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Post Authorisation Assessments

Bovalto Pastobov

Vm 08327/4173

•	12 April 2023	Change in the name or address or contact details of a
		qualified person for pharmacovigilance.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance
		system as described in the DDPS.
•	28 August 2020	Change in the name of the manufacturer of the finished product.
•	10 August 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
•	18 June 2020	Change in the name of the manufacturer of the finished product.
•	27 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	24 May 2019	Changes to the labelling and package leaflet.
•	16 November 2018	Change in the name and address of the marketing
		authorisation holder from Merial Animal Health Limited,
		Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United
		Kingdom to Boehringer Ingelheim Animal Health UK
		Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12
		8YS, United Kingdom.
•	20 April 2017	Change in the invented name of the veterinary medicinal
	•	product from Pastobov to Bovalto Pastobov.
•	27 February 2012	Variation to comply with the current European
		Pharmacopoeia.
•	20 January 2012	Change in the specification parameters.
•	23 November 2007	Renewal.
•	20 June 2005	Transfer of the medicinal product quality control tests
		and release.
•	29 March 2005	Addition of blending and primary packaging, as well as a secondary packaging site.
•	05 December 2003	Variation to change the Marketing Authorisation Holder
		address in France.
•	10 April 2003	Renewal.
•	26 March 2002	Variation concerning the ingredient specification.
•	05 June 1998	Variation to change the address of the Marketing
		Authorisation Holder.