Veterinary Medicines Directorate

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Post Authorisation Assessments

Bayvarol 3.6 mg Bee-hive Strips for Honey Bees

•	16 December 2021	Changes in imprints, bossing, or other markings including replacement, or addition of inks used for product marking. Changes to a test procedure for the finished product. Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. Change in the specification parameters and/or limits of the finished product.
•	23 September 2021	Addition of a manufacturer of the active substance.
•	14 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.
•	10 March 2020	Addition of a manufacturer of the active substance.
•	28 November 2018	Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	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.
•	18 May 2018	Change in RMS from UK to IE.
•	05 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.
•	08 June 2017	Change in container closure system of the finished product. To remove a foil type. Changes in the manufacturing process of the finished product.
•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	18 May 2016	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH

•	29 May 2015	Change in supplier of packaging components.
•	26 March 2015	Change in name of the manufacturer of the active substance.
•	07 November 2014	Addition of new specification parameters to the finished product specification.
•	23 June 2014	Change to the specification parameters for the active substance.
•	14 December 2011	Renewal.
•	22 February 2011	Change of distributor.
•	02 April 2008	To change the Marketing Authorisation Holder in Ireland
•	28 December 2006	Renewal of the Marketing Authorisation
•	12 October 2006	MRP (UK as RMS)
•	22 June 2005	Variation to provide an additional increased pack size.
•	29 September 2004	Variation to change the site of manufacture of the active substance.
•	04 June 2002	Variation to update the active substance test specification and methods.
•	03 February 2002	Change of Marketing Authorisation Holder address.
•	11 July 2002	Renewal.
•	03 January 2002	Harmonisation.
•	26 June 1997	Renewal.
•	26 April 1996	Extension of the shelf life.
•	02 December 1994	Change to the pharmaceutical warnings.
•	21 November 1994	Change to the active substance specification.
•	18 November 1994	Change to the legal status.
•	30 March 1994	Extension of product shelf life.