



Post Authorisation Assessments

Cydectin 1% w/v Solution for Injection for Sheep Vm 60021/3005

• 25 November 2024	Change in legal entity of MA holder for NI from Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Co. Dublin, Ireland.
• 24 July 2023	Change in primary packaging material not in contact with the finished product. Deletion of a non-significant specification parameter. Deletion of a non-significant specification parameter.
• 21 December 2022	Change in any part of the primary packaging material not in contact with the finished product formulation.
• 26 August 2020	Change in the address of the MAH from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London. EC4A 3AE to Zoetis UK Limited, 1 st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey. KT22 7LP.
• 09 July 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
• 24 April 2019	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in shape or dimensions of the container or closure (immediate packaging)
• 15 March 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
• 09 May 2018	Changes to the SPC/product labelling/package leaflet following an Article 35 referral. Changes to the labelling and package leaflet.
• January 2018	Replacement of a supplier of packaging components or devices
• 24 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer.
• 01 December 2016	Submission of a new Ph. Eur. Certificate of Suitability for the active substance.
• 15 July 2015	Submission of a new Ph. Eur. Certificate of Suitability.
• 07 October 2013	Grouped variation to transfer the Marketing Authorisation (including a change in distributor). Change in the name of the active substance manufacturer and of the finished product. Change to the name an/or address of an API manufacturer.

•	18 January 2012	Variation to update the details of the EU QPPV.
•	06 July 2011	To change a manufacturer from Fort Dodge Veterinaria S.A. to Pfizer Olot.
•	22 June 2011	Submission of a new Ph. Eur. Certificate of suitability.
•	25 March 2011	Change in the specification parameters or limits of the finished product.
•	10 June 2010	Simple layout changes to SPC/product literature.
•	23 February 2010	Change of Marketing Authorisation Holder.
•	21 January 2009	Change to comply with the Eur. Ph. or with the national pharmacopoeia of a member state.
•	31 July 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	14 February 2008	Simple layout changes to SPC/product literature.
•	24 January 2008	Renewal.
•	09 November 2004	Renewal.
•	22 November 2002	Change in the manufacturing process of the active substance.
•	23 December 1999	Addition of an active substance manufacturer.
•	23 September 1999	Change of legal category.
•	04 August 1999	Change in the contraindications.
•	24 March 1999	Change in therapeutic purpose.