Veterinary Medicines Directorate

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Post Authorisation Assessments

Actionis 50 mg/ml, Suspension for Injection for Pigs and Cattle

Vm 31592/3003

•	04 May 2024	Updating and correcting pathogen terminology.
•	28 April 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.
•	10 November 2023	Change in immediate packaging of the finished product. One-off alignment of the product information with version 9.0* of the QRD templates.
•	10 October 2023	Change in any part of the primary packaging material not in contact with the finished product formulation. Change in the name or address or contact details of a manufacturer responsible for batch release. Change in the name or address or contact details of the manufacturer of the finished product. Change in the name or address or contact details of the marketing authorisation holder. Changes to the labelling or the SPC package leaflet which shall not be connected with the SPC: administrative information concerning the holder´s representative. Deletion of a finished product manufacturer. Changes to the quality part of the dossier: Deletion of - one of the authorised finishes product containers.
•	10 August 2023	Substantial changes in an updated version of an ASMF.
•	25 August 2021	Variation to update the ASMF for the active substance manufacturer.
•	04 March 2021	Replacement to a test procedure for the finished product.
•	29 June 2020	Replacement to a test procedure for the finished product.
•	28 April 2020	Addition of a supplier of packaging components or devices.
•	24 July 2018	Addition of a manufacturing site of the finished product. Change in the batch size range of the finished product.
•	05 April 2018	Deletion of a manufacturing site for an active substance.
•	27 September 2017	Changes to a test procedure for the finished product.
•	26 July 2017	Submission of updated ASMF
•	05 July 2017	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	12 April 2017	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	06 April 2016	Renewal - UK as CMS

•	01 September 2015	Changes to the product labelling.
•	22 June 2015	Addition of a local UK representative
•	25 March 2015	Addition of a new manufacturer of the active substance. Addition of new specification parameters and the corresponding test methods.
•	29 March 2012	Changes in Summary of Product Characteristics (SPC), labelling or package leaflet following a referral procedure