



## Post Authorisation Assessments

### Florkem 300 mg/ml Solution for Injection for Cattle and Pigs Vm 15052/4046

•	September 2022	Addition of manufacturing site responsible for radiosterilisation of plastic vials.
•	26 September 2022	Change in the MAH address, from Ceva Animal Health Ltd, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	23 October 2019	Update of the active substance master file.
•	23 July 2018	Quantitative composition changes to the immediate packaging of the active substance. Extension of a re-test period of the active substance. Minor change to the restricted part of an Active Substance Master File.
•	09 May 2018	Minor change to the manufacturing process of the finished product. Change to the in-process controls.
•	17 January 2018	Addition of a second manufacturing site responsible for the radio sterilisation.
•	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.
•	06 January 2016	Submission of a revised DDPS.
•	19 June 2015	Change to a specification limit of the finished product.
•	13 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
•	04 August 2014	Renewal Procedure – UK Comment
•	11 October 2013	Changes to an existing pharmacovigilance system.
•	12 July 2013	Change in active substance manufacturer.
•	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,
•	24 January 2011	To change the name and address of the Marketing Authorisation Holder in Denmark only