Veterinary Medicines Directorate

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Post Authorisation Assessments

Aqupharm 1 (9 mg/ml) Solution for Injection/Infusion

Vm 32742/4019

•	07 August 2023	Change in test procedure for the finished product. Change in the batch size of the finished product. Minor change in the manufacturing process. Minor change in the manufacturing process. Change in the holding time of an intermediate or bulk product. Minor change in the manufacturing process of a sterile finished product after the primary packaging step. Change to importer, batch release arrangements and quality control testing of the finished product. Change to importer, batch release arrangements and quality control testing of the finished product. Change to in-process limits applied during the manufacture of the finished product. Change to in-process limits applied during the manufacture of the finished product. Change in the composition of the finished product. Change in the composition of the finished product. Replacement of a manufacturing site. Replacement of a manufacturing site. Submission of a new or updated Ph. Eur. certificate of suitability. Change in immediate packaging of the finished product. Substantial change to a biological/immunological/immunochemical test method. Change in the specification limits of the finished product.
•	14 July 2023	Replacement or addition of a secondary packaging site of the finished product.
•	11 August 2022	Change of MAH: from Animalcare Ltd, 10 Great North Way, York Business Park, Nether Poppleton, York, YO26 6RB, United Kingdom to Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium.
•	04 February 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	08 October 2021	Renewal – UK as CMS
•	03 December 2020	Approval of mock-ups.
•	23 October 2020	Harmonise the product information between Belgium and France. Change in the invented name of the veterinary medicinal product in France and Finland.
•	23 October 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the contact details of 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.

•	08 February 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance.