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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

MS-H Vaccine Oculonasal Suspension

Vm 61467/5000

14 September 2026	Change in the name of the testing site for a finished product.
16 December 2025	To increase the shelf life from four years to five years.
04 December 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
15 October 2025	Change in legal entity of MA holder from Pharmsure International Ltd, Unit 28 Moorlands Trading Estate, Moor Lane, Metheringham, Lincolnshire, LN4 3HX, United Kingdom to Pharmsure Veterinary Products Europe Limited, 4 Fitzwilliam Terrace, Strand Road, Bray, Wicklow, A98 T6H6, Ireland.
26 March 2025	Changes in the Summary of Product Characteristics and Package Leaflet due to update in the pharmaceutical form and route of administration. Changes in the Summary of Product Characteristics and Package Leaflet by amending the description of special precautions for safe use in the target species.
07 November 2024	To change the batch release specification (sterility) to low bioburden. To add an alternate test site for batch release sterility testing.
22 June 2024	Update to the national template.
18 May 2024	To introduce an alternative rubber stopper of the same quality but supplied by National Resources and manufactured by Datwyler.
28 July 2022	Change in the address of a sterility testing site.
22 April 2021	Change to in-process limits applied during the manufacture of the active substance.