Veterinary Medicines Directorate

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Post Authorisation Assessments

Cydectin 0.1% w/v Oral Solution for Sheep

Vm 42058/3026

•	22 December 2023	Change(s) in the SPC, labelling or package leaflet to sections 4.4 and 4.9 - updated resistance statements and prudent use warnings.
•	14 July 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
•	21 February 2023	Change in 2.5 L immediate packaging of the finished product.
•	20 February 2023	Change in dimensions of the closure of immediate packaging of a non-sterile finished product.
•	13 May 2022	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Change in shape or dimensions of the container or closure (immediate packaging).
•	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.
•	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.
•	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	Change in the batch size (including batch size ranges) of the finished product, from 5000 litres to a range of

		5000 to 6000 litres.
•	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, the manufacture responsible for finished product and batch release, and 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.
•	12 August 2013	Grouped variation to change the Marketing Authorisation Holder.
•	13 June 2012	Variation to change the DDPS.
•	04 November 2011	Variation to change the name of the manufacturer responsible for batch release.
•	02 September 2011	Submission of a new Ph. Eur. Certificate of suitability.
•	13 January 2011	Renewal.
•	11 May 2010	Change of Marketing Authorisation Holder.
•	09 February 2009	Comply with Ph. Eur. or MS national pharmacopoeia: former non EU (active).