Veterinary Medicines Directorate

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Post Authorisation Assessments

AviPro Salmonella Vac T

Vm 00879/3033

•	21 October 2024	Deletion of box of 2 x 500, 1,000, 1,500, 2,000 or 2,500 doses pack sizes.
•	08 July 2024	SRP to add 5 new CMS.
•	14 May 2024	Alignment of the SPC/QRD text with the newest EU version 9.0 QRD template and GB National SPC/QRD template.
•	04 May 2024	Changes to a non-significant specification parameter of a starting material used in the manufacturing process of the active substance.
•	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.
•	26 October 2020	Submission of an updated Ph. Eur. certificate of suitability.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	01 May 2019	Deletion of a non-significant parameter of an active substance. Alignment of Part 2 in accordance with the current data regarding methods of production and quality control.
•	29 November 2017	Minor change in the manufacturing process of the active substance.
•	20 April 2016	Deletion of 2 TSE Certificates of Suitability. Update of 2 TSE Certificates of Suitability.
•	17 December 2014	Minor change to a test procedure for an excipient.
•	21 November 2014	Update to the DDPS.
•	02 May 2014	Updates made to the product labelling not connected to the SPC.
•	07 February 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	08 July 2013	Change of source of an excipient. Change of specification parameters/limits of the finished product. Change in manufacturer of starting material, reagent or intermediate product used in the manufacture of the active substance. Replacement of a manufacturing site responsible for part of the manufacturing process of the finished product.
•	16 May 2012	Change of name of MAH. Change of Manufacturer responsible for quality control,

		batch release and packaging. Change of manufacturer of the active substance. Change of manufacturer of the finished product.
•	16 January 2012	Submission of 3 new Ph. Eur. Certificates of Suitability.
•	23 June 2011	Submission of an updated part 2 of the dossier.
•	09 June 2011	Changes to an existing Pharmacovigilance system as described in the DDPS.
•	09 September 2009	Change of QPPV.
•	24 August 2007	Renewal.
•	23 March 2007	Change of product name from 'TAD Salmonella Vac T' to 'AviPro Salmonella Vac T'.
•	26 June 2006	Change to batch size of the active substance.
•	21 December 2005	Repeat use procedure – Germany as RMS.
•	01 August 2005	Change to secondary packaging.
•	26 March 2003	Change of source of active substance.