Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac AE Lyophilisate for Suspension for Use in Drinking Water

Vm 42058/3027

•	14 November 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.
•	06 November 2018	Change of a test procedure for the finished product.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 January 2018	Change in the RMS for UK to DE.
•	20 September 2017	Change of a test procedure for the finished product.
•	21 November 2016	Change in test procedure for the finished product.
•	25 May 2016	Addition of an alternative test method.
•	15 March 2016	Renewal UK RMS
•	09 February 2016	Change in the name of a manufacturer of the active substance. Change in the name of a manufacturer of the finished product.
•	05 May 2015	Change to the QPPV contact details.
•	18 July 2014	Grouped variation: to replace a site responsible for batch control / testing of the finished product. Addition of in-process testing applied during the manufacture of the finished product. Changes to test procedures for the finished product.
•	22 November 2013	Change in the test procedure for an active ingredient by the respective method recommended by the EP Monograph 5.2.2.
•	25 October 2013	Transfer of the Marketing Authorisation Holder.
•	11 October 2013	Change of name and address of the Marketing Authorisation Holder in AT only.
•	11 October 2013	Grouped variation: to change the name of an active substance manufacturer. Change the name of a finished product manufacturer responsible for batch release. Change the name of a finished product manufacturer not responsible for batch release.
•	19 September 2013	Variation to rename a site for QC testing, and to delete a site responsible for secondary packaging and batch release.
•	16 July 2012	Variation to change the test method as recommended in the European Pharmacopoeia Monograph 5.2.2.
•	13 June 2012	Variation to change the DDPS.

•	15 September 2011	Addition of a site for labelling and batch release.
•	13 June 2011	Addition of a supplier of a starting material.
•	28 April 2011	Grouped variation: to change the name of the active substance manufacturer. Change the name of a manufacturer responsible for blending, filling, and assembly. Change to the name of a site responsible for QC testing, labelling, and batch release.
•	08 April 2011	Variation to change the address of the Pfizer office in PL.
•	17 March 2011	Renewal (UK as RMS).
•	21 April 2010	Variation to change the Marketing Authorisation Holder and distributor.
•	29 July 2009	Variation to change the finished product testing in line with the European Pharmacopoeia 2.6.25.
•	12 February 2008	New Marketing Authorisation (MRP, UK as RMS).