Veterinary Medicines Directorate

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Post Authorisation Assessments

Quantex 20 mg Spot-on Solution

Vm 08007/4172

21 January 2025	Incorporation of changes required following the Article 83 referral for products including NMP as an excipien
21 January 2025	NMP warnings added plus updated wording of Section 4.6.
01 December 2024	Downscaling of finished product batch size. Addition of new in-process tests applied during finished product manufacture. Deletion of a non-significant in-process test during the manufacture of the finished product. Minor change to an approved test procedure for the active substance.
01 December 2024	Change to test procedure for the immediate packaging of the finished product. Addition of a new specification parameter for the finished product immediate packaging. Addition of a batch control and quality testing site for the finished product. Deletion of obsolete specification parameters for the finished product immediate packaging. Deletion of obsolete specification parameters for the finished product immediate packaging. Deletion of obsolete specification parameters for the finished product immediate packaging. Deletion of Ph. Eur. CEP for an active substance. Addition of a manufacturer responsive for batch release of the finished product. Addition of a primary packaging site for the finished product. Addition of a secondary packaging site for a finished product.
01 December 2024	Addition of a test procedure for the finished product. Change in the specification parameters of the finished product. Change to in-process limit applied during the manufacture of the finished product. Addition of a manufacturing site for the finished product.
18 October 2022	Updated certificate of suitability from an already approved manufacturer.
19 October 2021	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.
09 June 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
03 March 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
09 October 2019	Renewal: UK as CMS
18 September 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance excipient from a new manufacturer.
31 July 2018	Changes to the labelling and package leaflet.
21 June 2017	Change in local representative from CVS (UK) Ltd. to MiGroup.
05 May 2017	Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD.
05 February 2015	Reduction in shelf-life of the finished product, from 5 years to 30 months. Addition of specification parameters for the finished product.