Veterinary Medicines Directorate

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Post Authorisation Assessments

Vitbee 1000, 0.100 % w/v Solution for Injection

Vm 36408/4012

•	25 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	18 August 2021	Change of Marketing Authorisation Holder from Dechra Ltd. to Alfasan Nederland B.V.
•	27 March 2020	Addition of a site where batch control/testing takes place.
•	26 February 2019	Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	05 October 2017	Changes to the labelling and package leaflet
•	29 September 2016	Change in the address of the Marketing Authorisation Holder.
•	07 May 2015	Submission of an updated certificate of suitability.
•	14 October 2013	Variation to increase the batch size and to change the manufacturing method.
•	25 February 2013	Variation to change the supplier of a packaging component.
•	14 February 2013	Submission of a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	06 January 2011	Change of distributor.
•	27 June 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
•	26 March 2008	Variation to change the Marketing Authorisation Holder.
•	05 September 2007	Renewal.
•	16 November 2004	Horse Passport Variation.
•	30 April 2003	Renewal.
•	12 March 1998	Renewal.
•	18 July 1996	Addition of a packaging presentation.