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

•	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.