Veterinary Medicines Directorate

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Post Authorisation Assessments

Ceftiocyl 50 mg/ml Suspension for Injection for Cattle and Pigs

Vm 08007/4122

•	14 December 2023	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)
•	28 July 2021	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Addition of a new specification parameter with its corresponding test method of a starting material used in the manufacturing process of the active substance. Minor change to the restricted part of an Active Substance Master File.
•	30 January 2019	Increase in batch size (75kg~85kg) of the active substance used in the manufacturing process of the active substance. Change in the name of the ASMF holder. Deletion of a non-significant in-process test applied during the manufacture of the active substance. Minor change to the restricted part of an Active Substance Master File.
•	11 September 2018	Change in the address of the marketing authorisation holder from Vétoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northamptonshire, NN12 7LS.
•	29 December 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	06 January 2016	Changes to update the QP declaration for the manufacturer of the active substance.
•	19 November 2015	To add a new manufacturer for the active substance.
•	17 April 2015	Renewal – UK as CMS.
•	12 September 2014	To reduce the shelf-life of the finished product, from 3 years to 2 years.
•	05 November 2012	Change in the batch size of the finished product. Change in the manufacturing process of the finished product.
•	06 June 2012	Change in the Summary of Product Characteristics and Package Leaflet following a procedure in accordance with Article 35 referral for all veterinary medicinal products containing systemically administered (parenteral and oral) 3rd and 4th generation cephalosporins intended for use in food producing species.

•	23 February 2011	Addition of a manufacturer of the active substance.