Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 43676/4000

•	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.
•	09 February 2023	Tightening of specification limits for finished products subject to Official Control Authority Batch Release.
•	20 October 2022	Tightening of specification limits for finished products subject to Official Control Authority Batch Release.
•	08 March 2022	Changes to a test procedure for a starting material.
•	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 February 2021	Renewal – UK as CMS.
•	10 March 2020	Addition of a supplier of packaging components or devices. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.
•	07 August 2019	Increase in the shelf-life of the finished product, from 12 months to 24 months
•	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 system as described in the DDPS
•	05 December 2018	Change in RMS from UK to NL.
•	17 August 2018	Change in the local representative and distributor in Germany
•	23 May 2018	Change in the address of a manufacturer used in the manufacture of the active substance. Change in the address of a manufacturer of the finished

		product, also responsible for batch release. Change in the address of the Marketing Authorisation Holder, to add 'Cesta'.
•	15 May 2018	Addition of a supplier of packaging components or devices. Addition of a supplier of packaging components or devices. Deletion of a non-significant specification parameter of an excipient. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product.
•	01 March 2018	Change in the fill volume of the finished product.
•	26 July 2017	Changes in the manufacturing process of the finished product.
•	21 March 2017	Change to the QPPV. Change to the database system outlined in the DDPS.