Veterinary Medicines Directorate

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Post Authorisation Assessments

AviPro ND C131 Lyophilisate for Suspension for Chickens and Turkeys

Vm 52127/5099

23 June 2026	To change the name of a supplier of SPC eggs (Charles River to AVS Bio)
22 April 2026	Addition of contact details to report suspected adverse reactions for the marketing authorisation holder.
08 August 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
02 June 2025	Change the named distributor from Elanco Europe Ltd. to Elanco UK AH Ltd. Change of Marketing Authorisation Holder from Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, 27472 Cuxhaven, Germany.
26 March 2025	Submission of mock ups for new pack sizes.
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. Update to the national template.
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 Updated certificate from an already approved manufacture Minor change in the manufacturing process of the active substance. Submission of an updated harmonised Part 2 Quality section Addition of a Certificates of suitability of a new supplier
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.