



Post Authorisation Assessments

Solacyl 1000 mg/g, Powder for Oral Solution for Cattle and Pigs

•	07 February 2019	Repeat Use application to add 6 new member states
•	24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	10 September 2018	Variation to update the ASMF.
•	23 February 2017	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms. Change to in-process limit applied during the manufacture of the finished product.
•	02 November 2016	Mock-ups approved. Change of distributor.
•	01 May 2013	Deletion of manufacturing site for the active ingredient.
•	06 March 2013	Change of QPPV and contact details for the QPPV of an existing pharmacovigilance system.
•	04 January 2013	Renewal procedure – The Netherlands as RMS.
•	15 August 2012	Variation to add an immediate packaging material.
•	13 January 2010	Change of distributor.
•	26 November 2009	To submit mock-ups for approval for an already authorised pack size of 100g.
•	05 November 2008	To bring the SPC and labels in line with the new legislation