minimum age of use of product in foals from 5 months to 2 months
•	25 May 2005	Mutual recognition procedure, UK as RMS Change of source of an excipient