EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director General

Brussels,
SANTE/E5/JS/NZ/mcd ares (2019) 4599820
Sent by e-mail only

Dear Prof Rasi,

Subject: Implementing measures under Article 37(5) of Regulation (EU) 2019/6 on veterinary medicinal products[1] as regards the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans

On 7th January 2019, the new Regulation on veterinary medicinal products ('VMP Regulation') was published.

In accordance with its Article 160, it will start applying 3 years from its entry into force, i.e. on 28th January 2022.

The Commission strongly supports the fight against antimicrobial resistance (AMR) in the EU and at global level. The misuse or overuse of antimicrobials in a veterinary setting can create an important source of antimicrobial resistant bacteria that can spread to humans through various channels. For this reason, improving the management of the use of antimicrobials in animals is paramount, in particular managing the use of those antimicrobials, which are essential for human medicine in order to help preserve the efficacy of those antimicrobials for people.

In this setting, a cornerstone of the new VMP Regulation is that the use of certain antimicrobials will be reserved for the treatment of certain infections in humans, thereby excluding their use in a veterinary context (Article 37(3); Article 107(5)).

The list of these antimicrobials or groups of antimicrobials will be laid down by the Commission through implementing acts (Article 37(5)), based on specific criteria, which will be defined in delegated acts to be adopted by the Commission (Article 37(4)) and on which the Agency was already asked on 6 February 2019 to provide advice (Ref. Ares(2019)688882).

[1] 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, OJ L 4, 7.1.2019, p. 43.

Prof Guido Rasi
Executive Director
European Medicines Agency
PO Box 71010
1008 BA Amsterdam
The Netherlands

In this context, I would ask you to provide us with the Agency's scientific recommendations on the content of such a list of antimicrobials to be reserved for human medicine, taking due account of the requirements under Article 37(4) and the work of the Agency's expert working group preparing the related advice on the criteria to establish that list. I would also invite you to bear in mind that in accordance with Articles 37(5) and 152(1), both antimicrobials for which a marketing authorisation has already been granted and antimicrobials for which no marketing authorisation has yet been granted (including new antimicrobials or groups of antimicrobials remaining to be identified or developed in the future) may be subject to evaluation under the criteria which will be established under the relevant delegated acts (Article 37(4)).

You may note that the antimicrobials or groups of antimicrobials that will figure on that list will fall under the scope of Article 118(1), providing for that operators in third countries shall not use these antimicrobials designated in the list for animals or products of animal origin to be exported from such third countries to the European Union.

Please also note that, as described in Article 107(5), these antimicrobials designated in the list shall not be used in accordance with Articles 112, 113 and 114.

Relevant excerpts from the VMP Regulation are included in Annex I for your convenience.

In accordance with Article 153(1) these implementing acts shall be adopted before 28 January 2022. We would kindly ask for your advice by the end of October 2020. Please note that the Commission is fully aware of the interconnections between the present request and the request made on 6 February 2019 referred to further above.

We would also ask that the Agency update our services on the main progress of its work on a monthly basis.

We would like to thank you for your collaboration.

Yours sincerely,

Anne Bucher

ANNEX I

Article 37

Decisions refusing marketing authorisations

1. Decisions refusing marketing authorisations referred to in Article 5(1) shall be taken on the basis of the documents prepared in accordance with Article 33(1) and shall be duly justified and include the reasons for refusal.

2. A marketing authorisation shall be refused if any of the following conditions are met:

(a) the application does not comply with this Chapter;

(b) the benefit-risk balance of the veterinary medicinal product is negative;

(c) the applicant has not provided sufficient information on the quality, safety or efficacy of the veterinary medicinal product;

(d) the veterinary medicinal product is an antimicrobial veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals or to increase yields from treated animals;

(e) the proposed withdrawal period is not long enough to ensure food safety or is insufficiently substantiated;

(f) the risk for public health in case of development of antimicrobial resistance or antiparasitic resistance outweighs the benefits of the veterinary medicinal product to animal health;

(g) the applicant has not provided sufficient proof of efficacy as regards the target species;

(h) the qualitative or quantitative composition of the veterinary medicinal product is not as stated in the application;

(i) risks to public or animal health or to the environment are not sufficiently addressed; or

(j) the active substance within the veterinary medicinal product meets the criteria for being considered persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, and the veterinary medicinal product is intended to be used in food-producing animals, unless it is demonstrated that the active substance is essential to prevent or control a serious risk to animal health.

3. A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the antimicrobial is reserved for treatment of certain infections in humans as provided for in paragraph 5.

4. The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Regulation by establishing the criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of those antimicrobials.

5. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. Those

implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

6. The Commission shall, when adopting the acts referred to in paragraphs 4 and 5, take into account the scientific advice of the Agency, the EFSA and other relevant Union agencies.

Article 107

Use of antimicrobial medicinal products

1. Antimicrobial medicinal products shall not be applied routinely nor used to compensate for poor hygiene, inadequate animal husbandry or lack of care or to compensate for poor farm management.

2. Antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth nor to increase yield.

3. Antimicrobial medicinal products shall not be used for prophylaxis other than in exceptional cases, for the administration to an individual animal or a restricted number of animals when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe.

In such cases, the use of antibiotic medicinal products for prophylaxis shall be limited to the administration to an individual animal only, under the conditions laid down in the first subparagraph.

4. Antimicrobial medicinal products shall be used for metaphylaxis only when the risk of spread of an infection or of an infectious disease in the group of animals is high and where no other appropriate alternatives are available. Member States may provide guidance regarding such other appropriate alternatives and shall actively support the development and application of guidelines which promote the understanding of risk factors associated with metaphylaxis and include criteria for its initiation.

5. Medicinal products which contain the designated antimicrobials referred to in Article 37(5) shall not be used in accordance with Articles 112, 113 and 114.

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.

When adopting those implementing acts, the Commission shall take account of the following criteria:

(a) risks to animal or public health if the antimicrobial is used in accordance with Articles 112, 113 and 114;

(b) risk for animal or public health in case of development of antimicrobial resistance;

(c) availability of other treatments for animals;

(d) availability of other antimicrobial treatments for humans;

(e) impact on aquaculture and farming if the animal affected by the condition receives no treatment.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

7. A Member State 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.

8. Measures adopted by the Member States on the basis of paragraph 7 shall be proportionate and justified.

9. The Member State shall inform the Commission of any measure it has adopted on the basis of paragraph 7.

Article 118

Animals or products of animal origin imported into the Union

1. Article 107(2) shall apply, mutatis mutandis, to operators in third countries and those operators shall not use the designated antimicrobials referred to in Article 37(5), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union.

2. The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Article by providing the necessary detailed rules on the application of paragraph 1 of this Article.

Article 152

Existing veterinary medicinal products, marketing authorisations and registrations

1. Marketing authorisations of veterinary medicinal products and registrations of homeopathic veterinary medicinal products granted in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 before 28 January 2022 shall be deemed to have been issued in accordance with this Regulation, and are, as such, subject to the relevant provisions of this Regulation.

The first subparagraph of this paragraph shall not apply to marketing authorisations for antimicrobial veterinary medicinal products containing antimicrobials which have been reserved for treatment in humans in accordance with implementing acts referred to in Article 37(5).

2. Veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 may continue to be made available until 29 January 2027, even if they are not in compliance with this Regulation.

3. By way of derogation from paragraph 1 of this Article, the periods of protection referred to in Article 39 shall not apply to reference veterinary medicinal products for which an authorisation has been granted before 28 January 2022 and, instead, the corresponding provisions in the repealed acts referred to in paragraph 1 of this Article shall continue to apply in that respect.

Article 153

Transitional provisions regarding delegated and implementing acts

1. The delegated acts referred to in Article 118(2) and the implementing acts referred to in Articles 37(5), 57(4), 77(6), 95(8), 99(6) and 104(7) shall be adopted before 28 January 2022. Such delegated and implementing acts shall apply from 28 January 2022.

2. Without prejudice to the date of application of this Regulation, the Commission shall adopt the delegated acts referred to in Article 37(4) at the latest by 27 September 2021. Such delegated acts shall apply from 28 January 2022.

3. Without prejudice to the date of application of this Regulation, the Commission shall adopt the delegated acts referred to in Articles 57(3) and 146(2) and the implementing acts referred to in Articles 55(3) and 60(1) at the latest by 27 January 2021. Such delegated and implementing acts shall apply from 28 January 2022.

4. Without prejudice to the date of application of this Regulation, the Commission shall adopt the delegated acts referred to in Article 109(1) and the implementing acts referred to in Articles 17(2) and (3), 93(2), 109(2) and 115(5) at the latest by 29 January 2025. Such delegated and implementing acts shall apply at the earliest on 28 January 2022.

5. Without prejudice to the date of application of this Regulation, the Commission is empowered to adopt delegated and implementing acts provided for in this Regulation as from 27 January 2019. Such delegated and implementing acts, unless otherwise provided in this Regulation, shall apply from 28 January 2022.

When adopting the delegated and implementing acts referred to in this Article, the Commission shall allow sufficient time between their adoption and their start of application.