



Post Authorisation Assessments

Baycox 50 mg/ml Oral Suspension for Piglets, Calves and Lambs

•	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.
•	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.
•	05 May 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
•	19 July 2016	Minor changes to an approved test procedure for an intermediate material used in the manufacturing process of the active substance Minor changes to an approved test procedure for a starting material used in the manufacturing process of the active substance Minor changes to an approved test procedure for a starting material used in the manufacturing process of the active substance Minor changes to an approved test procedure for a starting material used in the manufacturing process of the active substance Minor changes to an approved test procedure for an intermediate material in the manufacturing process of the active substance Other changes to a test procedure for a reagent used in the manufacturing process of the active substance. Tightening of the specification limits for the active substance. Tightening in the specification parameters of an intermediate used in the manufacturing process of the active substance. Change in the specification parameters of an intermediate used in the manufacturing process of the active substance. Deletion of non-significant specification parameters of a starting material used in the manufacturing process of the active substance. Addition of a test procedure for a starting material used in the manufacturing process of the active

		<p>substance</p> <p>Addition of a test procedure for a starting material used in the manufacturing process of the active substance</p> <p>Replacement of a test procedure for a starting material used in the manufacturing process of the active substance</p>
•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	8 December 2015	Addition of a secondary packaging site.
•	10 December 2014	Update to the finished product specifications.
•	23 May 2014	Renewal procedure – UK as RMS.
•	16 February 2011	To change the distributor.