Veterinary Medicines Directorate

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Post Authorisation Assessments

Modulis 100 mg/ml Oral Solution for Dogs

Vm 14966/3074

16 May 2026	Change in the pharmacovigilance system master file (PSMF) location. Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
22 April 2026	Change to the administration device which is not an integrated part of the primary packaging. Alignment of the labelling to conform with small immediate packaging requirements.
07 November 2025	Change in legal entity of MA holder from Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom to Ceva Sante Animale, 8 rue de Logrono, 33500 Libourne, France.
10 October 2025	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance. Addition of a manufacturing site responsible for batch control. (GB)
10 October 2025	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance. Addition of a manufacturing site responsible for batch control. (NI)
10 October 2025	Change in dimensions of the immediate packaging. Change in dimensions of the immediate packaging. Change in immediate packaging specification parameters. (NI)
10 October 2025	Minor change in the manufacturing process of the finished product. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer.(GB + NI)
18 September 2025	Alignment of the product information with version 9.0* of the QRD templates.
17 September 2025	Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. (GB + NI)
17 September 2025	Deletion of a Ph. Eur. CEP for an active substance. (NI) Submission of an updated Ph. Eur. CEP for an active substance. (NI)
04 April 2025	Addition of a manufacturing site responsible for batch release.
27 March 2025	Change in dimensions of the immediate packaging. Change in dimensions of the immediate packaging. Change in immediate packaging specification parameters. (GB)
16 August 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
04 August 2023	Change in the shelf-life of the finished product.

18 January 2023	Deletion of a certificate of suitability for an active substance. Updated certificate of suitability from an already approved manufacture.
14 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
19 August 2022	Change in the appearance of the finish product. Change in the clarity of the finish product. Change outside the approved specifications limits range.
28 July 2020	Change in the specification limits of the finished product.
17 December 2019	Renewal – UK as CMS
18 October 2018	Replacement of a manufacturer responsible batch release of the finished product.
09 March 2018	Change in RMS from UK to FR.
28 February 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Extension of a re-test period of the active substance.
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.
16 December 2016	Change in name of the site of batch release 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.