Veterinary Medicines Directorate

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Post Authorisation Assessments

Equipalazone 200mg/ml Solution for Injection

Vm 10434/4007

•	23 February 2024	Editorial changes to Part 2E of the dossier.
•	31 January 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
•	14 October 2022	Change in shape and dimension of the immediate packaging closure.
•	18 August 2022	Additional batch control testing site for the finished product.
•	15 June 2022	Deletion of manufacturing site for the finished product.
•	24 September 2021	Addition of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release including batch control/testing.
•	12 June 2019	Deletion of manufacturing site and packaging site for a finished product.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	09 May 2018	Deletion of a manufacturing site for an active substance.
•	13 December 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 June 2016	Submission of an updated Ph. Eur. certificate of suitability
•	14 April 2015	Changes to the product labelling/package leaflet.
•	17 October 2014	Change to the address of the MAH.
•	07 July 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of thee active substance.
•	23 May 2012	Addition of a manufacturer of the active substance
•	02 March 2011	Changes to the artwork of the Product Literature
•	15 December 2010	Change of distributor
•	28 August 2008	Corrections to section 4.11 of the SPC
•	11 June 2007	Harmonisation of SPC
•	15 March 2007	Addition of a manufacturing site for manufacture and assembly of the finished product Change of composition of a packaging component
•	13 March 2007	Batch control
•	28 February 2007	Addition of a manufacturing site for manufacture and assemble of the finished product
•	01 February 2007	Change of name of manufacturer and assembler of the finished product

•	02 January 2007	Changes to the SPC and Product Literature to bring in line with new legislation
•	30 August 2006	Change of MAH
•	05 April 2006	Submission of an updated Active Substance Master File (ASMF)
•	22 February 2006	Renewal
•	14 December 2005	Change of name of manufacturer of the finished product
•	21 November 2001	Additional manufacturing site for the active substance
•	27 July 2001	Addition of a manufacturer of the dosage form
•	23 November 2000	Change of storage conditions to 'store between 2˚C and 8˚C' Renewal
•	30 March 1999	Change of specification of the active substance