Post Authorisation Assessments

Avishield ND B1, Lyophilisate for Oculonasal Suspension/Use in Drinking Water for Chickens

Vm 43676/4003

•	18 April 2023	Changes in the manufacturing process of the active substance.
		Changes in the manufacturing process of the active
		substance.
		Changes in the manufacturing process of the active substance.
		Changes in the manufacturing process of the active
		substance.
•	05 October 2022	Unlimited renewal.
•	06 May 2022	Submission of an updated Ph. Eur. TSE certificate of
		suitability for a starting material from an already
		approved manufacturer.
		Changes to a test procedure (including replacement or
		addition) for the active substance.
•	12 January 2022	Deletion of a non-significant parameter of an active
		substance in the manufacturing process of the active
		substance.
		Changes to a test procedure for the active substance.
		Changes to a test procedure for the active substance.
		Deletion of a specification parameter of the finished
		product.
•	25 June 2021	Changes to a test procedure for the finished product.
•	25 March 2020	Addition of a supplier of packaging components or
		devices.
		Deletion of a non-significant parameter of a starting
		material used in the manufacturing process of the active substance.
		Deletion of manufacturing site for an active supplier of a
		starting material.
•	17 May 2019	Change in the QPPV of an existing pharmacovigilance
		system as described in the DDPS
•	02 April 2019	Change in the QPPV of an existing pharmacovigilance
	20 October 2010	system as described in the DDPS
•	30 October 2018	Change in RMS from UK to NL.
•	30 August 2018	Update to the labelling to add the local representative.
•	17 August 2018	Change in the local representative and distributor in
		Germany