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Post Authorisation Assessments

Awazom 800 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys Vm 01656/5071

•	09 April 2024	One-off alignment of the product information with version
		9.0 of the QRD templates.
•	19 December 2023	Introduction of a summary of the PSMF or changes to
		the summary of the PSMF not already covered
		elsewhere in this Annex.
•	17 October 2023	Unlimited renewal
•	14 July 2023	Change in the Marketing Authorisation Holder from
		KRKA UK ltd, Thames House, Waterside Drive, Langley,
		Berkshire, SL3 6EZ, United Kingdom to Krka,d.d, Novo
		Mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia.
•	30 January 2023	Updated certificate of suitability from an already
		approved manufacturer.
•	26 July 2022	Updated certificate of suitability from an already
		approved manufacturer.
•	07 July 2021	Change in the address of the marketing authorisation
		holder from KRKA UK Ltd Suite 1, 3rd Floor 11-12 St
		James's Square, London SW1Y 4LB United Kingdom to
		KRKA UK Ltd, Thames House, Waterside Drive,
		Langley, Berkshire SL3 6EZ United Kingdom
•	10 May 2021	Increase in the shelf-life of the finished product as
		packaged for sale, from 2 years to 3 years.
•	22 April 2021	Submission of a new Ph. Eur. certificate of suitability for
		an active substance from a new manufacturer.
•	09 December 2019	Introduction of a new pharmacovigilance system.
•	15 August 2019	Change in MAH and distributor from Billev Farmacija
		Vzhod d.o.o. to KRKA UK Ltd.
•	19 March 2019	Change in RMS from UK to SI.