Veterinary Medicines Directorate

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Post Authorisation Assessments

Alfaxan Multidose 10 mg/ml Solution for Injection for Dogs, Cats and Pet Rabbits

Vm 25296/4004

•	24 January 2023	Change to batch control arrangements and quality testing (replacement or addition of a site) for a finished product. Changes to quality control testing arrangements for the active substance: replacement or addition of a site where batch control or testing of the active substance takes place. Changes to the quality part of the dossier: Deletion of - a manufacturing site for an active substance, intermediate. Minor changes to an approved test procedure for the immediate packaging of the finished product.
•	18 January 2023	Additional site of batch release for Northern Ireland.
•	05 October 2022	Update of address of the external laboratory for sterility testing. Update of address of the external laboratory for microbial testing. Deletion of a manufacturing site for the intermediate of the active substance. Minor changes to an approved test for the immediate packaging of the finished product.
•	02 August 2022	Minor changes to the manufacturing process of the finished product.
•	17 June 2021	Replacement of a manufacturer responsible for batch release of the finished product.
•	12 May 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in the name/address of a manufacturer of an intermediate used in the manufacture of the active substance. Tightening of specification limits of the finished product.
•	30 December 2020	Update of SPC and package leaflet text as assessed under Regulation 1901/2006.
•	05 August 2020	Change in shape or dimensions of the container or closure (immediate packaging). Addition of a specification parameter of the finished product.
•	08 June 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.

•	11 February 2019	Change in RMS from UK to IE.