Veterinary Medicines Directorate

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Post Authorisation Assessments

Macrosyn 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep

Vm 50146/4042

15 September 2026	Change in the batch size of the finished product.
14 September 2026	Extension in the finished product shelf life as packaged for sale.
10 September 2026	Alignment of the product information with version 3 of the QRD templates.
01 May 2025	Introduction of a manufacturer of the active substance supported by an ASMF.
11 October 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
09 January 2023	Minor change in the manufacturing process.
13 April 2022	Change to part of the (primary) packaging material not in contact with the finished product formulation.
23 December 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
18 March 2021	Replacement of a secondary packaging site of the finished product.
26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
02 December 2020	Changes to the labelling and package leaflet.
07 October 2020	Change of MAH, from Triveritas Ltd, Bank Barn, How Mill, Brampton, Cumbria, CA8 9JY, United Kingdom to Bimeda Animal Health Limited, 2, 3, 4 Airton Close, Tallaght, Dublin 24, IE-D24 E032, Ireland.