Veterinary Medicines Directorate

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Post Authorisation Assessments

Curacef Duo, 50 mg/ml / 150 mg/ml, Suspension for Injection for Cattle

Vm 05653/3016

•	18 May 2024	Introduction of a manufacturer of the active substance supported by an ASMF.
•	18 May 2024	One-off alignment of the product information with version 9.0 of the QRD templates.
•	15 December 2023	Minor changes to an approved test procedure for the finished product.
•	10 June 2021	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.
•	28 September 2020	Increase in batch size (from 98kg – 294kg to 98kg – 1500kg) of the finished product. Minor change in the manufacturing process of an oral solution.
•	24 September 2020	Change in the specification parameters of the finished product.
•	20 July 2020	Minor changes to an approved test procedure of the finished product
•	27 May 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	25 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	29 October 2019	Extension of the shelf-life of the product from 24 months to 36 months for the glass vial presentations.
•	11 July 2019	Renewal – UK as CMS
•	11 October 2018	Addition of a new supplier of the starting material used in the manufacturing process of active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier. Addition of a new supplier of the starting material used in the manufacturing process of active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
•	01 August 2018	Change in primary packaging. Change in batch size of active substance. Change in test procedure for the finished product. Change in test procedure for the finished product. Change in the manufacturing process of the finished product. Change in address of a manufacturer of the active

		substance. Change in name of a manufacturer of the active substance. Change in storage conditions of the active substance. Change in specification limits of an active substance. Submission of an updated certificate of suitability.
•	31 July 2018	Change to an in-process limit applied during the manufacture of the finished product.
•	15 December 2016	Minor changes to an approved test procedure of the finished product.
•	19 August 2016	Submission of new mock-ups to achieve joint-labelling with Ireland.
•	28 May 2015	Additional site for batch control/testing.