FEDERATION OF VETERINARIANS OF EUROPE

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PUBLIC CONSULTATION ON DRAFT DELEGATED ACT TO SET CRITERIA FOR THE DESIGNATION OF ANTIMICROBIALS RESERVED FOR HUMANS

FVE FEEDBACK

Main inputs FVE:

FVE welcomes the opportunity to give feedback on the Draft Delegated Act (DA) via the public consultation. This is an extremely important Act as it has the potential to limit the already very limited therapeutic toolbox veterinarians have to treat animals.

Animals are sentient beings and deserve treatment too. When animals suffer a bacterial disease, treatment is a "medical act" to alleviate the health consequences and improve their welfare, not a productivity tool. Further to this, treatment of any bacterial disease in animals prevents spreading of disease to other animals and/or people (for zoonotic bacterial diseases).

Banning antimicrobials for use in animals is one of the **most severe AMR risk management measures possible** , and should be used with the greatest caution. We urge policy makers to consider such a radical measure as banning is, to be used only based on robust scientific evidence on the benefit for human health.

FVE believes that the most effective way to fight antimicrobial resistance is to ensure **prevention of disease in order to avoid the need to treat animals and humans with antimicrobials**, while ensuring **prudent and responsible use**, e.g. by using as much possible the bacterial culture and antibacterial susceptibility testing (C&AST).

FVE remains concerned over this Draft Delegated Act for the following reasons:

1. The "One Health principle" recognising that humans, animals and the environment are interconnected is overall ignored;
2. Animal health and welfare are not thoroughly considered;
3. Some new paragraphs deviate from the EMA advice and lack the support of sound scientific evidence;
4. Certain crucial terminology is unclear and vague;
5. This act will limit innovation and eliminates any incentive to authorise new antibiotic classes for animals in the future.

1. <u>One Health is not enough recognised</u>

FVE strongly recommends that the delegated act embraces the "One Health principle" by promoting responsible and prudent use of medicines in both the human and animal healthcare.

Inability to successfully treat a susceptible infection in animals due to lack of the proper treatment can have serious implications on animal health and welfare as well as on public health (zoonotic pathogens can be bacterial, viral, or fungal, and they represent 70% of all human diseases). If a bacterial animal disease can't be treated in animals, the causative bacteria can spread, which can constitute a very significant risk for subsequent infections to in-contact animals and/or humans or on food safety and security.

2. <u>Animal health and welfare have to be duly considered</u>

In the last decade, the veterinary sector has done great efforts which resulted in a substantial decrease of antibiotic use in animals. The latest ESVAC report, published in October 2020, shows that sales of antibiotics for use in animals in Europe fell by 34% between 2011 and 2018, including the use of critically important antibiotics (CIA's) that has also gone down significantly (24% 3 and 4th generation cephalosporins; 70% for polymyxins; 4% for fluoroquinolones; 74% for other quinolones).
Further than this, **restrictions are already in place and will be enhanced** when the new Regulations on Veterinary Medicines and Medicated Feed will come into force in January next year.

It must be taken into account that according to the EU Treaty animals are sentient beings and as such deserve treatment too. It is therefore of utmost importance to ensure their proper treatment as necessary. Whereas

- the availability of authorised veterinary antibiotics is anyway much more limited, in particularly for minor species or limited markets, the implications from additional restrictions on the use of antimicrobials in animals will have much higher impact on their health and welfare**;**
- the number of authorised antibiotic classes in human medicine is already much higher than in veterinary medicines.

Banning certain antimicrobials for use in animals will further increase the pressure on the limited number of available antimicrobials, risking to lead to the opposite results, i.e. increase resistance instead.

3*. <u>The DA deviates from the scientific EMA opinion</u>*

Different to the EMA opinion, the draft delegated act includes an **override** that ***will allow the reservation of an antimicrobial for human use despite the antimicrobial being essential in veterinary medicine***.

