Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac IB QX Lyophilisate for Oculonasal Suspension for Chickens

Vm 42058/5103

07 April 2026	To include Eurofins PROXY Laboratories B.V., Darwinweg 24, Leiden, 2333 CR, Netherlands as an additional finished product quality control testing site.
27 February 2026	Submission of updated mock ups.
03 January 2026	To add wording to the SPC and package leaflet regarding the interactions with other medicinal products (Poulvac IB Primer) to align the product information with NI.
31 January 2025	Update of section 4.8 of the SPC which now includes information on associated use of Poulvac IB QX and Poulvac IB Primer.
23 November 2024	Removal of extraneous agent testing from finished product testing in line with Ph. Eur. 5.2.5.
25 April 2024	Change in the specification parameters of the immediate packaging of the finished product.
21 April 2023	Change in type of container or addition of a new container - addition of a 7ml vial. G.I.18 update of product information according to the national SPC/QRD template.
09 January 2023	EDQM certificate for peptone updated to change the name of the holder and one of the sites of production to Life Technologies Corporation.
14 September 2022	Change in test procedures for the finished product.
25 November 2021	Change in the SPC, labelling or package leaflet due to new data.
29 July 2021	Change in the number of units (pack size) in a pack within the range of the currently approved pack sizes of the finished product.
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.
07 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
06 November 2018	Change of a test procedure for the finished product.
20 September 2017	Change of a test procedure for the finished product.
21 November 2016	Change in test procedure for the finished product.
06 June 2016	Change of test procedure for the finished product.
23 February 2016	Variation to remove the contraindication in Section 4.3 of the SPC that the vaccine could not be used during lay. Additional revision to Section 4.9 of the SPC to clarify instructions for administration by spray.

27 January 2016	Renewal UK as CMS
05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
20 December 2013	Deletion of a manufacturing site for the active substance for in-process control testing, site of finished product manufacturer, site of batch release, site of secondary packaging.
22 November 2013	Change to monitor a new test procedure for the active substance.
30 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS. Change to the name of the manufacturer of the active substance. To change the name of the manufacturer responsible for batch release
23 October 2013	Change to the name of the MAH from Pfizer to Zoetis in AT, BE, FR and LU only.