Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac AE Lyophilisate for Use in Drinking Water for Chickens

Vm 42058/5134

21 February 2025	One-off alignment of the product information with version 9.0* of the QRD templates (assessed to v3 of the GB template).
15 January 2025	Addition of 2000 dose presentation. Addition of RT-PCR method for Absence of Mycoplasma testing. Extension of storage for the antigen to 21 months. Deletion of extraneous agents tests on the finished product. Inclusion of gentamicin as a starting material of fish origin. Harmonisation of the quality dossier for the same purely national products and/or the same products approved in MR/DC procedures.
11 November 2024	Change in the invented name of the veterinary medicinal product in GB from Poulvac AE Lyophilisate Suspension for Use in Drinking Water to Poulvac AE Lyophilisate for Use in Drinking Water.
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).