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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Bovela Lyophilisate and Solvent for Suspension for Injection for Cattle
Vm 04491/5004

•	25 August 2023	Editorial changes to part 2 of the dossier.
•	12 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	17 February 2023	To register an alternative site for manufacturing of the active substances BVDV-1 & BVDV-2. To register an alternative site for quality control and batch release of the Bovela finished product. To register an alternative site for quality control of the Bovela active substances BVDV 1 and BVDV 2. To update the product information to version 9.0 of the QRD template. To register an alternative site for manufacturing of the freeze-dried pellet of Bovela. To modify the BVDV-2 target titre at formulation from 10^5.5 to 10^5.7 TCID50/dose.
•	19 January 2023	The aim of this variation is the introduction of an optional sterile in-line screen mesh clarification system between the blending vessel and the filling lines of the manufacturing process of the modified live vaccines, Bovela, Enterisol Ileitis, Ingelvac PRRSFLEX EU, and ReproCyc PRRS.
•	05 May 2022	Change of specification of an excipient to fully comply with the Ph. Eur.
•	08 March 2022	Change in the manufacturer of a starting material used in the manufacturing process of the active.
•	14 October 2021	Changes to the labelling and package leaflet.
•	28 September 2021	Change in the name and address of the manufacturer of the finished product.
•	28 July 2021	Minor change in the manufacturing process of an immediate release solid oral dosage form
•	25 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.