



Members of the European Parliament's  
Committee on Environment, Public Health and Food Safety  
European Parliament  
60 rue Wiertz  
B-1047 – Brussels

Brussels, 23 June 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 regulation<sup>1</sup> supplementing Regulation 2019/6 on veterinary medicinal products<sup>2</sup> 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.**

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.

Furthermore, criterion C only considers alternative treatments as an option to avoid the use of antibiotics that are prescribed to treat serious, life-threatening infections in animals. It does not take into account that **many of these infections may be avoided through better husbandry**, although certain husbandry practices are known to be associated with much higher levels of disease in livestock.<sup>3</sup>

<sup>1</sup><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>

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

<sup>3</sup>[https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11570-Drug-resistance-criteria-for-identifying-antimicrobial-medicines-reserved-for-treating-humans/F2239103\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11570-Drug-resistance-criteria-for-identifying-antimicrobial-medicines-reserved-for-treating-humans/F2239103_en)



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.

In view of the above, we call on you to **veto the current version of the draft Commission delegated regulation** scheduled to be discussed in the ENVI Committee on 28 June 2021 and voted on 12/13 July 2021, **requesting the European Commission to propose a text that gives due consideration to reducing AMR and protecting human health.**

We remain at your disposal for any further information.

Yours sincerely,

Prof. Dr Frank Ulrich Montgomery  
CPME President