Veterinary Medicines Directorate

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Post Authorisation Assessments

AviPro Salmonella Vac E

Vm 00879/4189

•	22 March 2024	Changes to a non-significant specification parameter of a starting material used in the manufacturing process of the active substance.
•	23 June 2021	Changes in the manufacturing process of the finished product. Change in the specification limits of the finished product.
•	16 December 2020	Change of MAH from Lohmann Animal Health GmbH, Heinz-Lohmann-Straße 4, D-27472 Cuxhaven, to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	18 February 2020	Deletion of a non-significant parameter of a starting material used in the manufacturing process of the active substance. Alignment of Part 2 of the dossier.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	29 November 2017	Minor change in the manufacturing process of the active substance.
•	01 August 2017	Increase in batch size of active substance or intermediate used in the manufacturing process of the active substance.
•	05 May 2017	Mock-ups approved.
•	20 April 2016	Deletion of 2 TSE Certificates of Suitability. Update of 2 TSE Certificates of Suitability.
•	06 April 2016	Submission of an updated certificate of suitability. Deletion of a certificate of suitability.
•	19 December 2014	Change in test procedure for an excipient.
•	13 October 2014	Update to the QPPV.
•	11 May 2012	Change of name of MAH. Change of manufacturer of the active substance. Change of manufacturer of the finished product. Change of manufacturer responsible for quality control, packaging and batch release.
•	17 November 2011	Submission of 3 updated Ph. Eur. Certificates of Suitability.
•	19 September 2011	Addition of a plant at an already approved manufacturing site for the manufacture of the active substance and the finished product.
•	09 June 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
•	08 October 2010	Submission of an updated part 2 of the dossier

		Introduction of an intermediate storage of finished product of up to 36 months.
•	08 November 2007	Changes to SPC and product literature to bring in line with new legislation.
•	12 July 2007	Change in source of an excipient.
•	10 January 2007	Change in name of the product from ‘Tad Salmonella Vac E’ to ‘AviPro Salmonella Vac E’.
•	19 October 2006	Change of finished product specification.
•	15 March 2006	Renewal.
•	02 February 2006	Change to manufacturing process.
•	23 June 2005	Change in container shape.
•	04 November 2002	Change to contraindications.
•	28 January 2002	Change in finished product specification.