



Post Authorisation Assessments

AviPro ND C131 Lyophilisate for Suspension for Chickens and Turkeys Vm 00879/3031

•	10 November 2023	To increase the shelf life of the finished product from 1 year to 18 months. From the currently available packaging sizes, the applicant intends to only keep the box with a vial with 5000 doses and the box with ten vials with 5000 doses and adds a box with a vial with 2000 doses and a box with ten vials with 2000 doses. Filling of harvest in containers and addition of stabilizer resulting in pre- bulk optional interim storage at ≤ -70°C optional thawing of pre-bulk containers, filtration of pre-bulk combining of pre-bulk to bulk vaccine in a vessel. Use of a new, so called SSPGb2 stabilizer containing sorbitol, sucrose, sodium phosphate compounds and gelatin. QRD update to v9.
•	05 December 2022	The addition of four alternative manufacturers for medium 199 to the dossier quality documentation.
•	17 March 2022	Renewal
•	17 August 2021	Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance Deletion of a specification parameter 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.
•	23 July 2020	Submission of an updated certificate of suitability.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	21 July 2017	Reduction of the age of target species chicken to 1 day old. Addition of turkey as a new target species.
•	18 January 2017	Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product.
•	01 August 2016	Deletion of an invalid certificate from an already approved manufacturer

		<p>Updated certificate from an already approved manufacture</p> <p>Minor change in the manufacturing process of the active substance.</p> <p>Submission of an updated harmonised Part 2 Quality section</p> <p>Addition of a Certificates of suitability of a new supplier</p>
•	21 November 2014	Update to the DDPS.
•	07 February 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	22 October 2012	To reduce the shelf life of the veterinary medicinal product from 24 months to 12 months.
•	20 December 2011	Renewal – UK as CMS
•	09 June 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
•	14 September 2009	Change of the QPPV Vaccines.
•	26 October 2007	To change the filling volume.