AAC Recommendation on the Real Impact of the Medicated Feed Regulation and its Implementation in the EU Member States

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I. Background

The EU aquaculture sector is being significantly impacted by new veterinary medicine legislation. This specifically includes Regulation 2019/4 (medicated feed) and Regulation 2019/6 (veterinary medicinal products), and it is especially relevant concerning their implementation rules (implementing and delegated acts).

The aquaculture sector is committed to supporting One Health and antimicrobial resistance (AMR) policies by reducing antimicrobial use. They have done so by prioritising preventative measures, such as good nutrition, effective management, enhanced biosecurity and vaccination. These practices have successfully reduced the overall need for antimicrobials.

Despite this positive trend, veterinary treatment is occasionally necessary to preserve fish health and welfare. Crucially, due to welfare concerns, it is impractical and unsuitable to treat each fish individually. Oral group treatment with medicated feed thus remains the essential and standard method for delivering antimicrobials in aquaculture.

The sector requires that the implementation rules provide safe and operational measures that accommodate this necessary group treatment practice. This will ensure that farmers can maintain fish health while complying with the legislation.

Accordingly, there is certain legislation that helps cover certain crucial issues related to the availability of adequate therapies for aquatic animals. This includes:

- the Commission Delegated Regulation 2024/1159 'Oral Medication Act' and
- the Scientific advice adopted by the European Medicines Agency (EMA) in May 2025, issued under Article 114(3) of Regulation (EU) 2019/6, which supports the process of defining the list of substances used in veterinary medicinal products that are authorised in the EU for use in food-producing terrestrial animal species. These products may be used in food-producing aquatic species in accordance with Article 114(1).

The EU's regulatory framework for veterinary medicines introduces several significant changes that are intended to improve the availability and responsible use of drugs in aquaculture. These features primarily aim to address the traditional difficulty of obtaining authorised treatments for **minor use and minor species (MUMS)** in the aquatic sector:

- **Single market for MUMS:** This framework establishes a **single EU market** for veterinary drugs that are specifically for aquatic animals that are considered MUMS. This simplifies access across the Member States.
- **Increased availability via terrestrial drugs:** New provisions allow for the drafting of a list of **drugs that are authorised for terrestrial animals** and that can also be used in aquaculture. This is expected to **increase the overall availability** of necessary treatments within the EU, provided they are used responsibly.
- **New 'cascade principle' formula:** This legislation, specifically including **Article 114 of Regulation 2019/6,** activates a revised **'cascade principle'** for aquatic animals. This principle allows veterinarians to use an unauthorised medicine legally when no

authorised product exists. This prioritises animal health and welfare.

- **'On-farm mixing':** The framework introduces the **possibility of 'on-farm mixing'** of veterinary medicines and feeds, as specified by **Article 6 of Regulation EU 2024/1159**. This allows for greater flexibility in preparing medicated feeds under controlled circumstances.

II. Justification

Despite the regulatory framework outlined above, the availability of veterinary medicines for farmed fish remains a problem that has a significant impact on the health and welfare of farmed fish.

An in-depth survey of members of the Aquaculture Advisory Council revealed the main critical issues that are summarised below.

- The impossibility of using a Veterinary Medicinal Product (VMP) that is suitable for the therapy and available in one Member State but faces import restrictions in other Member States due to different implementations of EU regulations.
- The failure to uniformly recognise national registrations of drugs in other Member States in the face of a costly and complex centralised recognition procedure (EMA).
- A reduced market due to the size of the EU's fish farming sector and the consequent lack of convenience for the pharmaceutical industry to invest in a restricted market.
- The impossibility of using VMPs that are authorised for terrestrial animals due to technological problems (e.g., the difficulty of mixing drugs for oral use in fish medications) or due to bureaucratic issues regarding the application of more restrictive national rules (e.g., the possibility of using on-farm mixing).
- Difficulty in the diffusion of vaccination practices that are developed ad hoc (e.g., the use of stabulogenic/autologous vaccines). This is due to different interpretations of the legislation regarding their strategic importance and also to reduce AMR. Additionally, 'cascade principle' (Article 114 of Regulation (EU) 6/2019) is not completely applicable to vaccines in the same manner as other VMPs.
- The 'on-farm mixing' allowed at the EU level by Regulation (EU) 1159/2024 in many Member States is limited, opposed or prohibited by national regulations.
- There are also specific problems in the different Member States due to different interpretations of prescription timing, the use of drugs outside the authorisation terms and the application of the 'cascade principle' in certain classes of VMPs, such as vaccines.

III. Recommendations

AAC recommendations:

To the European Commission

1. Address the critical issues that are mentioned above in this document. It is particularly important to ensure that Member States meet application procedures that are capable of truly expressing the potential envisioned by the current regulatory framework.
2. Define criteria and guidelines that can be implemented by Member States, thus overcoming the obstacles that are created in certain cases by the limited market.
3. Promote the exchange of best practices and procedures for the application of the 'cascade principle'. This includes the possibility of importing drugs and medicated feed from one country to another in the event of local unavailability.
4. With guidelines, better define the application of Article 6 of Regulation (EU) 1159/2024 regarding 'on-farm mixing'.
5. Follow up and complete the standardisation regarding the definition of the list of substances used in veterinary medicinal products authorised in the EU for use in food-producing terrestrial animal species. This list also covers substances contained in medicinal products for human use authorised in the EU, which may be used for food-producing aquatic species in accordance with Article 114(1) of EU Reg. 6/2019.

To the EU Member States

1. Address the critical issues mentioned above in this document. Open a dialogue with industry operators to identify, at the national level, the specific critical issues that are caused by the limited market and the farming of minor species.
2. Harmonise the implementation of the EU framework regarding VMPs and medicated feed with national frameworks, thus avoiding conflicts and/or overlaps between different regulations.

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