



## **Post Authorisation Assessments**

### **Vetofol 1.0% w/v Emulsion for Injection** Vm 02000/4244

•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
•	30 July 2019	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.
•	09 November 2016	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	06 July 2016	Change in packaging from blue flip off seals to blue 2 pin seals.
•	06 January 2016	Addition of a supplier for the 20ml glass vials.
•	13 August 2013	Submission of updated European Pharmacopoeia Certificates of Suitability for already approved active substance manufacturers.
•	02 November 2011	Variation to change the address of a distributor.
•	20 April 2011	Submission of a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	30 March 2011	Renewal.
•	29 October 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	11 April 2007	Variation to change a part of the primary packaging material which is not in contact with the finished product.
•	20 February 2007	Transfer of the legal category from POM to POM-V.
•	31 August 2006	Addition of an assembler.