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Post Authorisation Assessments

Rycarfa 20 mg Tablets for Dogs Vm 01656/4069

•	27 February 2024	Submission of an updated certificate of suitability. (NI)
•	12 January 2023	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	17 April 2023	Change to comply with Ph. Eur. reflect compliance with the Ph. Eur. by removing reference to the internal test method and test method number.
•	23 February 2023	Change to comply with Ph. Eur. reflect compliance with the Ph. Eur. by removing reference to the internal test method and test method number.
•	28 December 2022	Updated certificate of suitability from an already approved manufacturer.
•	08 March 2022	Minor change to an approved test procedure for the active substance.
•	16 December 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 November 2021	Minor changes to an approved test procedure of the finished product.
•	22 April 2020	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product.
•	25 February 2020	Changes to the labelling and package leaflet.
•	06 February 2020	Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a manufacturing site of the finished product.
•	16 December 2019	Deletion of manufacturing site for a finished product. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	10 December 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	12 November 2019	Change in the manufacturer of a starting material used in the manufacturing process of the active substance.
•	11 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 February 2019	Renewal - UK as CMS.
•	10 May 2017	Minor change to the restricted part of an Active Substance Master File.

•	19 May 2015	Addition of UK local representative information to the
		package leaflet.
•	08 September 2014	Variation to extend the maximum holding time for the
		finished product packaged in PE/Alu triplex bags, from 2 months to 12 months.