Veterinary Medicines Directorate

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Post Authorisation Assessments

Prinovox 250 mg + 62.5 mg Spot-on Solution for Large Dogs

Vm 00879/4154

19 January 2025	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance. (NI)
22 December 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
27 November 2024	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance. (GB)
21 February 2023	Change in the re-test period of the active substance.
13 February 2023	Change in the re-test period of the active substance.
09 February 2022	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
05 August 2021	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Introduction of a re-test period of the active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance.
23 June 2021	Renewal - UK as CMS.
08 October 2020	Change of MAH, from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
26 October 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
03 July 2018	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
23 April 2018	Change in RMS from UK to DE.
05 January 2018	Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD.
24 August 2017	Change in the name of a manufacturer used in the manufacture of the active substance.
15 June 2017	Change in the number of units (e.g. tablets*, ampoules*, etc.) in a pack outside the range of the currently approved pack sizes of the finished product.
16 May 2017	MRP (UK as RMS)
24 May 2016	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH

18 May 2016	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
25 August 2015	Change in test procedure for the finished product.
30 July 2015	Additional manufacturing site for secondary packaging.
30 June 2015	Submission of an updated certificate of suitability.