Statens legemiddelverk
Norwegian Medicines Agency

To whom it may concern

Our date
2016-07-06

Office
LU/VS

GENERAL INFORMATION:
MEDICINAL PRODUCTS USED IN FISH FARMING IN NORWAY

1. Possible legal statuses for veterinary medicinal products (VMPs) in Norway

- Marketing Authorisation (MA): Following an application from the manufacturer or his authorised representative, the product is approved by the Norwegian Medicines Agency (NoMA) to be put on the market after an assessment of quality, safety and efficacy according to the national (equals EU-) requirements.

- Special Exemption (SE): permission given to individual authorised veterinarians/fish health biologists to use proprietary medicinal products without a MA in Norway. Veterinarians/fish health biologists must apply for SE to NoMA. The use of vaccines against certain diseases also requires a Use Permit from the Competent Authority regarding animal health, the Norwegian Food Safety Authority.

- Exemption from Marketing Authorisation under exceptional circumstances: Following an application from the manufacturer or his authorised representative, the Norwegian Medicines Agency (NoMA) may under exceptional circumstances grant a special permit for a product to be put on the market without an MA. Such permits may be given on the condition that the manufacturer agrees to certain commitments. They are only valid for a specified time period, but may be renewed.

- Veterinary medicinal product extemporaneously prepared: prepared in the pharmacies according to a prescription from an authorised veterinarian/fish health biologist.

- Autogenous vaccines: vaccines made for a specific fish farm, and manufactured from an isolate of a pathogen from the same farm or a geographically close farm with the same disease problem, caused by the same microorganism/serotype. Used for rare/atypical infections. Manufacturers need approval for production of each type of vaccine antigen, and only inactivated vaccines are permitted. Veterinarians/fish health biologists need permission for each requisition of such vaccines (handled via SE procedure, see above) in addition to a Use Permit from the Norwegian Food Safety Authority.

- Medicated feed: Must be manufactured by feed mills authorised by NoMA for such production. GMP required.
- **All medicinal products for fish are prescription-only-medicines (POM) in Norway**. This applies regardless of which of the above mentioned categories the medicinal product belongs to.

2. General information on legislation

There is an extended EEA agreement between EFTA countries (except Switzerland) and EU in the field of medicinal products, which means that the legislation concerning medicinal products for animals and humans is similar in Norway and EU.

All veterinary medicinal products (VMPs) used for fish treatment in Norway must be prescribed by authorised veterinarians/fish health biologists. It is mandatory that prescribers report all such prescriptions to the Competent Authority responsible for quality control of fish products, including residue control, the Norwegian Food Safety Authority. Enquiries about amounts of different medicines prescribed for Norwegian Aquaculture should be directed to this Authority (internet: www.mattilsynet.no). This Authority is also responsible for the residue control and monitoring programme.

The Norwegian legislation concerning residues of VMPs in food intended for human consumption is also similar to the EU legislation. Thus withdrawal periods are based on EU approved Maximum Residue Limits (MRLs). All pharmacologically active substances used on fish intended for human consumption must be listed in Commission Regulation (EU) No 37/2010 (Replacing Annex I, II or III of Council Regulation 2377/90) for at least one food producing species.

According to EU and Norwegian legislation, veterinarians/fish health biologists may use medicinal products holding MA for other species for the treatment of fish, and also veterinary medicinal products prepared extemporaneously, in accordance with the cascade principle of Article 11 in Directive 2001/82/EC, as amended by Directive 2004/28/EC. This provision is implemented in Norway in § 4 and § 5 of the Regulation on Use of Medicinal Products in Animals of 2007-01-16.
Use of products approved in other EEA countries in accordance with the cascade requires permission from the Norwegian Medicines Agency; a special exemption (SE), see section 1 on legal status.

The NoMA is responsible for setting withdrawal periods for VMPs holding a Norwegian marketing authorisation (MA). When products not holding MA in Norway are used, the veterinarians/fish health biologists are responsible for setting adequate withdrawal periods. The withdrawal period when using medicines *off label* for fish (according to the cascade principle) must be ≥ 500 degree days (e.g. ≥ 50 days at water temperature 10 °C), according to § 5 of the Regulation on Use of Medicinal Products in Animals of 2007-01-16. The MRL requirement stated earlier must be obeyed.

3. Vaccines and pharmaceuticals holding marketing authorisation in Norway

Lists of vaccines and pharmaceuticals holding marketing authorisation for use in fish are found in 2 separate documents.

Oslo, 06.07.2016
Section for Veterinary Medicine
Norwegian Medicines Agency