



Post Authorisation Assessments

AviPro Salmonella Vac E

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| • | 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. |

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| • | 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. |