Veterinary Medicines Directorate

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Post Authorisation Assessments

Cydectin 10% LA Solution for Injection for Cattle

Vm 42058/3016

•	06 November 2023	Alignment of the product information with version 9.0* of the QRD templates.
•	03 August 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
•	13 June 2023	Change in flange height of the aluminium cap on the finished product.
•	05 September 2022	Change in flange height of the aluminium cap on the finished product.
•	28 January 2021	Change in batch size of the finished product.
•	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.
•	23 September 2019	Minor changes to an approved test procedure of the finished product.
•	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 September 2018	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).
•	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.
•	13 January 2017	Submission of a new certificate of suitability for an active substance.
•	04 August 2016	Variation to implement changes in the product information as requested by the RMS as a result of the review of PSUR.
•	10 July 2015	Submission a new Ph. Eur. Certificate of Suitability for the active substance.
•	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	Change in the name of manufacturer of the finished product and batch release. Change in QPPV contact details.
•	23 October 2013	Change of Marketing Authorisation Holder in Belgium, France and Luxembourg only.
•	12 August 2013	Change of Marketing Authorisation Holder and distributor.
•	04 November 2011	Change to the name of a manufacturer of the finished product.
•	02 September 2011	Submission of a new or updated certificate of suitability.
•	14 December 2011	Change of Marketing Authorisation Holder from Fort Dodge Animal Health Ltd to Pfizer Ltd.
•	19 October 2010	Renewal – UK as CMS
•	05 November 2009	To increase the shelf life, widen the specification limits for benzyl alcohol at end of shelf-life and inclusion of extra tests in the finished product shelf-life specification.
•	09 February 2009	Variation to comply with Ph. Eur. to change the specifications of the active substance.