Veterinary Medicines Directorate

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Post Authorisation Assessments

Cydectin 0.5% w/v Pour-On for Cattle

Vm 60021/3055

05 November 2026	Changes in the composition (excipients) of the finished product. Addition of a device which is not an integrated part of the primary packaging. Change in the specification parameters and/or limits of the finished product. Change in the specification parameters and/or limits of an excipient. Change in test procedure for the finished product.
05 November 2026	Deletion of a manufacturing process for the active substance or the finished product when an alternative is already approved. Change in name of an excipient.
16 February 2026	Change in the dimensions of the container of the non sterile finished product. Change in the dimensions of the container of the non sterile finished product. Change in the dimensions of the container of the non sterile finished product. Change in the dimensions of the closure of the non sterile finished product.
12 March 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
26 February 2025	Change in legal entity of MA holder in NI only to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood, Business Park, Loughlinstown, Dublin 18, D18 T3Y1, Ireland.
19 January 2025	Extension of a re-test period/storage period supported by real time data.
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.