

VPA10463/007/001

**Cevac MD Rispens concentrate and solvent for suspension for injection for chickens**

Variation	Summary	Date
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	08/06/26
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	15/04/26
Vet - C5	VNRA - Vet - C5 - - Vet - C5 - Change in the pharmacovigilance system master file (PSMF) location	15/04/26
Vet - F.II.f.1 a) 5.	VRA-R - Vet - F.II.f.1 a) 5. - - Vet - F.II.f.1 a) 5. - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - Extension of the shelf-life of a biological/immunological medicinal product in accordance with an approved stability protocol.	19/03/26
Vet - F.III.1 b) 1.	VRA-S - Vet - F.III.1 b) 1. - - Vet - F.III.1 b) 1. - Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability - For an active substance, For a starting material/reagent/intermediate used in the manufacturing process of the active substance, For an excipient - European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - New/updated certificate from an already approved/new manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agents is required	19/03/26
Vet - F.III.1 a) 1.	VRA-S - Vet - F.III.1 a) 1. - - Vet - F.III.1 a) 1. - Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability - For an active substance, For a starting material/reagent/intermediate used in the manufacturing process of the active substance, For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where mwater is used in the last steps of the synthesis and the material is not claimed to be endotoxin free	16/02/26
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	24/07/25

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)	14/11/23
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	14/11/23
Vet - B21	VNRA - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product - B21 Changes to the quality part of the dossier: Replacement or addition of a secondary packaging site of a finished product	03/01/23