Veterinary Medicines Directorate

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Post Authorisation Assessments

AviPro Precise Lyophilisate for Use in Drinking Water

Vm 52127/5151

26 June 2026	To change a name of supplier of SPF eggs.
06 November 2025	Change in name of distributor from Elanco Europe Ltd to Elanco UK AH Ltd. Change in legal entity of MA 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.
03 September 2025	Update to the product literature according to the National template Version 3.
30 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
11 February 2025	One-off alignment of the product information with version 3 of the GB SPC/QRD templates.
31 March 2023	Approval of mock-ups.
05 December 2022	The addition of four alternative manufacturers for medium 199 to the dossier quality documentation.
27 May 2022	Tightening of specification limits of the finished product. Change in the fill weight / fill volume of the finished product.
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.
19 February 2020	Update of the quality dossier intended to implement the outcome of a Union referral procedure.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
17 May 2019	Changes to the labelling.
17 October 2017	Repeat Use application to add 1 new member state.
27 July 2017	Changes to the labelling and/or package leaflet.
18 January 2017	Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product.
07 February 2014	Changes to an existing pharmacovigilance system as described in the DDPS.

16 April 2013	Change to batch release arrangements and quality control testing of the finished product. Change in test procedure on finished product.
27 April 2012	Change of name of MAH. Change of manufacturer of the active substance. Change in manufacturer responsible for batch release and quality control procedures.
04 April 2012	Submission of an updated part 2 of the dossier.
09 June 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
14 September 2009	Change of QPPV.
14 December 2007	Change to fill volume.
28 November 2007	Change in test procedures to bring in line with Ph. Eur. Monograph.
21 May 2007	Renewal.
14 August 2005	Change to secondary packaging material – different colour code.