Veterinary Medicines Directorate

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Post Authorisation Assessments

Phenoxypen Water Soluble Powder, 325 mg/g Powder for Oral Solution for Chickens

Vm 28365/4000

•	07 July 2020	Addition of a new container for the finished product.
•	05 December 2018	Changes to the labelling, or the package leaflet, which are not connected with the SPC. Change in distributor details from Bimeda, Airton Road, Tallaght, Dublin 24, Ireland to Duggan Veterinary Supplies Ltd, Holycross, Thurles, Co. Tipperary, E41 A093, Ireland.
•	20 June 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	07 March 2018	Changes to the labelling and/or package leaflet.
•	13 November 2017	Minor change in the manufacturing process of the finished product. Increase in batch size (including batch size range*) of the finished product.
•	11 December 2015	Changes to the design/layout of the mock-ups
•	03 February 2014	Deletion of a Ph. Eur. Certificate of Suitability for a manufacturer of the active substance.
•	11 July 2013	Change in distributor details
•	14 January 2013	Extension of the finished product shelf life.
•	26 July 2012	Addition of an egg withdrawal period of zero days.
•	03 May 2012	Submission of a new or updated Ph. Eur. Certificate of Suitability
•	14 June 2011	Renewal procedure.
•	18 August 2010	Changes to an existing pharamcovigilance system as described in DDPS.
•	15 December 2009	New/updated Ph. Eur CofS for active/active component.
•	21 January 2009	Change of distributor
•	19 December 2007	Change in composition of immediate packaging: all other pharm forms
•	12 December 2007	Replacement of an excipient with a comparable excipient
•	12 December 2007	Change shelf life of finished product, (after first opening)
•	12 November 2007	New/updated Ph. Eur CofS for active/active component/ new man/ other
•	12 November 2007	Change to container