Veterinary Medicines Directorate

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Post Authorisation Assessments

Bovilis INtranasal RSP Live, Nasal Spray, Lyophilisate and Solvent for Suspension for Cattle

Vm 01708/5104

•	26 February 2024	The variation is to mention the use of animal derived trypsin in the manufacture of the Byco-C hydrolysed gelatin provided by Croda and to declare a change in the hydrolysis step of the gelatin (excipient) by replacing porcine trypsin by the use of either porcine or bovine trypsin.
•	17 November 2023	To add tangential flow (TF) filtration perfusion as an optional method for BRSV jencine-2013 antigen production. To optimise the thawing process of stored BRSV jencine-2013 antigen.
•	15 June 2023	Unlimited renewal
•	31 August 2022	Change to the minimum age for administration. Change to the maximum PI3 titre.
•	27 April 2021	Change in the number of units (20 dose presentation) in a pack within the range of the currently approved pack sizes of the finished product. Change in the number of units (25 dose presentation) in a pack within the range of the currently approved pack sizes of the finished product. Change in the number of units (50 dose presentation) in a pack within the range of the currently approved pack sizes of the finished product.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	27 July 2020	Reduction of the shelf life of the finished product as packaged for sale from 5 years to 3 years. Increase in the shelf-life of the finished product, from 18 month to 2 years.