



The European Commission

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Regarding commission delegated regulation and annex supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans

The Danish Veterinary Association (DVA) acknowledges the need to except certain antimicrobials for human use only, to protect human health in cases where this is necessary because of antimicrobial resistance.

The DVA is very pleased to see, that both our comments, and comments previously made by FVE, are included, and that there are improvements in this draft, e.g. with the involvement of animal welfare. However, the criteria as formulated are still open for interpretation and therefore, as we see it, there are still some shortcomings in the draft.

The DVA therefore suggest the following changes to be made:

Annex PART B: CRITERION OF RISK OF TRANSMISSION OF RESISTANCE

1.(b)

For an antimicrobial or group of antimicrobials not authorised for use in animals, scientific evidence exists showing that:

- *“there is the potential for emergence, dissemination and transmission of resistance to this antimicrobial or group of antimicrobials or potential for inducing cross-resistance or co-selection of resistance to other antimicrobials and...”*

Comment: The content is far too restrictive and is likely to result in no new antibiotics being marketed in the future, as all antibiotics will have a “potential” for cross-resistance or co-selection of resistance to other groups of antibiotics.

Annex PART C: CRITERION OF NON-ESSENTIAL NEED FOR ANIMAL HEALTH

1.(c)

*“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.”*

Comment: the text marked in red is unclear and we therefore suggest using the wording “life-threatening infection” instead.

Yours sincerely,

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