Veterinary Medicines Directorate

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Post Authorisation Assessments

Equip Artervac Emulsion for Injection for Horses and Ponies

Vm 42058/5147

•	16 February 2023	Addition of Denmark, France, Germany and the Netherlands as a source of porcine pancreas used for the production of trypsin powder.
•	16 November 2022	Addition of Denmark, France, Germany and the Netherlands as a source of porcine pancreas used for the production of trypsin.
•	08 April 2020	Increase in the shelf-life of the finished product, from 18 months to 2 years.
•	14 November 2019	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	03 April 2019	Increase in the shelf-life of the finished product, from 12 months to 18 months.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	23 January 2018	Change in the number of units in a pack within the range of the currently approved pack sizes of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of an excipient. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Replacement of a secondary packaging site of the finished product. Changes to a test procedure for the active substance. Changes to a test procedure for the finished product. Change in manufacturing process of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Change in the immediate packaging of the finished product. Change in the manufacturer of the active. Changes in the manufacturing process of the finished product. Replacement of a manufacturer responsible for batch release including batch control / testing. Changes in the manufacturing process of the active substance. Replacement of a manufacturing site of the finished product.
•	27 November 2015	Change to in-process tests and limits applied during the

		manufacture of the active substance
•	30 April 2015	Change in the QPPV contact details.
•	31 July 2014	Deletion of a non-signification specification parameter.
•	17 October 2013	Change in the name/address of the MAH in France only.
•	09 October 2013	Change to the QPPV contact details.
•	20 June 2013	Transfer of MA and change of distributor from Pfizer Ltd to Zoetis UK Ltd. Change in distributor details.
•	13 June 2012	Introduction of a new pharmacovigilance system.
•	23 February 2012	Change in the invented name of the product from Artervac Emulsion for Injection for Horses and Ponies to Equip Artervac Emulsion for Injection for Horses and Ponies.
•	30 August 2011	Change in control of the finished product.
•	13 October 2010	Transfer of MA from Fort Dodge Animal Health Ltd to Pfizer Ltd.
•	03 September 2010	Change in the name of the manufacturer of the finished product, including quality control sites.
•	13 August 2010	Changes to the immediate packaging of the finished product. Addition of a new supplier of a starting material.
•	04 June 2010	Renewal.
•	23 January 2009	Changes to the manufacturing process. Addition of a supplier of a starting material.
•	23 October 2008	Addition of a test procedure for the finished product.
•	31 October 2007	Updated TSE Ph. Eur. certificate of suitability.
•	31 January 2007	Replacement of a supplier of an adjuvant.
•	03 December 2006	Addition of a starting material.
•	08 September 2006	Changes to the manufacturing procedure.