FEDERATION OF EUROPEAN AQUACULTURE PRODUCERS

Position Paper

December 2024

On Availability of Veterinary Medicines

Background

The principles on which FEAP considers the use of antibiotics and other drugs in fish farming are firmly focused on limiting the onset of antimicrobial resistance[1] and implementing sound management practices in fish disease management. Moreover, all possible biosecurity and prevention systems (e.g., vaccines) are needed to maximize disease control without resorting to therapy. It should be strictly used in a targeted and effective way whenever therapy is required. This is why appropriate and effective active ingredients/antibiotics are needed.

FEAP has welcomed the innovations introduced by the reform of the legislation framework on the matter through Regulation 2019/4 on the manufacture, placing on the market and use of medicated feed[2], Regulation 2019/6 on veterinary medicinal products[3], and all the subsequent implementing acts such as the "Oral Medication Act" (Commission Delegated Regulation 2024/1159 supplementing Regulation 2019/6 by laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals[4]). The main innovations are the following:

a) The theoretical opening of a single market for veterinary drugs for aquatic animals considered Minor Use and Minor Species (MUMS).

b) The activation in this sense of a new formula of the "cascade principle" for aquatic animals (see art. 114 of Regulation 2019/6).

c) The development of a list of drugs for terrestrial animals to be used in aquaculture, which should in fact increase the availability within the EU of drugs used responsibly and where necessary (see again art. 114 of Regulation 2019/6).

d) The possibility of "on-farm mixing" in the cases specified by the legislation (art. 6 Regulation EU 2024/1159).

[1] FEAP Position paper on Antimicrobial resistance: https://feap.info/wp-content/uploads/2022/01/220118-feap-position-paper_amr.pdf
[2] Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0004
[3] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0006
[4] Commission Delegated Regulation (EU) 2024/1159 of 7 February 2024 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401159&qid=1730630266776

Avenue des Arts 56, 1000 Brussels (Belgium) | Tel. : +32 4 3382995 | secretariat@feap.info

Justification

However, the availability of veterinary medicines for farmed fish remains a problem, creating difficulties in controlling fish diseases, not solving the problem related to "orphan drugs," and negatively affecting the desired level playing field, not only with third countries but also within the EU. Ultimately, this situation reduces the health and welfare of farmed fish..

Specifically, the problematic situations are the following:

1) The impossibility of using a particular drug due to import restrictions by some Member States because of different implementations of EU regulations.
2) Failure to recognise (uniformly) national registrations of drugs in other Member States in the face of a costly and complex centralised recognition procedure (EMA)
3) A reduced market due to the size of the EU fish farming sector.
4) The impossibility of using drugs authorized for terrestrial animals due to technological problems (e.g. difficulty of mixing drugs for oral use in fish medications) or because of bureaucratic issues related to the application of more restrictive national rules (e.g. in the possibility of using on-farm mixing).

Initiatives

FEAP has collected examples of bottlenecks that fish farmers and veterinarians face in their daily practice. This often determines the impossibility of carrying out effective vaccination prevention or therapy, creating at the same time important differences in the opportunities to control the onset of diseases and, therefore, ensure the health of farmed fish.

Examples of this situation are the following:

1. Difficulties in the free circulation of veterinary medicinal products in aquaculture between Member States: in contrast with the provisions of point 1.a) of art. 114 of EU Reg. 2019/6, due to restrictive application of free circulation:

- In some cases, an authorization procedure is required that also takes into account environmental aspects (in reality an aspect envisaged only in the case of the application of point 1.b) of the application of the cascade principle (use of medicinal products authorized for terrestrial animals) making the use of antibiotics but also of vaccinations very complex;
- In other cases, the use of veterinary medicinal products used in other Member States is practically prohibited;
- It is almost impossible, except in some rare exceptions, to use veterinary drugs authorized in the EFTA countries in the EU.

2. The on-farm mixing provided for pursuant to art. 6 of the EU Regulation EU 2024/1159 is permitted in some member states while in others it is prohibited.

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These examples draw attention to the lack of uniformity in implementing EU regulations and the restrictive application of the same by the Member States, which create significant problems for fish farmers and veterinarians. Furthermore, they cause disturbances to the management of fish health and welfare as well as to the market.

FEAP, December 2024

The Federation of European Aquaculture Producers is an organisation that represents the European fish farming profession and is based in Brussels. FEAP is composed of 24 national fish farming associations from 23 countries, both EU and non-EU. The combined yearly production of FEAP members surpasses 2,5 million tonnes of nutritious, safe, delicious and environmentally sustainable fish.

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