DG ENTREPRISE
Mr. Martin TERBERGER, Head of Unit
F/2 – Pharmaceuticals
European Commission
B-1049 Brussels
Belgium

Liège, 20th November 2009

Dear Sirs

Concerns: Availability of Veterinary Medicines for Farmed Fish in the EU.

European fish farming produces nearly 700,000 tonnes of marine and freshwater fish per year, primarily for human consumption. Neighbouring countries, including Norway, Turkey and the Faroe Islands, which export to the EU, bring the total farmed fish production in the European region to some 1,300,000 tonnes per year. Fish farming is therefore a very large and important sector of the European food economy and one on which the EU relies to meet the fish supply needs of its population.

On several occasions during the last decade, the Federation of European Aquaculture Producers (FEAP) has called attention to the fact that the availability of veterinary medicines to fish farmers in the EU is insufficient to meet the industry's needs. The health and welfare of millions of fish are thus potentially placed at risk. This point has been highlighted, most recently in a FEAP Resolution in December 2007 and in a position paper sent to the ACFA Working Group II[1] in May 2008.

We consider that the availability of veterinary medicines is not improving and may in fact be getting worse, with the list of fish species and fish diseases that cannot be treated satisfactorily becoming longer all the time. We are so concerned about this problem that we are writing to you to raise salient points of which you should be made aware. We believe these points indicate the need for priority action by the Community and/or individual Member States. We also consider that the unsatisfactory position of the fish farming sector must be considered within the scope of the EU Review of Veterinary Medicine Legislation 2010. In short, our view is that the present very unsatisfactory situation must be addressed with urgency.

During the last year, FEAP members and fish veterinarians (Vets) from different FEAP member countries have gathered practical examples of problems that are being experienced in most of the Member States**.** These fundamentally relate to the lack of specific veterinary medicines (VM), although in some cases that position is exacerbated by the application or interpretation of the current EU veterinary medicines legislation. Particular points we would like to highlight are set out below.

[1] Advisory Committee for Fisheries and Aquaculture, Working Group II on Aquaculture

Overview of Position in Regard to Fish Veterinary Medicines

Our overview of the present position in regard to fish medicines can be summarised as follows:

1. There is a total lack of specific VM that have a market authorization (MA) to treat numerous conditions in many of the non-salmonid fish species that are farmed in the EU. These include species such as sturgeon, perch, cod, char, turbot, and sole.

2. The number of *antibiotic* medicines available with a MA to treat bacterial fish diseases in many countries is very restricted. There are 4 approved active substances in Spain, Finland and France; 3 in the UK; 2 in Ireland and Denmark; 1 in Hungary; and none at all in the Netherlands. Most of these medicines were originally designed for terrestrial animals and are not optimised for uptake and therapeutic effect in fish.

3. There is a lack of VM with MA for treatment of many fresh-water and sea-water *parasitic and fungal* conditions affecting farmed fish. Examples include treatments for *Argulus* sp., *Ichthyophthirius multifiliis* (white spot), *Cryptocaryon irritans*, *Saprolegnia* sp., *Tetracapsula bryosalmonae* (proliferative kidney disease), gill amoebae, monogeneans infections (both in marine and freshwater fish), *Uronema* sp. and other internal ciliates.

4. There is a lack of *anaesthetics and/or sedatives* with a MA for fish in most Member States. It is therefore difficult completely to ensure the welfare of the fish, as requested by the Council of Europe in some of its specific recommendations. As specific examples:
   - In most EU-countries e.g. Denmark, Italy and France, no anaesthetics are registered for use in any farmed fish and/or in any farming situation.
   - There is no anaesthetic available in any Member State that is appropriate for the harvest of "caviar" from live fish (i.e. eggs for human consumption).
   - In Italy a temporary license can be obtained for importation of a limited quantity of MS222 from UK (where it has a MA). But MS222 can only be used during injection vaccination of rainbow trout and not in procedures such as the stripping of eggs from broodstock or fish transport.

