Veterinary Medicines Directorate

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Post Authorisation Assessments

Cydectin 0.5% w/v Pour-On for Cattle

Vm 42058/3024

•	06 July 2024	Alignment with the latest version of the QRD.
•	14 July 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
•	19 January 2023	Updates to Sections of SPC and PL to implement the outcome of a procedure concerning risk management measures in pharmacovigilance related to veterinary medicinal products.
•	01 July 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.
•	02 April 2019	Change in the specification parameters of an excipient.
•	22 November 2018	Change in the specification parameters of an excipient.
•	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.
•	30 November 2016	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	11 January 2016	Change in the manufacturing process of the finished product Change in the composition of the finished product
•	05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
•	04 July 2014	Submission of an updated Ph. Eur. Certificate of suitability.
•	30 October 2013	Grouped variation to change the name of an active substance manufacturer, to change the name of a

		manufacturer responsible for finished product and batch release, and to change the QPPV contact details.
•	22 October 2013	Variation to change the name and address of the Marketing Authorisation Holder in Austria, Belgium, France and Luxembourg only.
•	29 August 2013	Variation to seek approved for the introduction of a retest period for the active substance.
•	12 August 2013	Grouped variation to change the Marketing Authorisation Holder and distributor.
•	08 May 2013	Submission of a new European Pharmacopoeia Certificate of Suitability from a new active substance supplier.
•	13 June 2012	Change to the DDPS.
•	04 November 2011	Variation to change the name of the manufacturer responsible for manufacture and batch release.
•	02 September 2011	Submission of a new Ph. Eur. Certificate of suitability.
•	03 August 2011	Changes to the withdrawal period to ‘milk 6 days (144 hours).
•	16 June 2010	Change of Marketing Authorisation Holder.
•	08 January 2010	Change in the specification of the finished product.
•	09 February 2009	Comply with Ph. Eur. or MS national pharmacopoeia: former non EU (active).
•	31 January 2007	Renewal procedure.
•	09 October 2006	Renewal procedure.