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

15 July 2026	Change in the name of a manufacturer or importer of the finished product.
06 May 2026	Submission of an updated Ph. Eur. CEP for an active substance. (NI)
21 April 2026	Submission of an updated Ph. Eur. CEP for an active substance. (NI)
01 April 2026	Submission of an updated Ph. Eur. CEP for an active substance. (GB)
23 March 2026	Change in the batch size range of the finished product.
23 March 2026	Deletion of a Ph. Eur. CEP for an active substance.
23 March 2026	Replacement of a manufacturing site for all of the finished product manufacturing process.
14 March 2026	Submission of an updated Ph. Eur. CEP for an active substance. (GB)
18 February 2026	Submission of an updated Ph. Eur. CEP for an active substance. (NI)
20 January 2026	Submission of an updated Ph. Eur. CEP for an active substance.
19 February 2025	Alignment of the product information with version 9.0* of the QRD templates.
28 January 2025	Addition of a quality testing site for the finished product. Addition of a manufacturer responsible for batch release and batch control of the finished product. Addition of a manufacturer responsible for batch release and batch control of the finished product. (NI + GB)
18 January 2025	Addition of a secondary packaging site of a finished product. (NI)
17 December 2024	Addition of a secondary packaging site of a finished product. (GB)
02 December 2024	Addition of a manufacturer responsible primary packaging of the finished product. (NI + GB)
02 December 2024	Addition of a manufacturing site for the finished product. (NI + GB)
14 November 2023	Submission of an updated certificate of suitability. (NI)
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 p 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.