FEDERATION OF VETERINARIANS OF EUROPE

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EMA ADVICE ON SPECIFIC REQUIREMENTS FOR THE COLLECTION OF DATA ON ANTIMICROBIAL MEDICINAL PRODUCTS USED IN ANIMALS

FVE Input

Background:

- Regulation 2019/6 on veterinary medicinal products lays down in Article 57 that the 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 European Medicines Agency (EMA) within certain time limits. The European Medicines Agency shall cooperate with Member States and with other Union agencies to analyse those data and shall publish an annual report. The EMA shall take into account those data when adopting any relevant guidelines and recommendations.
- On 6 February 2019 the European Commission sent the mandate to the European Medicines Agency, particularly relating to the points of Article 57(3):
  - 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 these data and of their transfer to the Agency.
- The European Medicines Agency delivered its advice on 29 August 2019.

Main inputs FVE:

FVE very much welcomes the EMA advice. The ESVAC system is extremely precious to the profession and has made an enormous impact to promote and facilitate judicious and prudent use across Europe. FVE welcomes to strengthen the ESVAC system in the future such as by moving from sales to use data.
Nevertheless, FVE warns that the system should be kept implementable and focus on the key data that are important to measure in the fight against AMR, in other words we need to focus on the 'need to knows', not the 'nice to knows'. We need to keep clear what is that goal of this data collection and what is done with the collected data.

Main FVE feedback:

- FVE suggests to **limit the data collection to antimicrobials used systemically**, similar as in the human system. We strongly suggest to exclude antimicrobials used dermatological, nasal, ophthalmological or for otological use. The reasons for excluding them are that the volumes used of these products are very small, they are mostly used for companion animals, they are distributed through many different channels (making collection more difficult), dosage regimes vary greatly and their impact on AMR due to their topical nature is very small.
- It would be useful to add **data on antiparasitics.** The emerging risk of anthelmintic resistance is generally recognised and all food partners agree that it is time to take action to ensure the responsible use of veterinary anthelmintics in food-producing animals.[1] FVE believes the coccidiostats/anticoccidials and histomonostats containing antimicrobials should be under veterinary prescription and their use be monitored. [2] DG Sante final overview report on 'Measures to Tackle Antimicrobial Resistance through the Prudent Use of Antimicrobials in Animals' shows how some countries are starting to phase out Narasin and other coccidiostats with antibiotic properties as measure against AMR[3]. FVE emphasises that this transition should be done without losing the availability of these essential products.
- **Getting reliable population data will be extremely difficult for some species**. Although horses in the EU need mandatory identification and registration, the exact number of horses is unknown and thought to be between 4.2 and 7.7 million[4]. Getting population data for dogs is even more difficult as identification and registration is not mandatory in all EU countries. Cats nobody knows. Without proper population data, it will be extremely difficult to calculate mg/PCU. As FVE, we strongly support the collection of data on antimicrobial use in all these animals, but the lack of robust population data needs to be taken into account.
- **Species categories need to be clearly identified to allow comparison.** For example, the different categories of pigs. If taking unweaned pigs, weaning ages can vary between 3 weeks and 5 weeks. If taking fattening pigs, some countries fatten pigs to 80 kg, others to 100kg, other much higher. In some category groups, e.g. young piglets, mortality rates can be high which also needs to be taken into account.
- **Workload and responsibilities**: The report rightly so leaves it to national competent authorities how the data will be collected and only says '*the*

[1] EPRUMA best-practice framework on the use of anthelmintics in food-producing animals https://www.epruma.eu/wp-content/uploads/2019/04/Best-practice-framework.pdf
[2] FVE position on coccodiostats : https://www.fve.org/publications/fve-position-paper-on-coccidiostats-or-anticoccidials/
[3] EC final overview report: http://ec.europa.eu/food/audits-analysis/overview_reports/act_getPDF.cfm?PDF_ID=1427
[4] Removing the blinckers: https://www.eurogroupforanimals.org/wp-content/uploads/EU-Equine-Report-Removing-the-Blinkers.pdf

use data collected in these countries typically represent prescription data, dispensed amounts, data on amounts administered by the veterinarians on the farm or data from invoices. In these countries, the use data of antimicrobials are collected from the veterinarians, pharmacies, feed mills and/or end-users (farmers, breeders).' Amongst veterinarians there are serious concerns regarding the extra bureaucracy that this could introduce and regarding who will be responsible if mistakes are made. It should be recognised that an automated system needs to be developed without too much extra bureaucracy and coming at the expense of the veterinarian. As this is a public good, ultimately the extra costs should be borne by the government or the society. Responsibilities need to be clearly defined and honest mistakes not be penalised.

More detailed comments:

- On page 4, recommendation 1 last paragraph regarding off-label use, it should be clarified that this is antibiotics or antimicrobials, not all human medical products.
- On page 11-12, FVE very much supports to increase the reporting frequency of the JIACRA report e.g. to every two years.
- On page 5, first bullet, parent birds should also be included
- On page 15, FVE supports that Chlorhexidine should not be included.
- On page 16, point 3.2, second paragraph, it says that current knowledge is that monensin use in animals has not shown any negative impact on public health. However, no reference is given.
- On page 17, cattle – all categories. This needs to be further elaborated on what categories are meant in order to make sure data is comparable. Idem other species.

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EXTRACT REGULATION

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.