



Post Authorisation Assessments

Cydectin TriclaMox 5 mg/ml + 200 mg/ml Pour-on Solution for Cattle Vm 42058/3012

19 January 2025	Extension of a re-test period/storage period supported by real time data.
04 July 2024	Deletion of a manufacturing site for an intermediate of the active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
09 November 2023	One-off alignment of the product information with version 9.0 of the QRD templates.
03 August 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
22 December 2020	Update of SPC and package leaflet text as assessed under Regulation 1901/2006.
01 July 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
28 May 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
08 January 2020	Change in the address of the marketing authorisation holder 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.
19 June 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
07 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
19 April 2018	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
09 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
15 June 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
02 June 2017	Change of specification of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.

16 December 2016	Renewal – UK as CMS
30 November 2016	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
23 July 2015	Submission of a new certificate of suitability from a new manufacturer.
05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
10 October 2014	Increase to the batch size of an active substance, from 220±10 kg to 440±20 kg.
04 July 2014	Submission of an updated Ph. Eur. Certificate of suitability.
13 November 2013	Changes to therapeutic indications.
30 October 2013	Change in the name of manufacturer of the finished product and batch release. Change in QPPV contact details.
23 October 2013	Change of name of MAH in Austria, Belgium, France and Luxembourg only.
12 August 2013	Change of MAH and distributor.
21 March 2013	Amendments to the SPC and product literature to comply with the outcome of an EU Directive.
10 December 2012	Addition of text to section 4.2 of the Summary of Product Characteristics (SPC).