Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

# Post Authorisation Assessments

## Hyogen Emulsion for Injection for Pigs

Vm 14966/5050

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| 11 May 2026 | Addition of repeated batching as an alternative fermentation method for the antigen. Change in the preparation and sterilisation of the production media. |
| 10 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. |
| 22 August 2025 | To change the time at which expiry date is calculated from the date of finished product potency test to the date of filling. |
| 16 August 2024 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance. |
| 20 July 2024 | Approval of mock ups. |
| 28 April 2024 | Change in name of a quality control testing site. |
| 28 March 2024 | A new final product control test, testing the extractable volume of the finished product in addition to currently applied filling volume test performed during the filling process.<br>To extend the shelf life of the vaccine from 15 months to 24 months.<br>An additional new test measuring the paraffin oil content in the vaccine.<br>A sandwich ELISA assay for antigen quantification using the same methodology, like the proposed in-vitro sandwich ELISA potency test. The proposed test is intended as in-process control test on the inactivated, concentrated antigen suspension.<br>A new in-vitro method (sandwich ELISA assay) for control the potency of final product, replacing the current one, which is an in-vivo/iv-vitro test system measuring rabbit serology.<br>Follow-up updates based on earlier variations.<br>One-off alignment of the product information with version 9.0* of the QRD templates. |
| 27 January 2023 | Increase in the batch size of the finished product. |
| 13 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. |
| 16 March 2022 | Change in the SPC, labelling or package leaflet due to new data. |
| 06 September 2021 | Change in the fill volume of the finished product. |
| 06 July 2021 | Change in the manufacturer of a starting material used in the manufacturing process of the active substance. |
| 23 June 2021 | Replacement to a test procedure for the finished product. |

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| 10 June 2020 | Replacement of a site where batch control/testing takes place. |
| 27 March 2020 | Renewal - UK as CMS. |
| 21 November 2019 | Changes in the SPC, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006. |
| 21 November 2019 | Increase in batch size of active substance or intermediate used in the manufacturing process of the active substance. |
| 01 October 2019 | Change to an approved stability protocol. |
| 22 May 2019 | Change in the fill volume of the finished product. |
| 08 April 2019 | Change in test procedure for an excipient. |
| 31 January 2019 | Change in the invented name of the veterinary medicinal product from Hyobloc (SE) and Mhyogen (DK) to Mhyogen vet in SE and DK. |
| 19 September 2017 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.<br>Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| 08 August 2017 | Replacement to a test procedure for the finished product. |
| 06 October 2016 | Change in the specification limits of the finished product.<br>Change in the manufacturing process of the active substance. |
| 20 September 2016 | Addition of an alternative site for the animal testing phase of the potency test. |
| 06 January 2016 | Submission of an updated DDPS. |