Veterinary Medicines Directorate

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Post Authorisation Assessments

Anthelmin Plus XL Tablets for Dogs

Vm 01656/4016

•	23 February 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB)
•	23 February 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (NI)
•	19 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	January 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB)
•	04 December 2023	Introduction of a summary of the PSMF. (GB)
•	05 October 2023	Substantial changes in the updated version of the ASMF.
•	07 June 2023	Submission of a new certificate of suitability.
•	16 March 2023	New certificate of suitability from a new manufacturer.
•	06 January 2023	Updated certificate of suitability from an already approved manufacturer.
•	13 October 2022	Updated certificate of suitability from an already approved manufacturer.
•	07 April 2022	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.
•	13 April 2021	Minor changes to an approved test procedure of the finished product.
•	16 March 2021	Changes to the labelling and/or package leaflet.
•	26 January 2021	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.
•	19 November 2020	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the

		finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product.
•	17 September 2020	Submission of a new Ph. Eur. certificate of suitability for an active from a new manufacturer.
•	16 August 2019	Addition of a site where batch control/testing takes place.
•	11 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 April 2019	Addition of a manufacturer responsible for batch release including batch control/testing. Deletion of manufacturing site for a finished product. Replacement of a secondary packaging site of the finished product. Replacement of a primary packaging site of the finished product. Replacement of a manufacturing site of the finished product.
•	26 March 2019	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.
•	26 October 2018	Change in RMS from UK to IE.
•	23 October 2018	Update to the Local Representative details.
•	05 April 2018	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
•	09 January 2018	Deletion of a non-significant specification parameter of the finished product.
•	25 July 2017	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	12 April 2017	Deletion of manufacturing site for an active substance
•	01 December 2016	Mock-ups approved.
•	07 October 2016	Addition of a new test method. Addition of an active substance manufacturer.
•	05 September 2016	Change in the (invented) name of the medicinal product in Spain and Portugal.
•	02 June 2016	Renewal – UK as RMS
•	25 November 2015	To update the administration advice in section 4.9 of the SPC
•	22 April 2015	Addition of UK local representative information to package leaflet.
•	23 March 2015	Change in distributor details.
•	09 May 2014	Receipt of an updated Certificate of Suitability for an active substance.
•	19 December 2013	To update the pharmacovigilance system.
•	19 December 2013	Deletion of a manufacturing site for primary and secondary packaging.

•	01 November 2013	Submission of an updated Ph. Eur. certificate of suitability.
•	21 March 2013	Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics
•	01 March 2013	Deletion of a secondary packaging site and deletion of a manufacturing site responsible for batch release.
•	12 October 2012	Deletion of a manufacturing site for the active substance febantel; deletion of a manufacturing site for the active substance praziquantel; addition of a primary packaging site for the finished product; addition of a manufacturing site (not responsible for batch release or batch control) for the finished product.
•	10 August 2012	Change of invented name of veterinary medicinal product.
•	06 January 2012	Submission of a new or updated Ph. Eur. certificate of suitability.