Veterinary Medicines Directorate

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Post Authorisation Assessments

Equest Pramox 19.5 mg/g + 121.7 mg/g Oral Gel

Vm 42058/3041

19 January 2025	Extension of a re-test period/storage period supported by real time data.
30 December 2024	Text alignment, of the product information with version 9.0 of the QRD templates.
19 December 2023	Updates to Section 4.6 of the SPC and corresponding section in PL: Digestive discomfort (colic, loose stool) has been observed in very rare cases based on post-marketing surveillance data.
20 March 2023	Deletion of a manufacturer of an active substance.
15 March 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
23 July 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
10 January 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
17 April 2019	Changes (Safety/Efficacy) in the Veterinary Medicinal Product
01 April 2019	Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning PSUR.
07 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
10 July 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
18 April 2018	Introduction of a re-test period of the active substance.
14 February 2018	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
09 January 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
09 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
08 September 2016	Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics.
13 July 2016	Changes to section 4.6 of the SPC.
06 July 2016	Submission of a new Ph. Eur. certificate of suitability and

	deletion of a Ph. Eur. certificate of suitability.
05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
04 February 2015	Addition of a new test method to the finished product specification.
04 July 2014	Submission of an updated Ph. Eur. Certificate of suitability.
30 October 2013	Change of name for the finished product manufacturer responsible for batch release and change of QPPV contact details.
30 October 2013	Submission of new clinical data to support the modification of the SPC to allow the use of the product in breeding, pregnant or lactating mares.
23 October 2013	Change to the name of the MAH from Pfizer to Zoetis in AT, BE, FR and LU only.
31 July 2013	Change of MAH and distributor to Zoetis UK Limited.
18 July 2013	Change to the immediate packaging design and increase in size resulting in a change of supplier, changes to the finished product specification and increase in batch size of the finished product.
27 August 2012	Submission of a new Ph. Eur. Certificate of Suitability for an active substance.
13 June 2012	Introduction of a new Pharmacovigilance system.
04 November 2011	Change in name and/or address of the manufacturer of the finished product.
02 September 2011	Submission of a new/updated Ph. Eur. Certificate of suitability.
11 March 2011	Change in name/address of MAH.
19 November 2010	Renewal: UK as CMS
13 October 2010	To change the MAH and distributor from ‘Fort Dodge Animal Health Ltd’ to ‘Pfizer Limited’.
09 February 2009	To comply with Ph. Eur to change the specifications of the active substance.
22 September 2008	To add a new manufacturer for the active ingredient.
22 February 2008	To change the range of the specification of filled syringe weight.
22 February 2008	To change the primary packaging.
30 May 2007	To increase the shelf life from 18 to 24 months
27 February 2007	To change the packaging material not in contact with finished product formulation.
29 August 2006	To increase the shelf life of the finished product.