Veterinary Medicines Directorate

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Post Authorisation Assessments

Avipro Thymovac Lyophilisate for Use in Drinking Water

Vm 52127/3006

March 2025	To include an alternative titration and identity test method.
18 March 2025	Change in legal entity 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, D-27472, Cuxhaven, Germany.
19 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
17 December 2024	One-off alignment of the product information with version 2 of the GB SPC/QRD template.
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.
13 June 2019	Update the Part 2 of the dossier in VNeeS-format.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
27 April 2017	Change in the manufacturing process of the active substance.
18 January 2017	Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product.
21 November 2014	Update to the DDPS.
07 February 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
08 July 2013	Renewal.
16 April 2013	Change to batch release arrangements and quality control testing of the finished product. Change in test procedure for the finished product.
16 May 2012	Change in name of MAH. Change in name of Manufacturer of the finished product.
09 June 2011	Change to an existing Pharmacovigilance system as described in the DDPS.
30 November 2010	Change in container closure system of the finished product.
10 August 2010	To submit an updated part 2 to the current manufacturing and control.

03 February 2010	To change the described testing procedure for extraneous viruses
02 December 2009	To submit joint-labelling between the UK and Ireland after MRP.
14 September 2009	Change of QPPV vaccines.