Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Aftopur AlSap

Vm 08327/5002

•	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.
•	18 May 2022	Addition of a new specification parameter to the specification with its corresponding test method of an excipient.
•	07 December 2021	Change in control testing site.
•	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.
•	22 October 2020	Change in the specification parameters of the finished product. Changes in the manufacturing process 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 to a test procedure for the finished product. 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.
•	04 June 2015	Update to a starting material used in the manufacture of the finished product.
•	05 March 2015	Change in the manufacturing process of the active substance.
•	11 September 2014	Update to finished product manufacture and testing regime.
•	03 May 2013	Changes in manufacturing process of active substance.
•	09 August 2012	Submission of an updated Ph. Eur. Certificate of Suitability.
•	24 February 2012	Change to comply with Ph. Eur. or Pharmacopoeia of a member state.
•	19 September 2011	Change to comply with Ph. Eur. or Pharmacopoeia of a member state.
•	10 June 2010	Renewal (UK as RMS).
•	25 November 2009	MRP procedure (UK as RMS).
•	25 October 2001	Addition to SPC of experimental findings.