VPA10454/079/001

Gallivac IBD S706 NEO Effervescent tablet for use in drinking water for chickens

Variation	Summary	Date
Vet - B12 a)	VNRA - Vet - B12 a) - - Vet - B12 a) - Minor changes:— to an approved test procedure — for active substance or a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for the finished product;— for an excipient	22/10/26
Vet - B3 u)	VNRA - Vet - B3 u) - - Vet - B3 u) - Changes to the quality part of the dossier: Deletion of a Ph. Eur. Transmissible Spongiform Encephalopathy (TSE) CEP — for an active substance;— for a starting material, reagent or intermediate of an active substance;— for an excipient	02/10/26
Vet - G.I.18	VRA-S - Vet - G.I.18 - - Vet - G.I.18 - One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	30/09/26
Vet - A1 b)	VNRA - Vet - A1 b) - b) Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier. - A1 b) Administratvie changes: Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier.	02/08/24
Vet - F.II.b.2 a) 1.	VRA-S - Vet - F.II.b.2 a) 1. - a) Replacement or addition of a site where batch control/testing takes place 1. 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 - F.II.b.2 a) 1. Quality Changes - Finished Product -Manufacture - 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	15/07/24
Vet - B43	VNRA - Vet - B43 - Editorial changes to part 2 of the dossier	14/12/23

	if inclusion in an upcoming procedure concerning part 2 is not possible - B43 Changes to the quality part of the dossier: Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible	
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)	15/03/23