Veterinary Medicines Directorate

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Post Authorisation Assessments

Cydectin 1% w/v Solution for Injection for Sheep

Vm 42058/4027

•	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, 1st 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.