



Post Authorisation Assessments

Metaxol 20/100 mg/ml Solution for Use in Drinking Water for Pigs and Chickens Vm 16849/5008

•	14 May 2024	Changes in the SPC intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6.
•	14 May 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
•	07 April 2022	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	01 February 2022	Change in shape or dimensions of the container or closure (immediate packaging). Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	01 July 2021	Renewal - UK as CMS.
•	14 January 2021	Deletion of manufacturing site of the finished product.
•	20 August 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.
•	22 May 2018	Replacement of a manufacturer responsible for batch release including batch control/testing. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product. Addition of a manufacturing site for the manufacturing process of the finished product.