Veterinary Medicines Directorate

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Post Authorisation Assessments

Ovarelin 50 µg/ml, Solution for Injection for Cattle

Vm 14966/3058

12 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).
17 October 2025	Change of legal entity of the Marketing Authorisation 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.
21 July 2025	Submission of Mock ups.
19 December 2024	One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6.
31 May 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
04 May 2024	Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance: - Other changes
05 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.
06 March 2020	Modification to the manufacturing process of the finished product.
22 August 2019	Minor change in the manufacturing process of an immediate release oral solutions. Change to in-process tests applied during manufacture of finished product.
11 July 2019	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
18 April 2019	Change in the invented name of the veterinary medicinal product from Ovarelin 50 µg/ml, solution for injection for cattle to Ovareline 50 µg/ml, solution for injection for cattle in Norway. Changes (Safety/Efficacy) to Human and Veterinary

	Medicinal Products
19 February 2019	Change of RMS from UK to IE.
30 October 2018	Repeat use application to add 4 new member states.
29 March 2018	Updates to the SPC and PL following a repeat use procedure.
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.
30 August 2017	Renewal – UK as RMS.
07 November 2016	Approval of mock ups for the 20 ml presentation.
15 March 2016	Addition of a new therapeutic indication and modification of an approved indication.
22 December 2015	Updating of the DDPS system.
06 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
15 January 2015	Change in the address of the MAH in Czech Republic only.
17 August 2012	Repeat Use procedure.
06 January 2012	Change in the name and/or address of the Marketing Authorisation Holder.
01 December 2011	Renewal – UK as RMS.
16 December 2010	To change the medicinal product name in Spain.
13 January 2010	To change the manufacturing site for the active substance of the approved manufacturer.