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Post Authorisation Assessments

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

PREVEXXION RN+HVT+IBD Concentrate and Solvent for Suspension for Injection

Vm 04491/5043

•	31 October 2023	Update to the description of starting materials of biological origin.
•	29 September 2023	Extension of the shelf life of the finished product to 2 years - As packaged for sale.
•	16 June 2023	To introduce the use of cell dissociation of non-animal origin, to enlarge the description of already authorised recombinant trypsin as a substitute for porcine trypsin in the manufacturing process.
•	10 May 2023	Declaring the addition of Bioluz Laboratory as an alternative manufacturer responsible for the batch release of the solvent used for the resuspension Prevexxion RN+HVT+IBD.
•	24 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	27 February 2023	The variation regards the compatibility claim between PREVEXXION RN or PREVEXXION RN+HVT+IBD and VAXXITEK HVT+IBD. The new studies are aimed at demonstrating the absence of interference between the two vaccinal strains RN1250 and vHVT013-69 on Infectious bursal disease protection.
•	07 July 2022	Change in the invented name of the solvent to more general name 'Solvent for cell associated poultry vaccines'.
•	24 June 2022	Update of the test procedures to reflect compliance with the Ph. Eur and removal of the reference to the outdated internal test method.
•	22 June 2022	Deletion of a manufacturer responsible for quality control.
•	24 March 2022	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	26 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.