



Members of the European Parliament
European Parliament
60 rue Wiertz
B-1047 – Brussels

Brussels, 30 August 2021

Subject: Drug resistance – criteria for identifying antimicrobial medicines reserved for treating humans

Dear Member of the European Parliament,

The European Commission has proposed a draft delegated regulation¹ supplementing Regulation 2019/6 on veterinary medicinal products² by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans.

According to the draft delegated regulation, an antimicrobial or a group of antimicrobials need to meet three criteria set out in Parts A, B and C in order to be designated as reserved for treatment of certain infections in humans:

- Part A: criterion of high importance to human health,
- Part B: criterion of risk of transmission of resistance,
- Part C: criterion of non-essential need for animal health.

The Standing Committee of European Doctors (CPME) believes that **the current draft text fails** to safeguard antimicrobials that are critical for humans, to help contain the spread of antimicrobial resistance, and as a result, **to adequately protect human health and life**. This opinion was obviously shared by the members of the ENVI committee when they turned down the Commission proposal.

Of particular concern is criterion C, which states that an antimicrobial may be reserved for humans only if it is not essential for animal health. This conceptualisation **gives priority to animal health and welfare over human health** and the goal of containing antimicrobial resistance. This may lead to antibiotics of last resort still being used in large quantities in animal husbandry in the EU. Indeed, the intention **to wipe out “dirty farming” to increase animal welfare is circumvented** if the use of antibiotics of last resort remains possible. This constitutes an imminent threat to human welfare.

¹<https://www.cpme.eu/wp-content/uploads/adopted/2021/6/090166e5db1d341d-2.pdf>,

<https://www.cpme.eu/index.php?downloadunprotected=/uploads/adopted/2021/6/090166e5db1d341e.pdf>

²<https://eur-lex.europa.eu/eli/reg/2019/6/oj>

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Ultimately, requiring that the three criteria to be met cumulatively may open the way to blocking antimicrobials of highest importance from being designated as reserved for humans.

However, having in mind that Regulation 2019/6 will be in force in January 2022, I would like to propose a few amendments which will be lifesaving for humans and animals as well.

- 1) Criterion C has to be deleted and replaced by a regulation that
- 2) Allows individual treatment of individual animals after
- 3) Verifying that no less potent antibiotic is available and
- 4) A valid antibiogram has been performed.

This would also be in line with the criteria of the World Health Organization (WHO) which has by no means agreed to criterion C as a cumulative prerequisite for the regulation but includes only two criteria which correspond to Part A and Part B of the Commission's draft Regulation.

At some point we might be in a dramatic situation with no antibiotic left for some human diseases. We must do everything - already now - to prevent this from happening. From a medical profession's perspective there is hardly any alternative route of action.

In view of the above, we call on you to **veto the current version of the draft Commission delegated regulation** scheduled to be voted by the European Parliament's plenary in September 2021, at the same time **requesting the European Commission to propose a text that gives due consideration to reducing AMR and protecting human health by fulfilling the criteria mentioned above.**

We remain at your disposal for any further information.

Yours sincerely,

Prof. Dr Frank Ulrich Montgomery
CPME President

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