Veterinary Medicines Directorate

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Post Authorisation Assessments

Baycox 25 mg/ml, Solution for Use in Drinking Water for Chickens and Turkeys

Vm 00879/4112

•	15 September 2023	Change in the specification parameters of the active substance.
•	27 June 2023	Restriction period before the onset of lay during which the product must not be used in chickens amended to 6 weeks.
•	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.
•	11 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 September 2019	To obtain Joint-Labelling between the UK and Ireland.
•	11 July 2019	Renewal – UK as CMS
•	14 November 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.
•	10 August 2018	Deletion of a supplier of packaging components or devices
•	14 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.
•	21 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.
•	04 July 2017	Addition of a new specification parameter with its

		corresponding test method of an active substance
•	20 July 2016	Change to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH.
•	20 July 2016	Tightening of specification limits. Tightening of specification limits. Addition of a new specification parameter to the specification with its corresponding test method. Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) Minor changes to an approved test procedure Minor changes to an approved test procedure Minor changes to an approved test procedure Minor changes to an approved test procedure Minor changes to an approved test procedure Other changes to a test procedure (including replacement or addition) for a reagent, which does not have a significant effect on the overall quality of the active substance Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
•	21 May 2015	Change in the invented name of the veterinary medicinal product in Ireland only.
•	08 January 2015	Addition of a test method applied during the manufacture of the finished product.