Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetrimoxin L.A. 150 mg/ml Suspension for Injection for Cattle and Pigs

Vm 15052/4074

•	June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	18 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	02 June 2023	Decrease in withdrawal period for meat and offal in pigs to 16 days.
•	30 December 2022	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
•	21 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	September 2022	Addition of manufacturing site responsible for radiosterilisation of plastic vials.
•	27 May 2021	Addition of a manufacturing site for part of the manufacturing process of the finished product. Addition of a manufacturing site of the finished product.
•	05 May 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	06 March 2019	Introduction of a new site of manufacture. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Addition of a new specification parameter with its corresponding test method. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Change in the specification parameters and/or limits of an active substance.
•	16 July 2018	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	19 January 2018	Change in the name and address of the manufacturer of the finished product.
•	17 January 2018	Addition of a second manufacturing site responsible for the radio sterilisation.

•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	12 January 2017	Deletion of a non-significant specification parameter of the finished product. Change in the specification limits of the finished product. Minor changes in the manufacturing process of the finished product. Minor changes in the manufacturing process of the finished product.
•	08 December 2015	Change(s) in the safety database
•	11 February 2015	Renewal.
•	31 July 2014	Transfer of MA from Ceva Santé Animale to Ceva Animal Health Ltd.
•	19 December 2013	Approval of mock-ups for all presentations.
•	11 October 2013	Changes to an existing pharmacovigilance system.