Veterinary Medicines Directorate

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Post Authorisation Assessments

Apiguard Gel (25% Thymol) for Beehive Use

Vm 17017/4002

•	25 June 2021	Change in the name of a manufacturer of active substance.
•	23 September 2020	Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product. Addition of a manufacturing site of the finished product.
•	17 July 2020	Increase in batch size of the finished product. Minor change in the manufacturing process of the finished product. Replacement to a test procedure for the finished product. Change in the specification parameters and limits of an excipient.
•	12 March 2020	Replacement of a manufacturer responsible for batch release including batch control/testing.
•	12 February 2020	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.
•	30 July 2018	Minor amendments to the product literature.
•	27 February 2015	Amendment to section 4.6 of the SPC and corresponding product literature. Change to the name of the manufacturer responsible for batch release.
•	16 August 2012	Minor modifications to the DDPS.
•	17 October 2011	Change to the MA holder address.
•	23 March 2011	Harmonisation of the SPC and product literature for joint labelling with IE.
•	07 May 2010	Renewal.
•	16 October 2009	Change to a test procedure for the finished product and a minor change in manufacture of the finished product.
•	29 April 2005	Extension of product shelf life.