

VPA10387/051/001

**Poulvac IB QX lyophilisate for suspension for spray for chickens**

<b>Variation</b>	<b>Summary</b>	<b>Date</b>
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 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	09/02/23
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