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Post Authorisation Assessments

Norvax Compact PD Emulsion for Injection for Atlantic Salmon Vm 01708/5107

•	19 September 2023	Addition of alternative sterilisation method of the
		immediate packaging of the finished product.
•	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.