Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Pulmodox 500 mg/g Granules for Oral Solution for Pigs, Chickens and Turkeys

Vm 32823/3000

•	June 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	16 March 2022	Change in the address of the marketing authorisation holder from Lavet Pharmaceuticals Ltd., Ottó u. 14., Budapest, 1161 to Lavet Pharmaceuticals Ltd.,2143 Kistarcsa, Batthyány u. 6., Hungary. Addition of a new container for the finished product.
•	31 December 2019	Update of the test procedure to comply with the updated general Ph. Eur monograph. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 September 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	28 November 2013	Renewal procedure (Extension) – Hungary as RMS.
•	18 October 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer. Changes to the SPC and product literature following an Article 35 referral. Addition of round containers in 1 kg and 5 kg pack sizes.
•	12 April 2010	Change of batch release size.