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Post Authorisation Assessments

HydroDoxx 500 mg/g Powder for Use in Drinking Water for Chickens and Pigs Vm 30282/4012

•	July 2023	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance (GB).
•	30 June 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	24 September 2019	Changes to a test procedure for the finished product. Change in the specification limits of the finished product.
•	23 August 2018	Deletion of an immediate packaging container. Increase in batch size (including batch size range*) of the finished product. Minor change in the manufacturing process of the finished product. Deletion of manufacturing site for an active substance. Deletion of manufacturing site for an active substance. Change in the fill weight/fill volume of the finished product.
•	03 July 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	17 November 2014	Renewal.
•	31 July 2013	Submission of two updated Ph. Eur. Certificates of Suitability.
•	30 June 2011	To change the shelf-life of the veterinary medicinal product as packaged for sale from 18 months to 3 years.
•	30 June 2011	Submission of a new or updated certificate of suitability.
•	26 April 2011	To update the SPC and product literature following the commission decision.
•	13 July 2010	Change in immediate packaging of the finished product. Change in the batch size (including batch size range) of the finished product. Change in the manufacturing process of the finished product. Change to the batch release arrangements and quality control testing of the finished product. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished

		product.
•	09 April 2010	To extend the shelf-life of the veterinary medicinal product as packaged for sale from 12 months to 18 months.