Veterinary Medicines Directorate

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Post Authorisation Assessments

Baytril Max 100 mg/ml Solution for Injection for Cattle and Pigs

Vm 52127/3080

27 April 2026	Submission of a new Ph. Eur. CEP for an active substance.
17 April 2026	Addition of contact details to report suspected adverse reactions for Northern Ireland for the Marketing Authorisation Holder.
01 March 2026	Addition of quality control testing site for the finished product. Addition of quality control testing site for the finished product. Addition of quality control testing site for the finished product. Addition of quality control testing site for the finished product.
11 November 2025	Change of distributor details from Elanco Europe Ltd to Elanco UK AH Ltd. Change of legal entity of the 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.
17 October 2025	Updating the product information with applicable statements from the CVMP 'Guideline on the summary of product characteristics for veterinary medicinal products containing antimicrobial substances'. One-off alignment of the product information with version 9.0* of the QRD templates.
15 July 2025	Change in the name of a manufacturer of the finished product. (GB)
20 June 2025	Change in the name of a manufacturer of the finished product. (NI)
08 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance. (GB)
12 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. (NI)
21 March 2022	Change in the name and/or address of the manufacturer of the finished product.
03 June 2021	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
25 January 2021	Change in the name of the manufacturer of the finished product.
17 September 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.
14 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.

01 June 2018	Change to more restrictive storage conditions of the active substance.
21 December 2017	Replacement of a supplier of packaging components or devices. Change in the name of the manufacturer used in the manufacture of the active substance.
December 2017	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
07 December 2017	Renewal UK as CMS
20 July 2016	Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH
14 April 2014	Change in the name of the marketing authorisation holder in France.