

Post Authorisation Assessments

Quiflor 100 mg/ml Solution for Injection for Cattle and Pigs (Sows)

•	08 March 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	05 June 2018	Change in RMS from UK to DE.
•	26 October 2017	Change in contact details for local representative.
•	02 August 2016	Extension of retest period of active substance.
•	17 May 2016	Renewal – UK as RMS
•	20 May 2015	Change in manufacturing site of the active substance.
•	22 April 2015	Addition of UK local representative information to package leaflet.
•	15 November 2013	Change to batch release arrangements. Change in the shelf-life of the finished product, from 2 years to 3 years.
•	08 March 2013	To change the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	07 February 2013	Addition of a third route of synthesis (ROS3) for the active substance and deletion of Krka d.d as a manufacturing site for ROS1.
•	23 January 2013	Change of MAH from Miklich Laboratorios S.L. to Krka d.d