



Post Authorisation Assessments

Amphen, 200 mg/g Granules for Use in Drinking Water for Pigs

•	26 February 2019	Change in RMS from UK to NL.
•	02 July 2018	Renewal – UK as RMS
•	12 September 2017	Changes to the labelling and/or package leaflet.
•	03 March 2017	Change in the address of a manufacturer of the finished product.
•	21 September 2015	Approval of mock-ups.
•	16 July 2015	Introduction of a new pharmacovigilance system.
•	25 June 2015	Change to the product name, from 'Colfen 200 SP, 200 mg/g granules for use in drinking water for pigs' to 'Amphen, 200 mg/g Granules for Use in Drinking Water for Pigs'. Update to Section 4.9 of the SPC and corresponding sections of the product literature.
•	12 March 2015	Change in MAH, from Zoetis UK Limited to Huvepharma N.V. Change of distributor.
•	10 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS. Change of QPPV contact details.
•	10 October 2013	To change the name and/or address of the Marketing Authorisation Holder from Pfizer Ltd to Zoetis UK Limited in BE, FR and LU only.