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Post Authorisation Assessments

Dronspot 96 mg/24 mg Spot-on Solution for Large Cats Vm 08007/4161

•	14 September 2022	Renewal
•	02 February 2022	Introduction of a new pharmacovigilance system.
•	05 November 2020	Change of MAH from Bayer Animal Health GmbH, 51368 Leverkusen, Germany to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS.
•	09 June 2020	Change of MAH, from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Bayer Animal Health GmbH, 51368 Leverkusen, Germany.
•	02 April 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	02 September 2019	Tightening of specification limits of a reagent used in the manufacturing process of the active substance.
•	25 July 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	17 May 2019	MRP to add 10 member states
•	28 June 2018	To change the legal distribution category from POM-V to NFA-VPS
•	22 May 2018	Change in the name supplier of a starting material used in the manufacture of the active substance. Minor change in the manufacturing process of the active substance. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material used in manufacturing process of active substance from an already approved manufacturer.