Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Norvax Compact PD Emulsion for Injection for Atlantic Salmon

Vm 01708/3037

•	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.
•	22 December 2022	To include the MSD Animal Health site in Salamanca, Spain for quality control testing of the finished product.
•	08 September 2022	Change in the SPC and package leaflet intended to implement the outcome of a procedure concerning PSUR: implementation of wording agreed by the competent authority that does not require additional assessment and also some editorial changes in the product information.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	04 November 2019	Reduction of the shelf life of the finished product as packaged for sale from 24 months to 18 months.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	01 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	25 August 2016	Renewal – UK as CMS
•	08 December 2015	Minor change in the manufacturing process of the active substance Minor change in the manufacturing process of the active substance Minor change to an approved test procedure
•	27 November 2014	Update of the pharmacovigilance system as described in the DDPS.
•	05 March 2012	To change the name of the manufacturer of the finished product.
•	05 March 2012	To change the name of the manufacturer of the active substance.