Veterinary Medicines Directorate

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Post Authorisation Assessments

Cydectin 20 mg/ml LA Solution for Injection for Sheep

Vm 42058/5117

•	03 August 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
•	25 October 2022	Change in part of the primary packaging not in contact with the finished product formulation.
•	28 January 2021	Increase in batch size (including batch size range) 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.
•	02 October 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.
•	31 May 2019	Changes to the labelling and package leaflet
•	01 April 2019	Change in shape or dimensions of the container or closure (immediate packaging).
•	30 January 2019	Repeat use application to add one new member state.
•	07 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	07 November 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).
•	06 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 of a new Ph. Eur. Certificate of Suitability.
•	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.
•	08 January 2014	Renewal procedure – France as RMS.
•	30 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS. Change of the name and address of the manufacturer responsible for the finished product and for batch release.
•	22 October 2013	Change of MAH in France only.
•	12 August 2013	Change of MAH and distributor.
•	10 December 2012	Additional statement approved in section 5.1 of SPC: "The product has a persistent activity against the second instar larvae of Oestrus Ovis (L2 Larvae only) up to 80 days after treatment. However, re-infestation with 1st instar larvae is not prevented and clinical signs arising from such re-infestation may be observed during this period."
•	13 June 2012	Introduction of a new Pharmacovigilance system.
•	17 February 2012	To extend the shelf life of the finished product as packaged for sale from 24 months to 36 months.
•	04 November 2011	To change the name of the manufacturing site responsible for manufacture and batch release.
•	02 September 2011	Submission of a new or updated certificate of suitability.
•	16th June 2010	Change of MAH and distributor from Fort Dodge Animal Health Ltd to Pfizer Ltd.