

European Parliament
Committee on the Environment, Public Health and Food Safety
Rue Wiertz 60
1047 Brussels

12 July 2021

RE: Safeguarding the effectiveness of antimicrobials in human health

Dear Members of the ENVI committee,

We call on you to support the [motion for a resolution](#) in tomorrow's ENVI Committee meeting that objects to the [delegated regulation](#) establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans.

Article 37(4) of [Regulation \(EU\) 2019/6](#) on Veterinary Medicinal Products mandates the European Commission to adopt a delegated regulation to establish the criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans to preserve the efficacy of those antimicrobials. However, the delegated regulation adopted by the European Commission on 26 May 2021 establishes criteria that are far too restrictive to identify antimicrobials that should be reserved for human health and therefore do not sufficiently protect human health against the [increasing impact of antimicrobial resistance \(AMR\)](#).

We have three main concerns with the criteria proposed by the Commission:

1. The delegated regulation sets out three different criteria for the designation of antimicrobials reserved for humans, all of which need to be met in all species for antimicrobials to receive this designation. We believe it should instead apply these criteria on a species-by-species basis to evaluate whether antimicrobials should be removed from use in specific species.

Fluoroquinolones, for example, are not essential in poultry as demonstrated by their ban in the United States since 2005, while their misuse in food production has led to high levels of resistance in human *Campylobacter* infections. It might, however, be justified to continue their use in other species, restricted to individual non-prophylactic treatments where sensitivity

testing shows that other antimicrobials would not work, for animal welfare reasons.

2. Criterion B 1 (a-b) requires scientific evidence that transmission of resistance from animal sources to humans is 'significant' for antimicrobials authorised for animal use and 'likely significant' for antimicrobials not authorised for animal use. This requirement sets the bar far higher than the [WHO's second criterion](#) to categorise antimicrobial classes used in human medicine as 'critically important', 'highly important', or 'important'. This criterion states that the transmission of organisms that cause disease or their genes does not need to be demonstrated, and that the potential for such transmission to exist is sufficient evidence.
3. Criterion C 1 (b) does not apply the designation of 'non-essential for animal health' to antimicrobials that could be substituted with improved farming practices and animal husbandry. Some antimicrobials are used only to sustain irresponsible, intensive farming practices, such as colistin, which is used to treat post-weaning diarrhoea in piglets that are weaned early even though there are alternative prevention and treatment measures, such as later weaning. Colistin is the only last-resort treatment for life-threatening human infections caused by carbapenem-resistant *Enterobacteriaceae*.

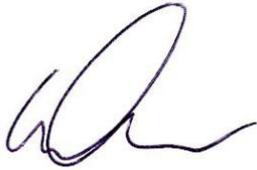
The criteria to be adopted under Article 37(4) of Regulation (EU) 2019/6 will lay the ground for designating antimicrobials to be banned in food production, for food both produced and imported into the EU, establishing an important international standard. It is therefore of paramount importance that the criteria provide the right framework to safeguard the effectiveness of key antimicrobials, which are often the last-resort tools healthcare professionals can use to fight drug-resistant infections in humans.

[Health Care Without Harm \(HCWH\) Europe](#) is a non-profit network of European hospitals, healthcare providers, and healthcare systems whose mission is to transform the European healthcare sector so that it reduces its environmental footprint, becomes a community anchor for sustainability, and a leader in the global movement for environmental health and justice.

We represent our members' interests in demanding the responsible use of antimicrobials in food production. Our 92 member organisations collectively serve a population of 60.7 million European citizens in 19 European countries, comprising over 4,917 healthcare facilities and 1,045,352 healthcare professionals.

We ask you to support the motion for a resolution in the ENVI Committee tomorrow to protect key antimicrobials for human health and keep much-needed resources in the fight against AMR, and remain available should you have any questions.

Yours sincerely,



Will Clark,
Executive Director – HCWH Europe

This letter is also supported by:

- [The Alliance to Save Our Antibiotics](#)



- [The European Public Health Alliance \(EPHA\)](#)

