

VPA10387/053/001

**POULVAC IBMM + ARK Lyophilisate for suspension for spray administration 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 - F.II.d.2 b)	VRA-R - 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)	24/03/25
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	19/06/24
Vet - F.I.a.2 a)	VRA-S - Vet - F.I.a.2 a) - a) Substantial change to the manufacturing process of the active substance which may have a significant impact on the quality, safety or efficacy of the medicinal product - F.I.a.2 a) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - Substantial change to the manufacturing process of the active substance which may have a significant impact on the quality, safety or efficacy of the medicinal product	19/06/24
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	17/04/24
Vet - G.I.18	VRA-S - Vet - G.I.18 - 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	03/04/24

	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	
B.II.a.3.b.3	II - B.II.a.3.b.3 - 3. Change that relates to a biological/immunological product - B.II.a.3.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product	04/02/22