Veterinary Medicines Directorate

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

Post Authorisation Assessments

Marbox 100 mg/ml Solution for Injection for Cattle and Pigs

Vm 14966/3042

12 May 2026	Change in the pharmacovigilance system master file (PSMF) location. Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
17 February 2026	Submission of updated mock ups.
03 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.
12 June 2025	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (GB + NI).
26 March 2025	Alignment of the product information with version 9.0* of the QRD templates.
01 August 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
October 2022	Addition of manufacturing site responsible for radiosterilisation of plastic vials.
14 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.
12 November 2020	Submission of a new certificate of suitability for an active substance.
22 November 2019	Replacement of a specification parameter with its corresponding test method of the finished product.
17 January 2018	Addition of a second manufacturing site responsible for the radio sterilisation.
22 December 2017	Minor change in the manufacturing process of an immediate release solid oral dosage form* or oral solutions. Change to in-process tests or limits applied during the manufacture of the finished product.
21 December 2017	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.
19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
06 January 2016	Submission of an updated DDPS.
08 October 2015	Renewal – UK as CMS
15 July 2015	Change in batch size of the active substance.

	Change in test procedure for the active substance. Changes in the manufacturing process of the active substance.
13 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
11 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS.
13 February 2012	To change the UK Marketing Authorisation Holder address.
06 January 2012	To change the name and address of the Marketing Authoristion Holder in Italy only
28 June 2011	To add a new manufacturer of the active substance.