Veterinary Medicines Directorate

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Post Authorisation Assessments

ReproCyc PRRS EU Lyophilisate and Solvent for Suspension for Injection for Pigs

Vm 08327/4301

•	April 2024	Replacement of the supplier for 10x trypsin solution. Expansion of the geographical sourcing of the trypsin to include Denmark, France, Germany, Ireland, Italy and The Netherlands. Addition of a new supplier for bovine serum. (NI)
•	04 July 2023	Change to comply with Ph. Eur.: change of specification of a former non-EU Pharmacopoeial excipient to fully comply with the Ph. Eur. (GB)
•	12 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	15 March 2023	To make changes in the manufacturing process of the finished product by standardising the fill line set-ups with the installation of a 225-micron stainless steel mesh screen inline between the blending and filling lines.
•	10 February 2023	The variation is to introduce the use of recombinant trypsin as a substitute to porcine trypsin for the manufacture of the active substance.
•	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.
•	02 March 2022	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	24 September 2021	Change in the name of the manufacturer of the finished product.
•	16 March 2021	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
•	28 August 2020	Change in the name of the manufacturer of the finished product.
•	26 March 2020	Renewal- UK as CMS.
•	06 December 2019	Change in the SPC, labelling or package leaflet due to new data.
•	24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	18 June 2019	Change in the name of a manufacturer of active substance. Addition of a secondary packaging site of the finished product.

•	10 May 2019	Change in the name of the manufacturer of the finished product. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer
•	28 March 2019	Extension of the in-use shelf-life of the reconstituted lyophilised finished product from 4 hours to 8 hours.
•	06 March 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	12 December 2018	Increase in the shelf-life of the finished product as packaged for sale, from 12 months to 24 months.
•	09 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	16 July 2018	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance Minor changes to an approved test procedure of the finished product
•	15 March 2018	Change in the RMS from UK to IE.
•	13 March 2018	Change in the specification parameters.
•	05 December 2017	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Deletion of a manufacturing site for an active substance. Deletion of a manufacturing site for testing site. Addition of a secondary packaging site of the finished product.
•	20 April 2017	Deletion of a manufacturer responsible for batch release
•	30 March 2017	Change in the SPC and package leaflet due to new data.
•	09 March 2017	Deletion of a test procedure for the active substance used in the manufacturing process of the active substance if an alternative test procedure is already authorised. Deletion of a test procedure for the active substance used in the manufacturing process of the active substance if an alternative test procedure is already authorised. Deletion of a test procedure for the active substance used in the manufacturing process of the active substance if an alternative test procedure is already authorised. Submission of a new Ph. Eur. TSE certificate of suitability for a starting material (used in manufacturing process of active) from an already approved manufacturer. Widening of the specification limits of a starting material

		used in the manufacturing process of the active substance.
•	19 April 2016	Deletion of a non-significant parameter of an active substance/starting material/intermediate/reagent used in the manufacturing process of the active substance.
•	22 September 2015	Change to the solvent name in Hungary, Slovakia and Slovenia only.
•	01 September 2015	Additional site for secondary packaging.