Veterinary Medicines Directorate

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Post Authorisation Assessments

Rhemox 500 mg/g Powder for Use in Drinking Water for Pigs, Chicken Broilers, Duck Broilers and Turkeys for Meat Production

Vm 36547/4005

•	14 September 2023	Change in the shelf-life or storage conditions of the finished product: - Extension of the shelf life of the finished product - After first opening (supported by real time data). Change in the shelf-life or storage conditions of the finished product: - Change in storage conditions of the finished product or the diluted/reconstituted product. Change in the specification parameters and/or limits of the finished product: - Other changes. Change in the specification parameters and/or limits of the finished product: - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue. Change in the specification parameters and/or limits of the finished product: - Reduction in the testing frequency of an analysis, from routine testing to skip or periodic testing (microbial testing of finished product). Change to in-process tests or limits applied during the manufacture of the finished product: - Other changes. Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product. Changes in the composition (excipients) of the finished product: - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the veterinary medicinal product.
•	25 July 2023	Change in the batch size (including batch size ranges) of the finished product: – up to 10-fold increase compared to the originally approved batch size of an immediate release oral pharmaceutical forms or of a non-sterile liquid based pharmaceutical form.
•	24 July 2023	Changes to the quality part of the dossier: Deletion of pack size(s) of the finished product.
•	30 June 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. (GB)
•	01 December 2020	Deletion of Ph. Eur. certificates of suitability for an active

		substance.
•	29 September 2020	Renewal - UK as CMS.
•	28 September 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance. Introduction of a re-test period of the active substance.
•	24 January 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	10 July 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	10 July 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	02 February 2017	Submission of a new certificate of suitability. Submission of a new certificate of suitability.