Veterinary Medicines Directorate

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Post Authorisation Assessments

Baycox Multi 50 mg/ml Oral Suspension for Cattle, Pigs and Sheep

Vm 52127/3077

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.
07 October 2025	Change to the production process or the storage of active substance where no Ph. Eur. CEP is part of the approved dossier of an active substance
07 October 2025	Change in the manufacturers of the active substance. Extension in the re-test period of an active substance.
19 September 2025	Alignment of the product information with version 9.0* of the QRD templates.
10 March 2025	Change in the manufacturer of a starting material used in the manufacturing process of the active substance. Change in the manufacturer of a starting material used in the manufacturing process of the active substance.
21 January 2025	Change in ATCvet Code.
22 December 2024	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. (NI)
06 December 2024	Change in the specification parameters of a starting material. (NI)
27 June 2024	Introduction of a manufacturer of the active substance supported by an ASMF.
01 December 2021	Renewal – UK as CMS.
23 October 2020	Change of MAH, from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
05 December 2019	Deletion of a supplier of packaging components or devices. Changes to a test procedure for a reagent used in the manufacturing process of the active substance. Deletion of manufacturing site for an active substance.
26 October 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
18 September 2018	Change in distributor details from Bayer plc, Animal Health Division, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green park, Reading, Berkshire, RG2 6AD.

14 August 2018	Deletion of a supplier of packaging components or devices.
February 2018	Changes to a test procedure (including replacement or addition) for a reagent used in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance. Change in the manufacturer of the active where no Ph. Eur. Certificate of Suitability is part of the approved dossier. Change in the specification parameters of a starting material used in the manufacturing process of the active substance.
10 January 2018	Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD.
09 November 2017	Addition of a new therapeutic indication
01 August 2017	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance