Veterinary Medicines Directorate

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Post Authorisation Assessments

HATCHPAK IB H120 NEO Effervescent Tablet for Oculonasal Suspension for Chickens

Vm 08327/5005

•	27 October 2024	Change in the name of the supplier of an intermediate used in the manufacture of the active substance.
•	20 October 2024	This variation was aimed to change the name and address change of this subcontractor.
•	06 December 2023	Editorial changes to part 2E of the dossier.
•	26 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	30 March 2023	To align the SPC and product information as per QRDv9 template and to change the pharmaceutical form to “Effervescent tablet for oculonasal suspension.”
•	23 November 2022	To add an alternative release test for mycoplasma detection by PCR to the existing culture technique.
•	04 April 2022	Repeat use to add 4 new CMS.
•	10 November 2021	Change to in-process tests applied during the manufacture of the finished product.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	11 June 2021	Renewal – UK as CMS.
•	28 August 2020	Change in the name of the manufacturer of the finished product.
•	22 July 2020	Change in the name of a manufacturer of the active substance.
•	19 June 2020	Increase in the shelf-life of the finished product, from 18 months to 24 months.
•	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.
•	14 August 2019	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
•	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.

•	15 August 2017	Widening of the specification limits of a starting material used in the manufacturing process of the active substance.