Veterinary Medicines Directorate

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Post Authorisation Assessments

Endogard Plus Flavour Tablets for Dogs

Vm 01656/4017

•	04 March 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
•	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)
•	11 December 2023	Submission of a new certificate of suitability. (NI)
•	04 December 2023	Introduction of a summary of the PSMF. (GB)
•	05 October 2023	Substantial changes in the updated version of the ASMF.
•	16 March 2023	New certificate of suitability from a new manufacturer.
•	06 January 2023	Updated certificate of suitability from an already approved manufacturer.
•	10 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.
•	09 November 2021	Change in the invented name of the veterinary medicinal product from Anthelmin Plus Flavour Tablets for dogs to Dehinel Plus Flavour Tablets for dogs in Poland only.
•	13 April 2021	Minor changes to an approved test procedure of the finished product.
•	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.
•	25 November 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
•	08 July 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. Addition of a manufacturer responsible for batch release of the finished product. Change in the shape or dimensions of the pharmaceutical form. Addition of a manufacturing site of the finished product.
•	16 August 2019	Addition of a site where batch control/testing takes place.
•	28 June 2019	Change in the invented name of the veterinary medicinal product from Dehinel Plus Flavour Tablets for Dogs to Anthelmin Plus flavour in PL only.
•	18 June 2019	Deletion of manufacturing site for an active substance. 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.
•	18 June 2019	Addition of a site where batch control/testing takes place. Deletion of manufacturing site for finished product and packaging site. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	11 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	26 October 2018	Change in RMS from UK to IE.
•	26 July 2017	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
•	11 April 2017	Changes to the package leaflet.
•	18 October 2016	Change in test procedure for the active substance. Submission of a new Ph. Eur. certificate of suitability for an Active Substance.
•	23 June 2016	Change in the shelf life of the finished product from 2 to 3 years
•	26 January 2016	Renewal – UK RMS
•	04 July 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
•	28 February 2014	Updates to the pharmacovigilance system.

•	13 February 2014	Deletion of a site responsible for manufacture of the finished product and packaging.
•	01 November 2013	Submission of an updated Ph. Eur certificate of suitability.
•	09 May 2013	To change the dimensions of the immediate packaging. Changes to the text on the immediate packaging and package leaflet.
•	12 October 2012	Deletion of manufacturing sites. Replacement or addition of manufacturing site for part or all of the process of the finished product.
•	02 May 2012	Changes to the labelling and package leaflet not connected to the SPC.
•	06 January 2012	Submission of a new Ph. Eur certificate of suitability.