



Post Authorisation Assessments

Equipramox 19.5 mg/g + 121.7 mg/g Oral Gel

•	24 June 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	03 December 2019	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.
•	28 June 2019	Changes in the SPC, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006.
•	03 April 2019	Renewal UK as CMS
•	27 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	15 August 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
•	01 February 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance.
•	22 December 2017	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	20 December 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance manufacturer.
•	4 May 2017	Change of MAH, from Continental Farmaceutica to Zoetis UK Limited.
•	12 January 2017	Implementation of wording agreed by the competent authority.
•	06 July 2015	Addition of a test procedure for the finished product.
•	05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure