

VPA10782/038/001

Huvamox 800 mg/g powder for use in drinking water for chickens, turkeys, ducks and pigs

Variation	Summary	Date
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	25/09/23
Vet - B45	VNRA - Vet - B45 - Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile active substance, starting material, reagent or intermediate, excipient - B45 Changes to the quality part of the dossier: Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	13/01/23
Vet - B26 a)	VNRA - Vet - B26 a) - a) Up to 10-fold increase compared to the originally approved batch size of an immediate release oral pharmaceutical forms or of a non-sterile liquid based pharmaceutical form - B26 a) Changes to the quality part of the dossier: Change in the batch size (including batch size ranges) of the finished product: — up to 10-fold increase compared to the originally approved batch size of an immediate release oral pharmaceutical forms or of a non-sterile liquid based pharmaceutical form	28/07/22