EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director General

Brussels,
SANTE/E5/CD/mcd 379717
Sent by e-mail only

Dear Prof Rasi,

Subject: Delegated acts under Article 57(3) of Regulation (EU) 2019/6 on veterinary medicinal products in relation to the collection of data on antimicrobial medicinal products used in animals[1]

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 data on the volume of sales and on the use of antimicrobial medicinal products used in animals. The collection and analysis of such data shall in turn enable to evaluate their use in food-producing animals at farm level (Article 57(1)).

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.

The data to be provided by Member States to the Agency shall include the volume of sales and the use per animal species and per types of antimicrobial medicinal products used in animals. It should then be analysed in collaboration with Member States and other relevant Union agencies and be published as an annual report. It should also set the basis for any relevant guidelines and recommendations prepared by the Agency (Article 57(2)).

[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
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In order to advise the Commission for the delegated acts described in Article 57(3), the Agency will provide a report describing the specific requirements, which need to be established as to the following elements:

- types of antimicrobial medicinal products used in animals, for which data are to be collected
- quality assurance to be put in place by Member States and the Agency to ensure quality and comparability of data
- rules on the methods of gathering this data of transferring it to the Agency.

Please bear in mind that new types of antimicrobials may emerge and that these should also be included in the data collection and analysis processes mentioned above.

These requirements will be laid down by the Commission through delegated acts (Article 57 (3)). In accordance with Article 153(3) these delegated acts shall be adopted at the latest by 12 months before the date of application of the VMP Regulation.

In this context, I would ask you to provide us with the Agency's recommendations to define those requirements, and where adequate to briefly describe how these recommendations will help achieve the objectives laid down in Article 57(1) and 57(2); also the Agency should already bear in mind the format of data collection (Article 57 (4) and (5)) and ensure that all relevant aspects of the methodology are covered.

I would count on receiving this advice from the Agency based on its own expertise and on the valuable input it may get through external experts (including experts from Member States, as appropriate) and through its collaborations with other EU bodies (including ECDC and EFSA), and where relevant taking into account the work of other international agencies, bodies or organisations.

Additional useful elements to be taken into account while drafting these recommendations are provided in Annex I. Relevant excerpts of the VMP Regulation are included in Annex II for your convenience.

In light of the strict timeline set for the adoption of the required delegated acts, as specified in Article 153(3), I would kindly ask for the Agency's advice by end of August 2019. 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

Encl. : Annex I – Annex II

ANNEX I

While drafting its recommendations as to how the requirements laid down in Article 57(3) of Regulation (EU) 2018/[…] of the European Parliament and of the Council on veterinary medicinal products should best be addressed, the European Commission invites the Agency to take into consideration the elements mentioned hereunder to guide its reflection. It also invites the Agency to include any external input which may be necessary and useful, be it input provided through external experts, through collaborators within other EU or international agencies, bodies or organisations.
Please note that these elements are not exhaustive and that the Agency shall complete the list with whatever other necessary elements that would improve the quality of its recommendations.

1. EMA:

- **ESVAC**
  Experience acquired through the preparation of the ESVAC annual reports will be precious in view of drafting recommendations on the requirements in Article 57(3) of the new VMP Regulation. Possible input from EMA Expert Advisory Groups (already available or which could be provided ad hoc), such as the ESVAC sales Expert Advisory Group and the ESVAC species Expert Advisory Group could be considered. Feedback received from previous ESVAC annual stakeholders meetings which may be relevant to the recommendations may also be considered.

  https://www.ema.europa.eu/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac

- **Stratification of sales data of antimicrobials by species_Data collection protocol 2017**
  Work progress and results from the pilot project which includes 6 volunteering countries and which tests the methodology for collecting and analysing this sales data for stratification will be valuable. In this context, the source of the collection of data may vary for each Member State.
  Please bear in mind that in the context of Article 57 of the new VMP Regulation, paragraph 1 stipulates that Member States will be to 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.
  How the requirements laid down in Article 57(3) will be fostering the achievement of this objective is important.
  https://www.ema.europa.eu/documents/report/stratification-sales-data-antimicrobials-species-data-collection-protocol-2017_en.pdf

- **EMA Guidance on collection and provision of national data on antimicrobial use by animal species/categories**

  https://www.ema.europa.eu/documents/scientific-guideline/guidance-collection-provision-national-data-antimicrobial-use-animal-species/categories_en.pdf

- **CVMP strategy on antimicrobials 2016-2020**

  https://www.ema.europa.eu/documents/scientific-guideline/cvmp-strategy-antimicrobials-2016-2020_en.pdf

2. OIE:

- **Revised OIE list of antimicrobial agents of veterinary importance**

  http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_OIE_List_antimicrobials_May2018.pdf

