Veterinary Medicines Directorate

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Post Authorisation Assessments

Qualimec 5 mg/ml Pour-on Solution for Cattle

Vm 13277/4022

07 October 2025	Change to comply with Ph. Eur. (NI)
11 August 2025	Change to comply with Ph. Eur. (GB)
14 May 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI).
13 December 2024	Addition of a site of batch control.
18 September 2024	Incorporation of changes required for products including NMP.
18 September 2024	Amendments to relevant sections of the SPC following the endorsement by the European Commission of the CVMP Opinion on the Article 83 referral regarding VMPs containing N-methyl pyrrolidone (NMP) as an excipient.
18 September 2024	Correction of a typographical error.
01 June 2023	Change of MAH address from Eco Animal Health Ltd, 78 Coombe Road, New Malden, Surrey, KT3 4QS, United Kingdom to Eco Animal Health Ltd, The Grange, 100 High Street, London, N14 6BN, United Kingdom.
15 February 2021	Addition of a site where batch control/testing takes place.
06 January 2021	Addition of a manufacturer responsible for batch release of the finished product. Deletion of manufacturing site for an active substance. Deletion of manufacturing site for a finished product.
09 March 2020	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
09 May 2019	Minor change in the manufacturing process of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Minor changes to an approved test procedure of the finished product.
25 October 2016	Change in the QPPV and/or QPPV contact details and/or back-up procedure. Change in the QPPV and/or QPPV contact details and/or back-up procedure.
13 June 2014	Changes to the limits of the finished product. To reduce the shelf-life of the finished product to 24 months.
23 May 2012	Approval of mock-ups.
02 May 2012	Change of distributor.
17 November 2011	Renewal – UK as CMS.
27 November 2008	To change the name of medicinal product name from Fatromectin 5 mg/ml Pour-on Solution for Cattle to Qualimec 5

	mg/ml Pour-on Solution for Cattle.
15 August 2008	To add an additional manufacturing site.
30 July 2008	To add an additional batch release site.
30 July 2008	To add additional batch sizes.