



## **Post Authorisation Assessments**

### **CEVAC IBird Lyophilisate for Oculonasal Suspension/Use in Drinking Water for Chickens Vm 15052/3011**

•	16 November 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF.
•	30 June 2023	Update of the QRD/SPC templates in accordance with Regulation (EU) 2019/6.
•	27 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.
•	05 March 2019	Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product. Qualitative and quantitative changes to the excipients.
•	12 July 2018	Renewal – UK as CMS
•	19 September 2017	Change / Replacement of a test procedure for the finished product.
•	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.
•	10 July 2017	Addition of a new therapeutic indication / modification of an approved indication. Addition of a new therapeutic indication / modification of an approved indication. Addition of a new therapeutic indication / modification of an approved indication.
•	06 January 2016	Submission of a revised DDPS.
•	16 November 2015	Mock-ups amended to include multi-lingual text.
•	13 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
•	08 May 2014	Changes to an existing pharmacovigilance system as described in the DDPS.