



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Enteroporc COLI AC Lyophilisate and Suspension for Suspension for Injection for Pigs Vm 15052/5002

•	September 2023	Extension of the storage period of the CpA/CpC toxoid concentrates and permeates produced by CZV from 18 months to 27 months supported by real time data. Introduction of a sterile filtration step after addition of sucrose solution. Addition of a site where in-process control testing for antigen quantification takes place. Addition of a site where batch control testing takes place for the CpA/CpC lyophilisate including test methods transfer. Addition of a manufacturing site of the CpA/CpC lyophilisate including minor changes in the lyophilisation process.
•	19 October 2022	Change in the address of the MAH 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.
•	25 May 2021	Changes to the labelling and package leaflet.
•	13 May 2021	Replacement of a manufacturer responsible for batch release of the finished product. Replacement of a secondary packaging site of the finished product
•	22 April 2021	Extension of a storage period of the active substance.
•	22 April 2021	Introduction of a new pharmacovigilance system.
•	05 February 2021	Change of MAH, from IDT Biologika GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany to Ceva Animal Health Ltd, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB, United Kingdom.