Veterinary Medicines Directorate

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Post Authorisation Assessments

ACEGON 50 micrograms/ml Solution for Injection for Cattle

Vm 31592/4005

04 September 2026	Updated Mock-ups submitted.
28 August 2026	Change in the address of a manufacturer of the finished product. (GB)
22 February 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
20 October 2025	Alignment of the product information with version 9.0* of the QRD templates.
20 October 2025	Change in the name and address of the marketing authorisation holder from: Laboratorios Syva S.A.U., Avda. Párroco Pablo Díez, 49-57, 24010 León, Spain to Laboratorios SYVA S.A., Calle Marqués de la Ensenada, 16, 28004 Madrid, Spain. Change in the address of a manufacturer of the finished product. Change in the address of a manufacturer of the finished product. Change in the address of a manufacturer of the finished product.
03 May 2023	Changes in specifications of the active substance to comply with an updated monograph of the Ph. Eur. (NI)
15 March 2023	Change of the test procedure for the finished product. Change of the test procedure for the finished product Change of the test procedure for the finished product
17 February 2023	Change to in-process tests or limits applied during the manufacture of the finished product.
31 January 2023	Change of the test procedure for the finished product. Change of the test procedure for the finished product. Change of the test procedure for the finished product.
15 November 2022	Changes in specifications of the active substance to comply with an updated monograph of the Ph. Eur. (GB)
20 November 2020	Change in distributor details from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street London EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead Surrey KT22 7LP.
13 May 2020	Increase in batch size (from 100L to 100-157.5L) of the finished product.
27 November 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.

28 August 2018	Deletion of a pack size of the finished product.
19 April 2018	Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.
07 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active from an already approved manufacturer.
13 July 2016	Renewal – UK as CMS
17 July 2014	Submission of a new Ph. Eur. Certificate of Suitability for the active substance.
02 July 2014	Changes to the therapeutic indications.
10 April 2014	Change in the invented name of the veterinary medicinal product in Italy only.
05 February 2014	Updated mock-ups approved.
23 October 2013	Repeat-Use procedure: UK comment.
22 July 2013	Change of distributor.
06 February 2013	Change of distributor.
02 January 2013	Change to the manufacturing process of the finished product.
27 August 2012	Deletion of a non-significant specification parameter from the Ph. Eur Certificate of Suitability.
27 August 2012	Submission of an updated Ph. Eur Certificate of Suitability for the active substance.