- **OIE's Global database on antimicrobial agents intended for use in animals**
  In the framework of the Global Action Plan on Antimicrobial Resistance, the OIE, supported by FAO and WHO within the tripartite collaboration, has taken the lead to build a global database on antimicrobial agents intended for use in animals. The database is designed to:
  -Monitor the type and use of antimicrobial products
  -Support Member Countries in implementing Chapter 6.9. of the Terrestrial Code* and Chapter 6.3. of the Aquatic Code (relating to the monitoring of the quantities and usage patterns of antimicrobials used in food-producing animals and aquatic animals)
  -Measure trends over time
  -Trace circulation and use patterns globally
  -Evaluate the quality and authenticity of antimicrobial products in use

  http://www.oie.int/en/scientific-expertise/veterinary-products/antimicrobials/

  The OIE is now in its third phase of data collection (which started in October 2017).
  After the second phase, a report was published in 2017: http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/Annual_Report_AMR_2.pdf

- **OIE Standards, Guidelines and Resolution on antimicrobial resistance and the use of antimicrobial agents**

  https://web.oie.int/delegateweb/eng/ebook/AF-book-AMR-ANG_FULL.pdf?WAHISPHPSESSID=03152ead00d06990fa9066b7b71fcabc

- **Relevant output from the 2018 OIE Global Conference on AMR**
  http://www.oie.int/amr2018/en/

3. Codex Alimentarius

- New work on antimicrobial resistance was approved by the Codex Alimentarius Commission (CAC) at its 40th Session in Geneva in July 2017. The CAC agreed to developing Guidance on Integrated Surveillance of Antimicrobial Resistance, and revising its 2005 Code of Practice to Minimise and Contain Antimicrobial Resistance.

These elements, when made available, should be taken into account while reflecting on how to best address the requirements set in Article 57(3).

http://www.fao.org/antimicrobial-resistance/news-and-events/news/news-details/en/c/1027130/

4. WHO

- **WHO and antimicrobial use**

  http://www.who.int/medicines/areas/rational_use/AMU_Surveillance/en/

- **WHO guidelines for surveillance of AMU/ WHO methodology for a global programme on surveillance of antimicrobial consumption**
  http://www.who.int/medicines/areas/rational_use/WHO_AMCsurveillance_1.0.pdf?ua=1

- **The ATCvet system of the WHO Collaborating Centre for Drug Statistics Methodology**
  The ATCvet system for classification of veterinary medicines is based on the same overall principles as the ATC system for substances used in human medicine. The ATCvet system is a tool for exchanging and comparing data on drug use in veterinary medicine at international, national or local levels.

  https://www.whocc.no/atcvet/

5. ECDC

- **European Surveillance of Antimicrobial Consumption Network (ESAC-Net)**
  a Europe-wide network of national surveillance systems, providing European reference data on antimicrobial consumption. ESAC-Net collects and analyses data on antimicrobial consumption from EU and EEA/EFTA countries, both in the community and in the hospital sector through the European Surveillance System (TESSy).
  The data sources will be national sales and reimbursement data, including information from national drug registers. ECDC will collect data at national level and intends to collect sub-national data based on the NUTS classification.

  https://ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/esac-net

6. FDA

- **Five-year action plan for supporting antimicrobial stewardship in veterinary settings**
  https://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/UCM620420.pdf

- **2016 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals**

https://www.fda.gov/downloads/forindustry/userfees/animaldruguserfeeactadufa/ucm588085.pdf

- **Final Rule to Collect Antimicrobial Sales and Distribution Information by Animal Species**

  https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm446786.htm

- **Collecting On-Farm Antimicrobial Use and Resistance Data Public Meeting of September 2015**
  https://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/ucm456380.htm

7. Other

- Front Vet Sci. 2017; 4: 213
  Why Antibiotic Use Data in Animals Needs to Be Collected and How This Can Be Facilitated
  Jorge Pinto Ferreira

  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5732972/

- PLoS Med. 2018 Mar; 15(3): e1002521.
  Surveillance of antimicrobial consumption in animal production sectors of low- and middle-income countries: Optimizing use and addressing antimicrobial resistance
  Daniel Schar, Angkana Sommanustweechai, Ramanan Laxminarayan, and Viroj Tangcharoensathien

  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5832183/

- Prev Vet Med. 2014 Jun 1; 114(0): 213–222.
  Comparison of two methods for collecting antibiotic use data on small dairy farms
  L. E. Redding, F. Cubas-Delgado, M.D. Sammel, G. Smith, D.T. Galligan, M.Z. Levy, and S. Hennessy

  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4197167/

- Vet Res. 2001 Nov-Dec;32(6):533-43.
  The crucial question of standardisation when measuring drug consumption.
  Chauvin C, Madec F, Guillemot D, Sanders P.

  https://www.ncbi.nlm.nih.gov/pubmed/11777005

- Rev Sci Tech. 2001 Dec;20(3):841-7.

Antimicrobial resistance: monitoring the quantities of antimicrobials used in animal husbandry.

Nicholls T, Acar J, Anthony F, Franklin A, Gupta R, Tamura Y, Thompson S, Threlfall EJ, Vose D, van Vuuren M, White DG, Wegener HC, Costarrica ML; Office International des Epizooties Ad hoc Group.

https://www.ncbi.nlm.nih.gov/pubmed/11732426

ANNEX II

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[2] 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.

[2] Commission Implementing Decision 2013/652/EU of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (OJ L 303, 14.11.2013, p. 26).

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.