Veterinary Medicines Directorate

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Post Authorisation Assessments

AquaVac Relera Concentrate for Dip Suspension or Suspension for Injection for Rainbow Trout

Vm 01708/3048

•	07 June 2023	Change in name and address details for a manufacturer of the finished product. Change in name and address details for a manufacturer of the active substance. (NI)
•	21 December 2022	Change in name and address details for a manufacturer of the finished product. Change in name and address details for a manufacturer of the active substance.
•	22 December 2021	Changes to a test procedure for the finished product. Addition of a site where batch control/testing takes place.
•	13 July 2021	Change in distributor details. From various addresses to Same as MAH, Alternative distributor in Northern Ireland, Intervet Ireland Limited, Magna Drive, Magna Business Park, Citywest Road, Dublin 24.
•	01 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	10 June 2020	Change of MAH from Intervet International BV, Represented by: Intervet UK Ltd., Walton Manor, Walton, Milton Keynes, Bucks, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	12 December 2018	Addition of a manufacturer responsible for batch release of the finished product. Replacement of a manufacturer responsible for batch release of the finished product. Replacement of a secondary packaging site of the finished product
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	09 February 2018	Change in the RMS from UK to ES.
•	16 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	04 December 2014	Update to the DDPS.

•	06 June 2014	Renewal.
•	15 May 2014	Change in the name and address of the manufacturing authorisation holder.
•	04 August 2011	To change the name of the MAH in Portugal only from Schering-Plough II – Veterinaria Lda to Intervet Portugal – Saude Animal Lda.
•	17 June 2010	Changes to an existing pharmacovigilance system as described in the DDPS.