Veterinary Medicines Directorate

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Post Authorisation Assessments

Ataxxa 500 mg/100 mg Spot-on Solution for Dogs Over 4 kg up to 10 kg

Vm 01656/3035

•	12 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	November 2023	Minor changes to an approved test procedure for an in-process test for the finished product.
•	12 June 2023	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	06 April 2023	Change in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid medicinal product following assessment of the same change for the reference product. One-off alignment of the product information with version 9.0* of the QRD templates.
•	18 November 2021	Changes to the labelling and/or package leaflet.
•	15 October 2021	Addition of a new therapeutic indication.
•	15 October 2021	Change in the number of units (e.g. tablets, ampoules, etc.) in a pack within the range of the currently approved pack sizes of the finished product.
•	16 June 2021	Minor change in the manufacturing process of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product.
•	06 January 2021	Renewal – UK as CMS
•	11 November 2020	Minor changes to an approved test procedure of the finished product.
•	13 March 2020	Update to indications section of the SPC.
•	03 March 2020	Minor change in the manufacturing process of the finished product. Change of specification of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
•	29 August 2019	To change a local representative from Krka UK Ltd, 20-22 Bedford Row, London, WC1R 4JS to KRKA UK Ltd, United Kingdom.
•	11 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 December 2018	Change to in-process tests or limits applied during the manufacture of the finished product Minor changes to an approved test procedure of the finished product

•	20 June 2018	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
•	27 February 2018	Change in the RMS from UK to IE.
•	05 December 2017	Increase in batch size from 10Kg-100kg to up to 150kg used in the manufacturing process of the active substance. Change in the manufacturer used in the manufacturing process of the active where no Ph. Eur. Certificate of Suitability is part of the approved dossier. Extension of a re-test period of the active substance.