Veterinary Medicines Directorate

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Post Authorisation Assessments

Droncit Spot-on 20mg Solution

Vm 08007/5026

16 September 2026	Changes to the summary of the PSMF not already covered elsewhere in this Annex.
12 June 2026	One-off alignment of the product information with version 3 of the GB QRD templates.
27 November 2025	Submission of an updated Ph. Eur. CEP for an active substance.
09 January 2025	Incorporation of required changes for products containing NMP as an excipient.
09 January 2025	Updated wording to Section 4.6 and 4.9 subsequent to the worksharing PSUR assessment for praziquantel spot-on.
16 October 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.
16 October 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.
16 October 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.
19 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.
18 September 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance excipient from a new manufacturer.
18 September 2018	Change in distributor details from Bayer plc, Animal Health Division, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green park, Reading, Berkshire, RG2 6AD.
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.
27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
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.
27 November 2013	Replacement of the manufacturing site responsible for secondary packaging.
31 July 2013	Deletion of 2 non-significant parameters of an active substance used in the manufacturing process of the active substance.
12 June 2013	Changes to labelling/package leaflet that do not affect the SPC.
22 February 2011	Change of distributor to Unidrug Distribution Group Ltd.
02 February 2011	Minor changes to part of the dossier.
20 November 2009	Renewal.
23 June 2009	Submission of 2 new/updated Ph. Eur. Certificates of Suitability for active substance or material used to manufacture the active substance.
28 June 2006	Variation to update the SPC and product literature in line with the new legislation.
19 September 2005	Renewal.
14 July 2005	Corrections/simple text layout changes to package leaflet and carton.
21 November 2003	Change to legal category from Prescription only medicine (POM) to General Sales List (GSL).
18 September 2003	Change in MAH name/address.
20 September 2001	Update licence particulars.
29 June 2001	Shelf life extended from 36 to 60 months.