Veterinary Medicines Directorate

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Post Authorisation Assessments

Paracox-5, Suspension for Oral Suspension for Chickens

Vm 01708/3031

•	27 June 2024	G.I.18 update to SPC and QRD.
•	14 November 2023	To include an additional sterilization method of PET bottles used as primary packaging for a range of the applicant's vaccines and solvents.
•	10 November 2023	To increase the maximum batch size of the finished product.
•	27 July 2022	To change the approved specification limit for the pH of the solvent.
•	01 December 2021	Change in the address of a quality control testing site. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Addition to a test procedure for the finished product.
•	20 May 2021	Addition of a site where batch control/testing takes place.
•	01 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
•	14 August 2020	Replacement of a site where batch control/testing takes place.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	24 January 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	08 November 2018	Increase in the shelf-life of the finished product as packaged for sale, from 15 months to 24 months.
•	03 August 2018	Change in manufacturer of active substance. Change in quality control and batch release site. Change in manufacturing site of finished product.
•	01 May 2018	Change in RMS from UK to FR.
•	12 April 2018	Change in the SPC, labelling or package leaflet due to new data. Change in the composition (excipients) of the finished product.
•	23 June 2016	Change in the manufacturing process of the active substance.
•	06 November 2014	Change in the manufacturing process of two active substances.
•	21 August 2014	Approval of mock-ups following a minor correction and layout change. Addition of a distributor for Northern Ireland.

•	16 April 2014	Change in name and/or address details of the manufacturer of the active substance and change in name and/or address details of the manufacturer of the finished product.
•	20 January 2014	Change in the manufacturing process of the active substance.
•	17 November 2013	Change in the manufacturing process of the active substance.
•	04 August 2011	Variation to change the name of the Marketing Authorisation Holder in Portugal.
•	05 August 2010	Renewal (UK as RMS).
•	26 May 2010	Variation to change the legal category from POM-V to POM-VPS.
•	08 April 2010	Variation to change the Marketing Authorisation Holder.
•	14 August 2009	Change of name and address of the Marketing Authorisation Holder in France.
•	19 November 2008	To revise seed lot system.
•	07 December 2006	Change of name and address of the Marketing Authorisation Holder.
•	28 September 2001	Route of administration.
•	28 September 2001	Route of administration.
•	12 July 2000	Change to shelf-life.