Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac IB H120

Vm 60021/3068

25 March 2026	To add an already authorised site for finished product quality control testing.
24 April 2025	Change of Marketing Authorisation Holder Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Dublin 18, D18 T3Y1, Ireland.
13 March 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
22 January 2025	Addition of alternative residual moisture test. Addition of manufacturing site for the active substance and final product. Deletion of extraneous agents tests on the finished product based on assessment conducted in accordance with Ph. Eur. 5.2.5. Update of Part 2 in order to align with current manufacturing practices at the currently approved sites, and to harmonise Part 2. Introduction of the 7 ml vial and stopper as result of the site addition.
04 May 2024	To align the product information with the version 9.0 of the QRD template.
22 June 2023	The proposed change is to widen the limits of residual humidity.
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.
February 2019	Change of a test procedure for the finished product.
24 December 2018	Renewal – UK CMS
25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
10 October 2017	Change in RMS from UK to DE.
20 September 2017	Change of a test procedure for the finished product.
08 December 2016	Change of MAH address in France, Czech Republic and Slovakia.
21 November 2016	Change in test procedure for the finished product.
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.
7 January 2016	Change in test procedure for the finished product
05 May 2015	Change to the QPPV contact details.

09 January 2014	MRP – UK as RMS.
27 June 2013	Grouped variation to change the Marketing Authorisation Holder and distributor. Change in the name of the active substance manufacturer, site for blending, filling and assembly. Change to the name and address of the site for QC testing, labelling, and batch release. Deletion of an importer of final dosage form from outside the EU.
07 June 2013	Variation to update the dossier.
16 July 2012	Variation to replace a test method recommended in the Ph. Eur. Monograph 5.2.2.
01 February 2012	Variation to provide clarification for the release testing, secondary labelling/packaging and batch release site.
27 July 2011	Variation to change the name of the manufacturing site which is currently approved for QC testing, labelling, and batch release.
13 June 2011	Change in the supplier of a starting material/reagent/intermediate used in the manufacturing process of the active substance.
03 June 2011	Change in the specification parameters/limits of the finished product.
07 December 2010	Grouped variation to change the name of the manufacturer of the active substance, sites for blending, filling and assembly, site for QC testing, site for labelling, and site for batch release.
23 November 2010	Variation to change the name of the manufacturing site of the active substance.
08 July 2010	Renewal.
21 April 2010	Variation to change the name and address of the Marketing Authorisation Holder.
13 November 2008	Variation to change a test method (finished product).
12 March 2008	Addition of a production facility.
12 March 2008	Addition of a testing site and site for QP release.
11 October 2007	Variation to increase the upper limit of the release titre specification.
20 July 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-VPS.
24 May 2006	Variation to comply with the European Pharmacopoeia.
17 October 2005.	Reviewed MA.