



## Post Authorisation Assessments

### Cevaxel-RTU 50 mg/ml, Suspension for Injection for Cattle and Pigs Vm 15052/4051

•	28 September 2022	Change of MAH address from: Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	30 July 2020	Change in the address of a supplier of active substance. Change in the address of a manufacturer used in the manufacture of the active substance. Change to more restrictive storage conditions of the active substance. Minor change to the restricted part of an Active Substance Master File. Change in the manufacturer of a starting material used in the manufacturing process of the active of the active. Change in the specification parameters and/or limits of an active substance.
•	07 May 2020	Update to the ASMF.
•	23 October 2019	Addition of a new specification parameter, with corresponding test method to the specification of the immediate packaging of the active substance. Minor change in the manufacturing process of the active substance. Change to comply with Ph. Eur. - change from in-house method to Ph. Eur. method for sulphated ash and heavy metals. Minor change to the restricted part of an Active Substance Master File.
•	28 January 2019	Minor change in the manufacturing process of the finished product. Change to the in-process controls.
•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 February 2016	Renewal –UK CMS
•	06 January 2016	Submission of a revised DDPS.
•	13 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
•	22 October 2014	Addition of a manufacturing site for part of the manufacturing process of the finished product. Change in the manufacturing process of the finished

		product.
•	19 June 2014	To add an additional manufacturer of the active substance.
•	11 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS, including the change of the Qualified person.
•	20 December 2012	Addition of a 5 ml presentation.
•	11 May 2012	To change the summary of product characteristics and product literature following a procedure in accordance with an EU Directive.
•	13 February 2012	To change the UK Marketing Authorisation Holder address.
•	06 January 2012	To change the name and address of the Marketing Authorisation Holder in Italy only.