5. Because the limited range of products available, treatment of some bacterial and parasitic conditions (e.g. furunculosis, yersiniosis and sea lice) has needed to be made with the same few drugs for many years and this leads to the development of drug resistance. For example, in Spain there is reported antibiotic resistance in *Vibrio sp.* and *Photobacterium damselae*; in France, resistance to five antibiotics has sometimes been observed been with *Yersinia ruckerii*; in Scotland and Norway there are indications of sea lice resistance to a number of products. These problems further reduce the range of VM available for fish vets and farmers.

6. Some authorized VM available will shortly disappear from the market because pharmaceutical companies are going to stop their production or distribution in a member state. This is about to happen with oxolinic acid and with anti-yersiniosis immersion vaccine in France.

7. In other cases, the pharmaceutical companies are delaying the introduction of a VM product because they consider there is insufficient market return to justify the cost of introduction to the EU/Member State market. This has been the case several times in France with regard to new vaccines and in Italy with antibiotics.

8. Where no VM exists, substances with biocide activity such as formaldehyde, hydrogen peroxide, chloramine T, copper sulphate, and others have been widely used in fish treatment, in some cases for decades. According to the current EU legislation this use is only allowed according to the cascade system of VM prescription (see below) or as a water disinfectant under the biocide legislation. Use of these substances is inconsistently regulated in different EU Member States, and there would be benefit from simpler legislation facilitating a more consistent approach.

9. Finally, the availability of VM is also threatened by the lack of flexibility in interpretation environmental impact under Directive 2006/11/EC and the "Water Framework" Directive 2000/60/EC). This has caused problems for the fish farming industry in most Member States, which are disproportionate to the environmental risk posed by the industry.

Regulation of Hormone Treatments

Hormones treatments are necessary in aquaculture in a few specific circumstances and are approved under EU legislation. However, despite that, use is prevented in some Member States. Thus, Directive 96/22/EF Article 5, allows fish in the first three months of life to be treated with androgenic products to achieve sex inversion but there a lack of harmonisation of this approval between Member States; for example, use of the treatments is fully approved in Denmark and France, but is not permitted in Italy. We should note, for clarity that hormone treatment is only used for breeding purpose and no treated fish are entering the food chain.

Regulation of Premix Medicines

The legislation applying to the mixing of premix medicines in feeds often leads to excessive delays and can create problems for the aquaculture industry. Most small hatcheries cannot obtain quickly the small quantities of medicated feed they require - often less than one kg. Most fish feed retailers are unable commercially to prepare and deliver such small quantities. At the same time, the cost of an on-farm mixing licences is very high and totally disproportionate to the very small food safety risk associated to such practices. .

Use of the Cascade System: Consequences of EU Legislation

Due to the lack of VM with MA, where no specific treatment is available, vets – as their only solution – have to use the **'**cascade system**',** as set out under Directive 2004/28/EC, Article 11. However, this raises a number of problematic issues related to the wording of the Directive and its inconsistent interpretation by Member States or to related administrative procedures controlling the use of medicines under the cascade system. We can summarise the problems in these areas as follows.

1. Under the Directive a veterinary medicinal product authorised in the Member State *'for use with another animal species, or for another condition in the same species'* should be used before *'a veterinary medicinal product authorised in another Member State'.* In practice this leads to consequences that are wholly illogical, for example:

- In Italy, a porcine (swine) medicine (Nuflor) must be used instead of the product (Aquaflor) which is made specifically for the treatment of fish but which has a MA for fish in another Member State. Both products contain florfenicol as active substance but at different concentrations to meet the

requirements of their target species (4 % active ingredient in porcine medicine and 50 % in fish medicine).

- For some 'cascaded' VM the concentration of the active substance may be too low where fish feed consumption is reduced as a result of environmental or physiological factors. In France, for example, the treatment of lactococcosis in rainbow trout in late summer (where the high temperature reduces appetite) can be problematic since active substance levels in the VM approved under the cascade are too low to comply with a good feed mixing practice. However, the Agence Nationale du Médicament Vétérinaire has refused to allow the importation of an adequately concentrated premix from Italy because another VM with the same active substance has a MA in France and therefore must be used, despite its technical inadequacy.

