Veterinary Medicines Directorate

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Post Authorisation Assessments

Aftopur DOE

Vm 08327/5001

14 December 2024	To declare three editorial changes in the Part II.D “in-process controls”. To implement a change in the manufacturing of the active substance “inactivated FMD virus” to remove the use of chloroform at virus harvest and to reduce the use of antibiotics in the virus culture
27 June 2024	Removal of a strain for the veterinary vaccine.
25 October 2023	Update to the description of starting materials of biological origin.
25 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
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.
24 September 2021	Changes to a test procedure for an excipient.
02 July 2021	Change in the specification parameters and/or limits of the immediate packaging of the finished product.
May 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
26 November 2020	Change in the name of the manufacturer of the finished product.
21 October 2020	Minor changes to an approved test procedure of the finished product. Tightening of specification limits of an excipient. Changes in the manufacturing process of the active substance.
22 July 2020	Change in the name of a manufacturer of the active substance.
27 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
14 October 2019	Deletion of Ph. Eur. TSE certificates of suitability for a starting material. Addition of alternative control tests for a starting material used in the manufacture of the active substances. Tightening of specification limits of an excipient. Modification of an in-process control test applied during the manufacturing of the active ingredient. Introduction of a minor change in the manufacturing of the active ingredient.
08 January 2019	Change in the name of a manufacturer used in the manufacture of the active substance.

	Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name and address of the marketing authorisation holder From Merial Animal Health Limited, PO Box 327, Sandringham House, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Limited, Ellesfielfd Avenue, Bracknell, Berkshire, RG12 8YS.
20 September 2018	Addition of a manufacturer responsible for batch release of the finished product.
26 June 2018	Addition of a new vaccine strain. Addition of a new vaccine strain.
20 June 2018	Change in RMS from UK to DE.
28 February 2018	Changes in the manufacturing process of the active substance. Changes in the manufacturing process of the finished product. Changes in the manufacturing process of the active substance.
31 October 2017	Replacement of a test procedure for the active substance.
05 March 2015	Change in the manufacturing process of the active substance.
11 September 2014	Update to the finished product manufacture and testing regime.
13 March 2014	Change in the specification limits of starting materials used in the manufacturing process of the active substance and of in-process tests.
03 May 2013	Change in manufacturing process of active substance.
09 August 2012	Submission of an updated Ph. Eur. Certificate of Suitability.
19 September 2011	Change to comply with Ph. Eur. or Pharmacopoeia of a member state.
10 June 2010	Renewal.
25 November 2009	Extension.
05 May 2005	MRP procedure (UK as RMS).
22 October 2001	Addition of immunological properties on SPC.