Veterinary Medicines Directorate

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Post Authorisation Assessments

Vulketan 2.5 mg/g Gel for Horses
Vm 44684/4005

•	21 December 2020	Change of MAH, from Eli Lilly and Company Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Audevard, 42-46 Rue Médéric, 92110 Clichy, France.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	09 August 2016	Addition of a site where batch control/testing takes place.
•	01 August 2016	Renewal – UK as CMS
•	02 December 2015	Addition of the suffix “vet” in the registered Danish and Icelandic trade names
•	03 September 2015	Changes in the specification parameters of the active substances.
•	29 October 2014	To reduce the batch size of the finished product, from 1000 kg to 450 kg.
•	25 April 2014	Changes to an existing pharmacovigilance system.
•	23 December 2013	Change to the information of the finished product via addition of a new test parameter. Addition/replacement of a manufacturing site for part of the production process for the finished product packaging. Extension of shelf-life from 24 to 36 months.
•	22 October 2013	Change to the address of the MAH in Portugal only.
•	24 May 2013	Change in address of MAH in France only
•	11 July 2012	To approve mock-ups.
•	20 June 2012	Change of Marketing Authorisation Holder from Janssen Pharmaceutical NV to Eli Lilly and Company.