Veterinary Medicines Directorate

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Post Authorisation Assessments

Fipralone Duo 268 mg/80 mg Spot-on Solution for Large Dogs

Vm 17902/4086

•	08 December 2022	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	25 October 2022	Change in the name or address or contact details of a manufacturer of active substance.
•	24 October 2022	Change to an approved stability protocol of an active substance.
•	October 2022	Change to an approved stability protocol of an active substance.
•	20 October 2022	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	27 November 2020	Change in the name of the manufacturer of the finished product. Deletion of manufacturing site for an active substance.
•	19 June 2020	Renewal- UK as CMS.
•	26 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	22 January 2019	Change in RMS from UK to FR.
•	12 October 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. monograph 2869.
•	09 January 2018	Change in the name of the manufacturer of the finished product.
•	26 June 2017	Minor changes to an approved test procedure of the finished product.
•	14 June 2017	Change in the name and address of a manufacturer used in the manufacture of the active substance. Addition of a manufacturer of the active substance.
•	15 March 2017	Minor change in the manufacturing process of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	04 February 2016	Change in the invented name of the product in ES, IT, and NL only.
•	17 November 2015	To change the invented name of the medicinal product from 'Fipralone Combo' to 'Fipralone Duo' in UK and ‘Fiprokil Combo’ to ‘Fiprokil Duo’ in France.