Veterinary Medicines Directorate

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Post Authorisation Assessments

Pro-Tel Flavoured Tablets for Large Dogs

Vm 15052/4056

•	05 September 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
•	31 May 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI) Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	12 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire HP10 0HH, United Kingdom.
•	29 December 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	21 December 2020	Updates to the SPC and labelling following a Periodic Safety Update Report.
•	18 November 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	16 January 2019	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	08 June 2018	Change in RMS from UK to IE.
•	23 November 2017	Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	19 September 2017	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.
•	10 March 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	19 April 2016	Submission of an updated certificate of suitability.
•	22 December 2015	Updating of the DDPS system.
•	31 March 2015	Renewal procedure – UK as RMS.
•	11 July 2014	Change to the manufacturing process. Change to the specification of the finished product. (Large dogs product only).
•	06 March 2014	To change the name of the veterinary medicinal product to 'Pro-Tel' in the UK and 'Prowormer' in Ireland.
•	09 January 2014	Change in the batch size of the active substance and change to manufacturing process of the active substance.
•	09 January 2014	Submission of a new or updated European Pharmacopoeia certificate of suitability.
•	31 December 2013	Submission of a new or updated European Pharmacopoeia certificate of suitability.
•	30 December 2013	Change to manufacturing process for finished product and an intermediate used in the manufacture of the finished product.
•	11 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS.
•	16 September 2013	Change in the invented name of the medicinal products from Prowormer Flavoured Tablets for Large Dogs to Pro-Tel Flavoured Tablets for Large Dogs, in Ireland only.
•	25 April 2012	Approval of mock-ups prior to marketing.
•	14 March 2012	To change the distributor.
•	06 January 2012	To change the address of the MAH.
•	07 December 2011	New MRP.
•	14 September 2011	Change in the invented name of the medicinal product from Proworm Flavoured Tablets for Large Dogs, to Prowormer Flavoured Tablets for Large Dogs.