

Post Authorisation Assessments

Progressis Emulsion for Injection Vm 14966/3078

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| 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. |
| 04 September 2025 | 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. |
| 19 March 2025 | Approval of mock-ups. |
| 18 January 2025 | Change to an approved stability protocol. |
| 12 June 2024 | One-off alignment of the product information with version 9.0* of the QRD templates. |
| 15 August 2023 | Deletion of a manufacturing site for an active substance. |
| 24 January 2023 | Change in product name from Progressis Vet Emulsion for Injection for Pigs to Progressis Emulsion for Injection for Pigs in DK only. |
| 12 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. |
| 21 July 2021 | Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name of a manufacturer of the finished product, also responsible for batch release. |
| 15 July 2021 | Changes to the labelling and/or package leaflet. |
| 23 March 2021 | Change to part of the (primary) packaging material not in contact with the finished product formulation. Removal of the details of sterilisation for the aluminium cap in the quality documentation. |
| 12 June 2020 | Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Change in the manufacturer of a starting material used in the manufacturing process of the active. Change in the manufacturer of the active. Addition of a site where batch control/testing takes place. Addition of a manufacturing site of the finished product. |
| 19 March 2019 | Change in the manufacturing process of the finished product |
| 03 September 2018 | Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. |

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| | Minor change in the manufacturing process of the active substance. |
| 16 July 2018 | Introduction of a new pharmacovigilance system. |
| 13 June 2017 | Change of MAH address from Merial Animal Health Limited to Ceva Animal Health Ltd. Change in distributor details from Merial Animal Health Limited to Ceva Animal Health Ltd. |
| 28 March 2017 | Addition of a manufacturer responsible for batch release of the finished product. Addition of secondary packaging site of the finished product Addition of secondary packaging site of the finished product |
| 17 January 2017 | Changes to a test procedure (including replacement) for a reagent used in the manufacturing process of the active substance. |
| 17 January 2017 | Minor change in the manufacturing process of the active substance. |
| 29 June 2016 | Addition of site as alternative manufacturing site for the active ingredient. |
| 11 September 2015 | Changes in the manufacturing process of the active substance. |
| 09 July 2015 | Submission of two new TSE certificates for a starting material. |
| 17 June 2014 | Change of the MA holder address in Portugal only. |
| 31 March 2014 | Change of the MA holder address in Spain only. |
| 23 January 2014 | Change to the MA holder address in Belgium only. |
| 14 July 2010 | Renewal, UK as CMS. |
| 09 January 2008 | Change to comply with the Ph. Eur. or MS National Pharmacopoeia. |
| 26 April 2006 | Variation to update labels to allow dual labelling with IE. |
| 22 February 2005 | Renewal. |
| 22 January 2004 | Change in the address of the manufacturer responsible for batch release in the EEA. |
| 05 December 2003 | Change in the name of the Marketing Authorisation Holder in France. |
| 10 June 2003 | Addition of suppliers of an active substance. |
| 26 March 2002 | Variation concerning a change to the specification of a starting material. |
| 03 November 2000 | New MRP. |