



Post Authorisation Assessments

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

•	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