



## Post Authorisation Assessments

For details of post authorisation assessments prior to 1<sup>st</sup> January 2021,  
please refer to the [EMA](#) website.

### Bovela Lyophilisate and Solvent for Suspension for Injection for Cattle

Vm 04491/5004

• 01 July 2024	Editorial changes to part 2.E of the dossier.
• 22 June 2024	Clarification of dossier wording for the supply of trypsin.
• 22 June 2024	Replace the current company preparing and testing the 10 X porcine trypsin solution with Boehringer Ingelheim (BI) company that will use the current porcine trypsin source and solution recipe. Expand the geographical sourcing for porcine trypsin. Add a new foetal bovine serum supplier holding a valid CEP.
• 18 May 2024	Addition of an approved manufacturing site responsible for batch control of the Bovela diluent.
• 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 <sup>5.5</sup> to 10 <sup>5.7</sup> TCID <sub>50</sub> /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.