



Post Authorisation Assessments

Potencil, 10% Premix for Medicated Feed for Pigs

•	07 March 2017	Introduction of a new pharmacovigilance system.
•	16 March 2016	Change in distributor details Change in legal entity
•	02 February 2014	Minor change in the manufacturing process of the finished product.
•	09 December 2014	Addition of a packaging site.
•	20 August 2014	Change in test procedure for the finished product.
•	11 March 2013	Change in the specification parameters of an excipient.
•	07 April 2008	Renewal.
•	11 March 2008	Change to batch release arrangements.
•	29 November 2007	Change to the Marketing Authorisation Holder and Distributor address.
•	21 July 2007	Variation to update a Certificate of Suitability for an Active Substance.
•	23 November 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	17 July 2006	Variation to update a Certificate of Suitability for an Active Substance.
•	21 September 2005	Change in the qualitative composition of the immediate packaging material.
•	07 September 2005	Change in the qualitative composition of the immediate packaging material.
•	24 August 2005	Variation to change the Manufacturer of the Dosage Form.
•	18 February 2005	Renewal.
•	17 December 2004	Submission of a European Pharmacopoeia Certificate of Suitability. Change in the Manufacturer of the Dosage Form.
•	13 March 2003	Harmonisation of the UK and Irish SPC.
•	19 September 2001	Change of Marketing Authorisation Holder.
•	21 May 2001	Addition of an Active Substance Manufacturer.
•	23 August 2000	Variation concerning the Manufacturer and Assembler of Dosage Form.
•	15 July 1998	Renewal.
•	17 January 1997	Change in packaging presentation.