



## Post Authorisation Assessments

### Nytox 1000 mg/g Powder for Solution for Fish Treatment Vm 05653/4229

•	27 April 2023	Change of MAH holder from Naqua Limited, Laboratory E12, Ground Floor, East Block, Building 500 Discovery Park, Ramsgate Road, Sandwich, Kent, CT13 9ND United Kingdom to VIRBAC, 1ère avenue, 2065m LID, 06516 Carros, France.
•	13 January 2023	Change of address from Naqua Ltd, Unit 8, Starborough Farm, Starborough Road Nr, Edenbridge, Kent, TN8 5RB, United Kingdom to Naqua Ltd., Laboratory E12, Ground Floor, East Block, Building 500, Discovery Park, Ramsgate Road, Sandwich, Kent, CT13 9ND, United Kingdom.
•	11 November 2022	Renewal
•	27 July 2022	Change to batch release arrangements of the finished product. Change to quality control testing of the finished product. Deletion of a manufacturing site for an active substance. Change in the manufacturer of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
•	27 July 2022	Replacement of a primary packaging site of a non-sterile finished product. Replacement of a secondary packaging site of a non-sterile finished product.
•	27 July 2022	Replacement of the manufacturing site of the finished product.
•	12 April 2022	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	21 June 2021	Change in the address of a manufacturer of the finished product, also responsible for batch release. Change in the address of the marketing authorisation holder from Naqua Ltd, Unit 8, Starborough, Farm, Starborough Road, Nr. Edenbridge, Kent, TN8 5RB, United Kingdom to Naqua Ltd, Laboratory E12, Ground Floor, East Block, Building 500, Discovery Park, Ramsgate Road, Sandwich, Kent, CT13 9ND, United Kingdom.
•	27 February 2019	Change in RMS from UK to NO.
•	27 September 2018	Change in the name of a manufacturer of the finished product, also responsible for batch release. Change to the name of the local representative.
•	11 September 2018	Change in Distributor details. From: Neptune Pharma Ltd, Unit 8, Starborough Farm, Starborough Road, Nr

		Edenbridge, Kent, TN8 5RB to Naqua Ltd, Unit 8, Starborough Farm, Starborough Road, Nr Edenbridge, Kent, TN8 5RB.
•	06 April 2018	Change of MAH, from Neptune Pharma Ltd, Unit 8, Starborough Farm, Starborough Road, Nr. Edenbridge, Kent, TN8 5RB to NAQUA Ltd, Unit 8, Starborough Farm, Starborough Road, Nr. Edenbridge, Kent, TN8 5RB.
•	15 February 2018	Change in the address of a manufacturer of the finished product, also responsible for batch release.
•	07 December 2017	Change in the address of the marketing authorisation holder from Regus House, Victory Way, Admirals Park, Crossways, Dartford, DA2 6QD to Unit 8, Starborough Farm, Starborough Road, Nr Edenbridge, Kent, TN8 5RB.
•	24 May 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.