Veterinary Medicines Directorate

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Post Authorisation Assessments

AviPro Salmonella Duo Lyophilisate for Use in Drinking Water

Vm 00879/4188

•	19 March 2024	Changes to a non-significant specification parameter of a starting material used in the manufacturing process of the active substance.
•	31 May 2022	Repeat Use to add one CMS
•	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.
•	16 September 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Update of format 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.
•	12 July 2017	Increase in batch size of active substance or intermediate used in the manufacturing process of the active substance.
•	27 March 2017	Repeat Use application to add one new Member State.
•	28 July 2016	Renewal – UK CMS
•	17 December 2014	Minor change to a test procedure for an excipient.
•	21 November 2014	Update to the DDPS.
•	19 March 2014	Addition of turkey as a target species.
•	07 February 2014	Changes to an existing pharmacovigilance system.
•	16 May 2012	Change to the name of the MA holder, change to the name of the active substance manufacturer and change to the name of the finished product manufacturers responsible for packaging, quality control and batch release.