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 acts under Article 57(4) of Regulation (EU) 2019/6 on veterinary medicinal products[1] relating to the format of the data to be collected on antimicrobial medicinal products used in animals

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 text of the new VMP Regulation foresees the obligation for Member States to collect relevant and comparable data on the volume of sales and the use per animal species and per types of antimicrobial medicinal products used in animals. The collection and analysis of such data shall enable in particular the direct or indirect evaluation of their use in food-producing animals at farm level (Article 57(1) and 57(2)).
It is important to underline that, in order to meet this obligation, Member States will be able to follow a stepwise approach under the conditions laid down in Article 57(5). Such an approach should facilitate the work inherent to the implementation of these measures and allow for a progressive build-up of capacities.

In this setting, the European Commission already asked the Agency on 6 February 2019 that it provides advice for the delegated acts described in Article 57(3) (Ref. Ares(2019)688882). These delegated acts shall describe the specific requirements to be established as to: 1) the types of antimicrobial medicinal products used in animals, for which data are to be collected; 2) quality assurance to be put in place by Member States

[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.

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and the Agency to ensure quality and comparability of data; 3) rules on the methods of gathering this data of transferring it to the Agency.

Moreover, the Regulation states that the Commission shall by means of implementing acts set up the format for the data to be collected (Article 57(4)).
In this context I would ask you to provide us with the Agency's scientific recommendations to set up the format for the data to be collected, taking due account of the requirements described in Article 57(3) and of the work of the Agency's expert working group preparing the related advice on this topic, while also bearing in mind the minimum requirements as to the animal species and categories for which data need to be collected (Article 57(5)).
The format defined in protocols or guidance documents for data collection, which were previously drafted by the Agency in the context of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, and regrouping what is there frequently termed 'variables', may also serve as an element for reflection. Similarly, information to be included in veterinary prescriptions (Article 105) and in records kept by owners and keepers of food-producing animals (Article 108) may be of interest.

In order to allow for comparability of data at international level on sales and use per species of antimicrobials used in animals, consideration should be given, wherever possible and appropriate, to data formats (including 'variables' and units of measurement) used in international guidelines.

In accordance with Article 153(1), the implementing act shall be adopted at the latest by 28 January 2022.

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

In light of the strict timeline set for the adoption of the required implementing acts, as specified in Article 153(1), I would kindly ask for the Agency's advice by end of June 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 57

Collection of data on antimicrobial medicinal products used in animals

1. Member States shall collect relevant and comparable data on the volume of sales and on the use of antimicrobial medicinal products used in animals, to enable in particular the direct or indirect evaluation of the use of such products in food-producing animals at farm level, in accordance with this Article and within the time limits set out in paragraph 5.

2. Member States shall send collated data on the volume of sales and the use per animal species and per types of antimicrobial medicinal products used in animals to the Agency in accordance with paragraph 5 and within the time limits referred to therein. The Agency shall cooperate with Member States and with other Union agencies to analyse those data and shall publish an annual report. The Agency shall take into account those data when adopting any relevant guidelines and recommendations.

3. The Commission shall adopt delegated acts in accordance with Article 147, in order to supplement this Article, establishing the requirements as regards:

(a) the types of antimicrobial medicinal products used in animals for which data shall be collected;

(b) the quality assurance that Member States and the Agency shall put in place to ensure quality and comparability of data; and

(c) the rules on the methods of gathering data on the use of the antimicrobial medicinal products used in animals and on the method of transfer of those data to the Agency.

4. The Commission shall, by means of implementing acts, set up the format for the data to be collected in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

5. Member States shall be allowed to apply a progressive stepwise approach regarding the obligations set out in this Article so that:

(a) within two years from 28 January 2022, data shall be collected at least for the species and categories included in Commission Implementing Decision 2013/652/EU (24) in its version of 11 December 2018;

(b) within five years from 28 January 2022, data shall be collected for all food-producing animal species;

(c) within eight years from 28 January 2022, data shall be collected for other animals which are bred or kept.

6. Nothing in point (c) of paragraph 5 shall be understood to include an obligation to collect data from natural persons keeping companion animals.

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.