Regulation (EU) 2019/6 on veterinary medicinal products

Aquaculture Advisory Council

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Delegated Act on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via other routes than medicated feed.

background

Legal provision: article 106 (6)

The Commission shall adopt delegated acts in accordance with Article 147, in order to supplement this Article, as necessary, which establish the 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, such as mixing of water for drinking with a veterinary medicinal product or as manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food-producing animals. The Commission shall take into account the scientific advice of the Agency, when adopting those delegated acts.

Article 147 (2):

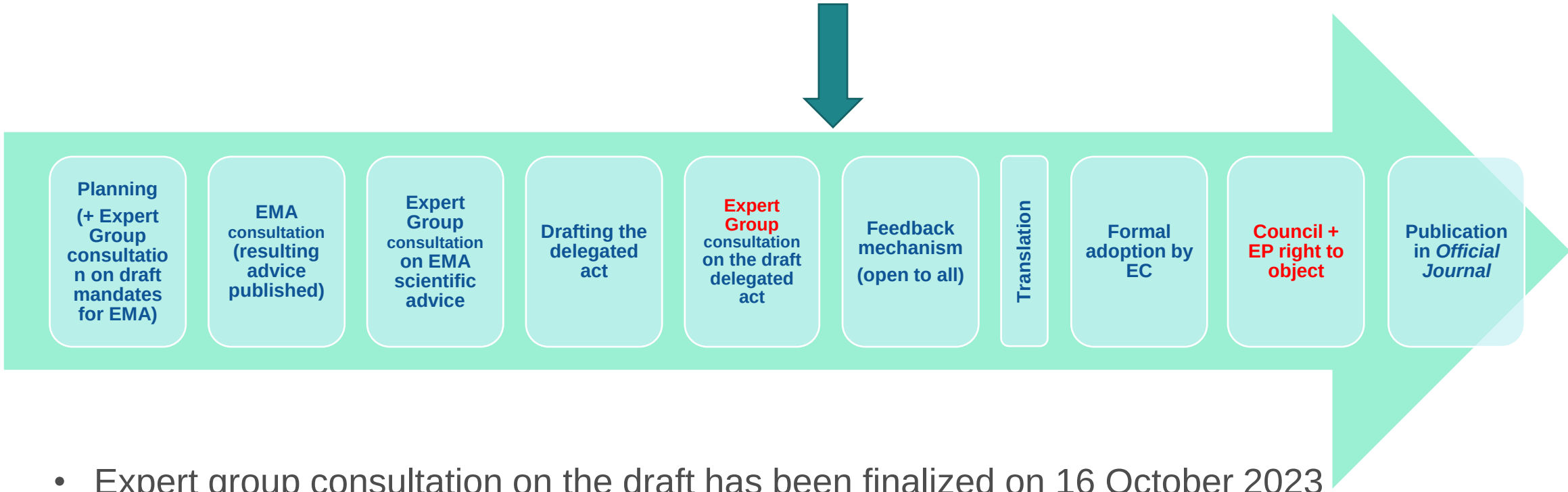
The power to adopt delegated acts referred to in Articles 37(4), 57(3), 106(6), 109(1), 115(3), 118(2), 136(7) and 146(1) and (2) shall be conferred on the Commission for a period of five years from 27 January 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for the periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

background

Recital 14

To ensure the proper administration and appropriate dosing of certain veterinary medicinal products which are to be administered orally in feed or drinking water to animals, especially in the case of treatment of groups of animals, such administration should be properly described in the product information. Additional instructions for cleaning the equipment used for administration of those products should be set out to avoid cross-contamination and reduce antimicrobial resistance. In order to improve the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed, such as mixing of water for drinking with a veterinary medicinal product or manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food-producing animals, the Commission should, where necessary, adopt delegated acts. The Commission should take into account scientific recommendations of the European Medicines Agency, established by Regulation (EC) No 726/2004 ('the Agency'), for example concerning measures to minimise over-dosage or under-dosage, unintended administration to non-target animals, the risk of cross-contamination and dissemination of those products in the environment.

State of play



- Expert group consultation on the draft has been finalized on 16 October 2023
- Intra-santé consultation is ongoing

European Commission

Use of medicinal products outside the terms of the marketing authorisation in food-producing aquatic species

Use of VMPs outside the terms of the MA

Article 114

where there is **no authorised veterinary medicinal product** in a Member State for an indication concerning a food-producing aquatic species, the veterinarian may, under his or her direct personal responsibility, and in particular **to avoid causing unacceptable suffering**, treat the animals concerned with:

STEP 1 : a VMP authorised in the Member State or another Member State for use in the same or in another food-producing aquatic species for the same or another indication

STEP 2: a VMP authorised in the Member State or another Member State for use with a food-producing teresterial species

STEP 3: a Medicinal product authorised for human use

STEP 4: an extemporaneously prepared VMP

Use of VMPs outside the terms of the MA

Article 106(3)

Member States may lay down any procedures they deem necessary for the implementation of Articles 110 to 114 and 116.

Article 107(6)

The Commission may, by means of implementing acts, and taking into consideration scientific advice of the Agency, establish a list of antimicrobials which:

(a) Shall not be used in accordance with Articles 112, 113 and 114; or

(b) Shall only be used in accordance with Articles 112, 113 and 114 subject to certain conditions

Use of VMPs outside the terms of the MA

Article 107(7)

A Member States may further restrict or prohibit the use of certain antimicrobials in animals on its territory if the administration of such antimicrobials to animals is contrary to the implementation of a national policy on prudent use of antimicrobials

Article 114(3)

The Commission shall, by means of implementing acts, at the latest within five years from 28 January 2022, establish a list of substances used in veterinary medicinal products authorised in the Union for use in food-producing terrestrial animal species or substances contained in a medicinal product for human use authorised in the Union in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004, which may be used in food-producing aquatic species in accordance with paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

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Thank you

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