

VPA10387/051/001

Poulvac IB QX lyophilisate for suspension for spray for chickens

Variation	Summary	Date
Vet - F.II.b.2 a) 1.	VRA-R - Vet - F.II.b.2 a) 1. - - Vet - F.II.b.2 a) 1. - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place - Replacement or addition of a site where batch control/testing takes place for a biological/immunological veterinary medicinal product and any of the test methods performed at the site is a biological/immunological method	27/02/26
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	10/01/25
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17	10/01/25
Vet - G.I.4	VRA-S - Vet - G.I.4 - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - G.I.4 Safety, Efficacy, Pharmacovigilance changes - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.	06/01/25
Vet - F.II.d.1 b)	VRA-S - Vet - F.II.d.1 b) - b) Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product - F.II.d.1 b) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product	06/09/24
Vet - F.II.e.2 z)	VRA-R - Vet - F.II.e.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.2 z) Quality Changes - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	16/02/24
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product	09/02/23

	information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	
Vet - F.II.e.1 b) 2.	VRA-S - Vet - F.II.e.1 b) 2. - b) Change in type of container or addition of a new container 2. Sterile medicinal products and biological/ immunological medicinal products - F.II.e.1 b) 2. Quality Changes - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/immunological medicinal products	09/02/23
Vet - F.II.d.2 b)	VRA-S - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	09/09/22