While FVE recognises that the policy makers want to prioritise human health above animal health, we believe that any decision to reserve antimicrobials for human use only should be **based on robust scientific evidence.** Additionally, FVE notes also that the

draft DA does not make any distinction between food producing and companion animals or between the different methods of administration, although the EMA- AMEG categorisation recognises the need for distinction and exceptions e.g. for companion animals can be given exceptionally Cat A antimicrobials and the importance of the rout of administration in respect to the risks posed. This override introduced in the DA can potentially strongly endanger public health on top of animal health and welfare, leading to conditions where due to lack of available treatment against bacterial infections in animals, especially for life-threatening or zoonotic ones (Zoonotic diseases are defined by the OIE as infectious diseases that are naturally transmitted from vertebrate animals to humans and vice versa), could be potentially detrimental for human health.

FVE highlights, as well, that a serious, life-threatening infection when is inappropriately treated may lead to more unfavoured conditions than 'limited morbidity' or 'limited mortality' – see sentence: "…*the antimicrobial or group of antimicrobials is used to treat* ***serious, life-threatening infections*** *in animals which, if inappropriately treated, would lead to* ***limited morbidity or limited mortality*** *and there is scientific evidence showing an overriding public health interest in not using it*."

4. <u>Certain terminology is unclear and vague</u>

The DA includes some terminology which is vague and open for different interpretations. This means that the criteria themselves will be difficult to advise upon and evaluate.

FVE would like to draw particularly your attention to the following definitions:

- "***limited treatment alternatives***" – „***limited treatment options***" should be better defined
- a „***significant***" contribution of transmission specific scientific parameters should be defined to measure transfer and what is 'significant';
- '***alternative treatment***' *'(8) When considering the use of alternative medicinal products instead of certain antimicrobial medicinal products, it is important that those products are adequate and available. Such alternatives should be authorised medicinal products in suitable formulations for the treatment of the disease in the animal species requiring treatment. '*
- Despite trying to describe what is an ***alternative treatment*** in point 8, it is still not clear. Is it another antibiotic or substances that inactivates/kills bacteria? Or can it also include vaccines, immunomodulators, homeopathic remedies, etc? Should it be available in all regions or only in a couple of countries? It should be noted that most substances classified under 'alternatives to antimicrobials' are not real alternatives. They can be used to prevent animal diseases e.g. vaccines, but cannot replace an antibiotic treatment to treat a bacterial infection. DA should state that available alternatives (antimicrobials or other alternative management strategies) should not pose a risk of worsening the resistance patterns (i.e. increased use of other critically important antibiotics (CIA's) or increased use of antibiotics with a risk to potentially increase co-selection), which will have counterproductive results for public health. The available alternatives should also not pose a (higher) risk for the environment. **Alternative treatments should be adequate, effective, available and evidence based and not posing a higher risk for resistance or the environment.**

- "**no robust evidence that an antibiotic is needed in veterinary…**": this quote is very vague and will differ very much per region/species. FVE strongly suggests the use of the OIE list of antimicrobials of veterinary importance and the corresponding poultry list as reference. On a later stage, different species lists will be added.
- parameters to define what is considered „**significant morbidity and/or mortality**" and „**limited morbidity or limited mortality**" are needed.
- It is unclear what defines '***overriding public health interest'*** and who will decide about this?

The **procedure of the assessment and who will do the assessment is very important and should be transparent and publicly available with actors involved from both the human as veterinary sector.** Different interests (human, veterinary etc. etc.) will have to be weighed and this demands for a clear process, including clear transparent scientific background and decision making with the involvement of all actors impacted.

5. This DA will greatly limit the possibility to develop and authorise in the future new antibiotic classes for animals

Criteria 1b is still too strict and most probably will lead to no future development and authorisations of new veterinary antibiotics, as all antibiotics classes have the 'potential' for cross resistance and co-resistance.

Extra considerations:

- As these criteria will be used later to draft the implementing act, **third country impact will also be worth considering and how to effectively enforce this for imported animal products.**
- Many pathogens are relevant to animals, while at this moment, resistance on an EU level is only recorded for specific zoonotic ones. It would be beneficial to build an European Antimicrobial Resistance Surveillance network in veterinary medicine (EARS-Vet) to show which antibiotics are effective for specific infections. See EU-JAMRAI publication on this.
- You can find the earlier FVE input on reserving antimicrobials for humans here.