2) The Directive requires that when using the cascade system to treat a fish species for which no VM has an MA*, the vet has to set a minimum withdrawal period of 500 degree-days*. However, this applies even where the active substance is authorized for other fish species and has a much shorter withdrawal period or where it is used in an extemporaneously prepared VM classified in Annex II of the MLR regulation. This requirement therefore reduces the availability of convenient treatments for fish which are closer than 500 days to harvest.

3) In the case of '*a veterinary medicinal product authorised in another Member State'*, aquaculture producers often face problems due to the slowness and constraining nature of the administrative procedures allowing the use of an imported VM. For example:
   - In Denmark, France, Spain and Italy, vets are allowed to use "*veterinary medicinal products authorized in another Member State*" only after obtaining a permit from the authorities. This can often take weeks or even months and the fish stock may be compromised or dead by the time approval is granted.
   - There are also cases where Member States may grant of 'emergency licenses' for some products, but the approval procedures are very extended and the licences are temporary, for only 3 – 12 months, and specific for a stated quantity of product and a named place of use.
   - Understandably, pharmaceutical companies find it difficult to justify the cost of meeting complex administrative burdens to import a product into a country where there will only be a small market, and this acts as a barrier to VM availability. As an example, in France there are neither anaesthetics with a MA for fish, nor anaesthetics '*authorised for use with another animal species'* but suitable for fish. Thus, French vets need to import an anaesthetic with a MA for fish from another Member State or from Norway (EEA). However, authorisation of such an import can only be granted to a pharmaceutical company which is prepared to follow the administratively demanding the rules of the ANMV which came into force 1 February, 2008.

Further Points

The aquaculture industry and the industry vets, based on their experience, also wish to highlight three further points:

1. The procedures to obtain autologous vaccines should be simplified since autologous vaccines are very difficult to apply given the bureaucratic procedures adopted in several Member States. As specific examples:

- In Italy and France, the use of autologous vaccine is restricted to the farm in which the causative agent was isolated.
- In Italy, the process to obtain the official authorization to produce a new autologous vaccine takes more than one year.
- The minimum period between t a fish vet requesting use of an autologous vaccine and the authorisation its use is unreasonably long – as illustration, 5 weeks in France and 8 weeks in Italy.

2. The on-farm storage of small quantities of VM (for example antibiotic premix for feeds) is often useful, in dealing with 'emergency' fish health problems. However, is not allowed in some Member States or Member State regions, preventing the VM being quickly unavailable when required. There are examples in Denmark, France and Spain, where medicated feed cannot be delivered to the farm for 5-8 days after a prescription has been issued. As a result the disease develops in the affected fish, appetite falls and treatment becomes more difficult. This can lead to higher mortality rates and also may increases the risk of developing antibiotic resistance.

3. In order to implement the cascade principle (Directive 2001/82/CEE, as modified by Directive 2004/28/CE, Art.11.1.b.ii), fish vets need access to a complete database listing all VM for food producing animals registered in Member States of the European Economic Area. As far as we are aware, no official list of this type is currently available. FEAP has recently compiled its own list of fish VM with MA in individual Member States, and we have enclosed this for your information.

Request to the Commission

We have outlined above a range of areas where we are concerned about the practical availability of VM products for the treatment of farmed fish, and we ask the EU Commission to take action to address the issues we have raised as matters of priority.

We believe that there will be opportunity to do this within the framework of the review of the Veterinary Medicines Legislation of 2010, and we would urge that the scope of that review be expanded accordingly.

Additionally, we believe it would be a good starting point for the Commission to arrange a workshop at which it could bring together representatives of the fish farming industry, fish vets, pharmaceutical industry and, most important, representatives from the competent authorities in the Member States. FEAP members would strongly support and welcome such a meeting, taking place in the early part of 2010.

Yours sincerely

Courtney Hough
General Secretary

Copy: DG SANCO, Mr. A. LADDOMADA, Head of Unit D/1 - Animal health & Standing Committees,
DG SANCO, Mr. A. GAVINELLI, Head of Unit D/5 - Animal welfare,
DG MARE, Mr. JC. CUEFF, Head of Unit A/2 - Common Fisheries Policy & Aquaculture.