



To whom it may concern

Your date	Your reference	Our date 2010-06-21	Our reference	Office/officer LU/VS/TH
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## MEDICINAL PRODUCTS USED IN FISH FARMING IN NORWAY

### Possible legal status for veterinary medicinal products (VMPs) in Norway

- Marketing Authorisation (MA): Following an application from the manufacturer or an 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.
- Veterinary medicinal product extemporaneously prepared: prepared in the pharmacies (or feed mills with special permission for such production of medicated feed) 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. Used for rare/atypical infections. Manufacturers need approval for production of each type of vaccine (infectious agent), and veterinarians/fish health biologists need permission for each requisition of such vaccines (SE).
- Medicated feed: Must be manufactured by feed mills authorised by NoMA for such production.

### General information

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.

*Letters should be addressed to the Norwegian Medicines Authority. Please state our reference.*

All 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 concerning pharmaceuticals 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](http://www.mattilsynet.no)). This Authority is also responsible for the residue control 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 the Regulation on Use of Medicinal Products in Animals of 2007-01-16 §4. Use of products approved in other EEA countries in accordance with the cascade requires a special permission from the Norwegian Medicines Agency (SE).

The NoMA is responsible for setting withdrawal periods for VMPs holding a Norwegian MA. When products not holding MA in Norway are used, the veterinarians/fish health biologists are responsible for setting withdrawal periods. The withdrawal period when using medicines *off label* for fish (according to the cascade) must be  $\geq 500$  degree days (e.g.  $\geq 50$  days at water temperature 10 °C). The MRL requirement stated earlier must be obeyed.

### **Vaccines and chemical substances used in Norwegian fish farming - general**

The following medicinal substances and vaccines are/may be used in Norway, either having a MA, being used on SE, or being used as extemporaneously manufactured preparations, autogenous vaccines or medicated feed<sup>1</sup>:

#### Inactivated vaccines containing one or more of the following antigens:

*Aeromonas salmonicida* var *salmonicida* (Furunculosis)

*Aeromonas salmonicida* var *achromogenes* (Atypical furunculosis)

*Vibrio salmonicida* (Cold water vibriosis)

*Listonella anguillarum* (former *Vibrio anguillarum*) serotype O1, O2<sub>α</sub> and O2<sub>β</sub> (Classical vibriosis)

*Moritella viscosa* (former *Vibrio viscosus*) (Winter sore disease/wound disease)

*Francisella* sp. (Francisellosis, only used for cod and saithe)

*Yersinia ruckeri* (Enteric red mouth disease)

*Flavobacterium* sp. (Flavobacterium infection)

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<sup>1</sup> In special cases other medicinal products may be used, in accordance with the cascade.

*Infectious Pancreas Necrosis Virus* (Infectious pancreas necrosis)

*Pancreas Disease Virus* (Pancreas disease)

*Infectious salmon anaemia virus* (Infectious salmon anaemia, site specific use permit required)

Antibacterials containing the active substances:

Oxolinic acid

Flumequine

Florfenicol

Sulphadiazine/trimethoprim

Oxytetracycline

Lincomycin/spectinomycin

Ectoparasiticidals (sea lice treatment) containing the active substances:

Cypermethrine

Deltamethrine

Emamectin

Diflubenzuron

Teflubenzuron

Azamethiphos

Hydrogen peroxide

Endoparasiticidals (tapeworm treatment) containing the active substances:

Praziquantel

Fenbendazole

Anaesthetics containing the active substances:

Benzocaine

Tricaine (= metacaine)

Medicinal disinfectants (for eggs/fry) containing the active substances:

Bronopol

Formaldehyde

Hydrogen peroxide

Iodine (Iodophors)

Chloramine

Hormonal treatment (for synchronisation/spawning induction) containing the active substance:

Azagly-nafarelin

Salmon Gonadotropin Releasing Hormon analogue

Sincerely,

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