Veterinary Medicines Directorate

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Post Authorisation Assessments

AMX 10 mg/ml Concentrate for Solution for Fish Treatment

Vm 21714/4004

•	09 November 2023	Amendments to relevant sections of the SPC following the endorsement by the European Commission of the CVMP Opinion on the Article 83 referral regarding VMPs containing N-methyl pyrrolidone (NMP) as an excipient.
•	28 January 2022	Deletion of manufacturing site for a site where batch control takes place.
•	03 November 2021	Deletion of manufacturing site for a finished product. Deletion of manufacturing site for a finished product. Change in the shelf life of the finished product from 5 years to 3 years.
•	13 April 2021	Change in specification limit of the finished product.
•	25 March 2021	Changes to the labelling and package leaflet.
•	21 May 2020	Minor changes to an approved test procedure of the finished product. Addition of a new specification parameter with its corresponding test method of an active substance. Deletion of a non-significant parameter of an active substance. Deletion of a non-significant parameter of an active substance. Change in the specification parameters of the finished product. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.

		Change in the specification parameters of a starting material used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance. Deletion of a non-significant parameter of an active substance. Addition of a manufacturing site of the finished product. Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	03 December 2019	Change in the name of the manufacturer of the finished product. Addition of a site where batch control/testing takes place.
•	17 August 2017	Change to the environmental properties information in the SPC and product literature.
•	13 September 2016	Change in the name of a manufacturer/importer of the finished product (including batch release or quality control testing sites).
•	11 June 2015	Change in the name of the manufacturer of the active substance.
•	02 June 2015	Update to the DDPS.
•	21 March 2014	Addition of 1000 ml presentation. Updating of the SPC to amend calculation of treatment dose.
•	12 July 2013	Addition of user safety warnings.
•	13 August 2012	Increase in fill volume range.
•	19 December 2011	Renewal procedure – UK as CMS.
•	25 November 2011	Deletion of a non-significant specification parameter for an excipient.
•	12 November 2010	Change in test procedure of the finished product.
•	22 October 2010	Submission of Environmental Risk Assessment Report.
•	25 September 2009	To change the finished product test procedure.
•	11 September 2009	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.