Veterinary Medicines Directorate

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Post Authorisation Assessments

Zodon 150 mg Chewable Tablets for Dogs

•	06 October 2021	Change in the SPC, labelling or package leaflet due to new data.
•	26 July 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 May 2019	Replacement of a site where batch control/testing takes place
•	09 April 2019	Renewal – UK as CMS
•	06 July 2018	Change in RMS from UK to FR.
•	28 June 2018	Deletion of a manufacturer responsible for batch release
•	14 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 March 2018	Change in product name in DK, FI, NO, NL, LU only.
•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 September 2017	Change in the name and/or address of the MAH in Spain only.
•	22 August 2017	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
•	20 October 2016	Change in shelf-life of the veterinary medicinal product as packaged for sale from 21 months to 3 years.
•	08 September 2016	Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name of the manufacturer of the finished product.
•	06 September 2016	Change in the name an address of the MAH in Italy only.
•	29 June 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	16 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd.