EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR MARITIME AFFAIRS AND FISHERIES

The Director-General

Brussels,
MARE.A.2/BVT

Subject: AAC Recommendation on the real impact of the medicated feed Regulation and its implementation in the EU Member States

Dear Mr Brian Thomsen,

I would like to thank you for your mail of 30th October 2025 including the "*Recommendation on the real impact of the medicated feed Regulation and its implementation in the EU Member States"*.

We observe that its content mainly concerns the implementation of Regulation (EU) 2019/6 on veterinary medicinal products (the VMP Regulation hereinafter). It is important also to note that the EU legal framework on VMPs includes a wide range of tailored provisions that recognise the specific characteristics of the aquaculture sector. After consulting the relevant Commission services, please find below some feedback regarding the recommendations for the European Commission.

- *Address the critical issues that are mentioned in the 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.*
  One of the main objectives of the VMP Regulation is to enhance the functioning of the internal market and increase the availability of VMPs. In this respect, it establishes various procedures ([1]) enabling that marketing authorisations granted in one Member State (MS) are recognised by other MSs. The implementation of these procedures falls under the competence of the MSs. Therefore, we would invite you to identify specific aspects or elements linked to such implementation that would prevent the achievement of the overall objectives of the VMP Regulation. Those cases could be shared with Member State authorities in the context of the interested parties' meetings of the Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv).

([1]) Chapter III of the Regulation (EU) 2019/6: Decentralised procedure, Mutual recognition procedure and subsequent recognition in the mutual recognition and decentralised marketing authorisation procedure.

Mr. Brian Thomsen
Chairman of the AAC
Email : brian@danskakvakultur.dk
Rue de la Science, 10
B – 1000 Brussels
Belgium

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: J-99 05/014 - Tel. direct line +32 229-50483

charlina.vitcheva@ec.europa.eu

- *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.*
  The VMP Regulation recognises VMPs for food-producing aquatic species as a limited market. The VMP Regulation, being directly applicable in Member States, establishes a unified framework that minimises possible discrepancies in national implementation, thereby facilitating a consistent and harmonised approach across the EU.
  Furthermore, the European Medicines Agency (EMA) conducts the assessment to qualify products as eligible for limited markets, ensuring a fully harmonised approach at the EU level. For further information, the limited markets section of the EMA's website ([2]) provides detailed guidance and the latest updates.
- *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.*

  The VMP Regulation provides for clear and harmonised conditions under which VMPs can be used outside the terms of the marketing authorisation. However, by virtue of Article 106(3) of the VMP Regulation, Member States may lay down procedures for the implementation of Articles 110 to 114 and 116. Therefore, in view of the possible specificities at Member State level on the practical implementation of the cascade provisions, the development of specific guidance is most effectively carried out at national level. Such development may benefit from the close cooperation between national competent authorities, the veterinary profession and stakeholders, including representatives from the aquaculture sector. In this context, it may be useful to consult the *FVE Leaflet on the cascade use for veterinarians* ([3]).

  The Commission is not aware of substantial unclarities as regards import conditions. If specific difficulties are encountered, the need for further clarification can be discussed with the MSs.

- *With guidelines, better define the application of Article 6 of Regulation (EU) 1159/2024 regarding 'on-farm mixing'.*

  When drafting Commission Delegated Regulation (EU) 2024/1159, the unique needs of the aquaculture sector, as well as the various geographical regions and production systems within the Union were carefully considered by the Commission and the MSs. In that context, it was concluded that the MSs are the best positioned to develop guidelines on good practices addressing the needs of their aquaculture sectors.

- *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.*

  As per Article 114(3), the Commission is currently working with the MSs to establish a list of substances contained in medicinal products authorised for food-producing terrestrial animals or humans that may be used in food-producing aquatic species under Article 114(1). The availability or lack thereof of medicinal products for aquatic species is being considered for the establishment of that list. Stakeholders will

([2]) https://www.ema.europa.eu/en/veterinary-regulatory-overview/research-development-veterinary-medicines/veterinary-limited-markets

([3]) https://fve.org/publications/the-updated-fve-leaflet-enhances-clarity-in-veterinary-cascade-regulation/

have the opportunity to provide their views on the draft implementing act establishing that list during a public consultation via the Commission Better Regulation portal ([4]).

Finally, please note the following remarks on some of the elements mentioned in your document:

- Single market for MUMS (Minor Use Minor Species): "This framework establishes *a single EU market for veterinary drugs* that are specifically for aquatic animals that are considered MUMS*" (emphasis added)*.
  While the VMP Regulation provides for a single legal framework, the market is not entirely unified. Unless a marketing authorisation is granted by the European Commission under the centralised procedure, national authorisations under Article 23 of the VMP Regulation are only valid in the relevant Member States.
- '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* (emphasis added).

  Please note that Regulation (EU) 2024/1159 specifically applies to VMPs administered orally via mixing into or adding onto feed and to the mixing of VMPs in drinking water or in liquid feed by the animal keeper. It does not apply to the mixing of VMPs into feed by feed business operators with a view to produce medicated feed, whether they operate in a feed mill, with a mobile mixer or an on-farm mixer. These activities are covered by Regulation (EU) 2019/4 on medicated feed.

- Use of vaccines under the cascade: *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*** (emphasis added).

  As it is the case for all animal species, vaccines having a marketing authorisation granted in accordance with the VMP Regulation may be used in food-producing aquatic species under Article 114.

  Furthermore, under Article 116 of the VMP Regulation, MSs may allow the use of VMPs, including vaccines, that are authorised by another MS where the health situation so requires.

  Article 110 of the VMP Regulation allows MSs to use vaccines not authorised within the Union in line with the relevant provisions in paragraphs 2, 3 and 4 of that article.

I am looking forward to our continued fruitful cooperation. Should you have further questions on this reply, please contact Ms Julia RUBECK, coordinator of the Advisory Councils (Julia.Rubeck@ec.europa.eu ; +32.2.296.88.89), who will forward them to relevant colleagues.

Yours sincerely, Charlina Vitcheva

c.c.: Cynthia Benites: Cynthia.benites@aac-europe.org ; secretariat@aac-europe.org;

([4]) https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives_en