Veterinary Medicines Directorate

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Post Authorisation Assessments

Advantix Spot-on Solution for Dogs over 4kg up to 10kg

Vm 00879/4109

•	29 February 2024	Amendments to relevant sections of the SPC following the endorsement by the European Commission of the CVMP Opinion on the Article 83 referral regarding VMPs containing N-methyl pyrrolidone (NMP) as an excipient.
•	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.
•	05 July 2022	Addition of a new specification parameter to the specification with its corresponding test method. Deletion of a non-significant specification parameter. Minor changes to an approved test procedure for an active substance. Tightening of specification limits for an active substance. Deletion of manufacturing site for an active substance. Change in the specification for an active substance. Changes in the manufacturing process of the active substance.
•	26 February 2021	Addition of a new therapeutic indication.
•	23 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.
•	08 August 2019	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Tightening of specification limits of an intermediate used in the manufacturing
•	17 July 2019	Increase in batch size of the active substance. Minor change to an approved test procedure for the active substance used in the manufacturing process. Minor change to an approved test procedure for the active substance used in the manufacturing process. Deletion of a test procedure for the active substance used in the manufacturing process of the active substance if an alternative test procedure is already authorised. Change in the name of a supplier of active substance. Minor change in the manufacturing process of the active substance. Change in manufacturer of the active substance.

		Change in limit of a starting material used in the manufacturing process of the active substance.
•	27 June 2019	Addition of a new container for the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	26 October 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	18 September 2018	Change in distributor details from Bayer plc, Animal Health Division, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green park, Reading, Berkshire, RG2 6AD.
•	29 December 2017	Change in the address of the marketing authorisation holder from Animal Health Division Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD.
•	27 September 2017	Addition of a new therapeutic indication.
•	31 March 2017	Change in the name of a manufacturer used in the manufacture of the active substance.
•	21 June 2016	Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH
•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	14 August 2015	Change in pack size of the finished product.
•	01 October 2014	Change in name of the MAH in France only.
•	10 June 2013	Changes to labelling/package leaflet unconnected with the SPC.
•	20 July 2012	Change of in process test/limits applied during the manufacture of the finished product.
•	13 April 2012	Variation to make several changes to the manufacturing process and in-process controls of the active substance and make changes to specification(s)/test procedures of starting materials and reagents/solvents used in the manufacture of the active substance.
•	22 December 2011	Change to in process tests/limits applied during manufacture of the active substance.
•	12 December 2011	Addition of a therapeutic indication.
•	23 February 2011	Change of distributor.
•	17 January 2011	Change in manufacturer of starting material/reagent/intermediate used in the manufacture of the active substance.
•	17 August 2009	Change in the shelf life of the finished product.
•	17 August 2009	Change in the shelf life of the finished product after first opening.
•	25 June 2009	Renewal.
•	25 October 2007	Change in manufacturing process of the active substance.
•	24 August 2006	Corrections/simple text layout changes to SPC and Product literature.
•	07 July 2006	Change of name/address of manufacturer of the active substance.

•	16 March 2006	Addition of an ‘Indiciation’.
•	19 August 2004	Change in shelf life of finished product in final packaging from 2 to 3 years, and after opening from 1 year to 18 months.