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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Clynav Solution for Injection for Atlantic Salmon

Vm 52127/5003

•	20 October 2023	Alignment of the product information text with version 1 of the GB and QRD template.
•	27 February 2023	To update the re-use specification of the membranes used for tangential flow filtration in the purification and concentration steps of the Clynav manufacturing process.
•	24 January 2023	Reduction of the shelf life of the finished product to 14 months.
•	12 January 2023	Addition of Lohmann Animal Health as the testing site for the residual genomic DNA (gDNA) test on the finished product. Introduction of a dual colour duplex PCR method as the test method for gDNA to be used at the proposed additional testing site.
•	12 April 2022	Renewal.
•	08 July 2021	Increase in batch size (from 100L to 220L) of the active substance used in the manufacturing process of the active substance.