



Post Authorisation Assessments

Awazom 800 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys Vm 01656/3071

20 March 2025	Updated CEP for an already approved manufacturer for an active substance.
09 April 2024	One-off alignment of the product information with version 9.0 of the QRD templates.
23 January 2024	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.