Veterinary Medicines Directorate

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Post Authorisation Assessments

Virbagest 4 mg/ml Oral Solution for Pigs

Vm 05653/4136

•	22 December 2021	Change to Active Substance Specification to harmonise across all suppliers. Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	19 October 2021	Change in shape or dimensions of the container or closure (immediate packaging). Minor change in the manufacturing process of the finished product. Correct the appearance of the packaging in the finished product specification.
•	11 September 2020	Extension of a re-test period of the active substance.
•	08 September 2020	Change in the manufacturer of the active where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
•	06 July 2020	Increase in batch size of the active substance used in the manufacturing process of the active substance. Increase in batch size of the finished product. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.
•	26 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	24 July 2018	Change in RMS from UK to FR.
•	20 January 2017	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	19 July 2016	Repeat use application to add Denmark and Poland as additional Concerned Member States.
•	22 April 2015	Addition a new active substance manufacturer.
•	02 January 2015	Update to the restricted part of the ASMF.
•	21 December 2012	Renewal procedure.
•	20 September 2012	Change in shape/dimensions of container or closure. (Immediate packaging).
•	10 November 2009	Repeat use application to add Austria, Bulgaria, Cyprus, Greece, Ireland, Italy, The Netherlands, Portugal and Romania as additional Concerned Member States.