Veterinary Medicines Directorate

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Post Authorisation Assessments

Soludox 500 mg/g Powder for Use in Drinking Water for Pigs and Chickens

Vm 16849/4015

•	27 October 2023	Deletion of previously approved API manufacturer. (GB) CEP update for doxycycline hyclate API. (GB)
•	11 March 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	01 June 2018	Change in RMS from UK to IE.
•	02 May 2018	Tightening of specification limits of the finished product. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	14 February 2018	Changes to the labelling and/or package leaflet.
•	December 2017	Repeat Use application to add 7 new member states
•	28 February 2017	Change in batch size of the finished product. Minor change in the manufacturing process of the finished product.
•	01 November 2016	Deletion of Ph. Eur. certificates of suitability for an active substance.
•	05 August 2016	Change in distributor details.
•	16 March 2016	Submission of an updated Ph. Eur. certificate of suitability
•	09 December 2015	Renewal – UK as RMS
•	13 September 2013	Submission of an updated Ph. Eur certificate of suitability and submission of a new Ph. Eur certificate of suitability.
•	21 August 2013	To change the meat and offal withdrawal period for chickens from 12 days to 9 days following a dose rate of 20 mg/kg body weight for 4 days.
•	19 April 2013	Change of QPPV and QPPV contact details for an already existing pharmacovigilance system.
•	29 September 2012	Addition of an immediate packaging material of polyethylene terephtalic acid / aluminium / polyamide and an inner layer of polyethylene.

•	25 August 2011	To make changes to the SPC following a Commission Decision.