Veterinary Medicines Directorate

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Post Authorisation Assessments

Cydectin TriclaMox 1 mg/ml + 50 mg/ml Oral Solution for Sheep

Vm 42058/5111

•	May 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.
•	14 May 2024	Minor change to an approved test procedure for the finished product. Minor change to an approved test procedure for the finished product. Minor change to an approved test procedure for the finished product. Minor change to an approved test procedure for the finished product. Minor change to an approved test procedure for the finished product.
•	14 May 2024	Addition of a new test procedure for the finished product. Addition of a new test procedure for the finished product. Addition of a new test procedure for the finished product.
•	04 December 2023	Approval of mock ups.
•	13 October 2023	Deletion of an identification test from the finished product specification. Addition of a new test to the finished product specification.
•	22 September 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.
•	17 April 2023	Change in shape or dimensions of the container or closure of a non-sterile finished product.
•	07 March 2023	Change in immediate packaging of the finished product: - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms.
•	10 November 2021	Changes in the SPC and product information following a periodic safety update report.
•	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 February 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.
•	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 December 2014	Renewal.
•	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.
•	30 October 2013	Change in the name of manufacturer of the finished product and batch release. Change in QPPV contact details.
•	28 October 2013	Variation to change the name and address of the Marketing Authorisation Holder in Austria, Belgium, France and Luxembourg only.
•	15 October 2013	Change in the invented name of the product in Sweden only.
•	12 August 2013	Change of distributor and change of MAH from Pfizer Ltd to Zoetis UK Limited.
•	29 May 2013	Change in SPC section 4.11 to ready “not authorised for use in ewes producing milk for human consumption including the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.
•	13 June 2012	Introduction of a new Pharmacovigilance system.

•	04 November 2011	Change in name/address of manufacturer of the finished product.
•	02 September 2011	Submission of a new or updated certificate of suitability.
•	16 July 2010	Change in the shelf-life or storage conditions of the finished product.
•	14 July 2010	Change of MAH holder and distributor from Fort Dodge Animal Health Ltd to Pfizer Ltd.