European Parliament

To:
Stella Kyriakides
Commissioner for Health and Food Safety

March 31 2022

RE: Concern about EMA's advice on the designation of (groups of) antimicrobials for treatment of certain infections in humans

Dear Commissioner Kyriakides,

We hereby follow up on the Exchange of views with the Commission and the European Medicines Agency (EMA) in the ENVI committee of the European Parliament on March 15 on the upcoming draft implementing act reserving certain antimicrobials for treatment of infections in humans.

As it was clearly visible during the exchange, the vast majority of political groups expressed serious concern about EMA's advice informing the implementing act. With this letter the undersigned Members of Parliament call on the Commission to carefully assess EMA's advice and to not adopt it in its present form. We also explicitly ask the Commission to share this letter with the members of the Standing Committee on Veterinary Medicinal Products that convenes on April 4 to examine the draft implementing act.

Our main reasons of concern with the EMA proposal are the following:

The EMA advice does not recommend reserving for human health any of the antimicrobials on the WHO's list of critically important antimicrobials for human medicine (CIA) that are authorised for veterinary use in the EU. Regarding the five Highest Priority Critically Important Antimicrobials (HP CIA) for human medicine, one single antimicrobial class has been proposed to be reserved (Glycopeptides) - the only one of this list that was not allowed in veterinary medicine in the EU. EMA's advice will therefore result in no change to current intensive farming practices that rely on antimicrobial use and will not help curb the rising threat of antimicrobial resistance (AMR), which causes the direct death of 1.27 million people globally every year.

We would also like to stress that while EMA's proposal claims to be protective of animal health, it clearly fails to address some animal welfare concerns related to the overuse and misuse of

antimicrobials. EMA's Criterion C only evaluates the existence of other antimicrobials to replace the ones that are being currently used but it does not take into consideration how antimicrobials could be substantially reduced by responsible farming practices.

In the case of colistin, the EMA fails to present a compelling argument for its essential use in food-producing and companion animals. Almost all colistin sales in Europe are in forms typically used for group treatment in food-producing animals, which suggests colistin is mainly used to sustain intensive farming practices such as early weaning. Between 2011 and 2020 the consumption of colistin in European hospitals has risen by 67%. These data suggest that colistin is increasingly crucial in healthcare in Europe and particularly needs to be safeguarded. EMA's recommendation on colistin should give enough reason to carefully re-assess EMA's advice of all other HP CIAs.

The EMA acknowledges that "*the emerging and steady increase in the occurrence of bacteria that are resistant to multiple antibiotics has become a global public health threat due to the lack of therapeutic options to treat certain infections in humans*". However, it disregards WHO's advice on CIAs and claims that the efforts of the Commission should be tailored to the EU, without taking into consideration their wider global impact. As the antimicrobials included in the list will also apply to food products in third countries intended for the EU, should the Commission decide to follow EMA's advice it will be a missed opportunity for the EU to play a meaningful role in the global fight against antimicrobial resistance.

We call on you to take these arguments into consideration when assessing EMA's proposal, also in the Standing Committee on Veterinary Medicinal Products, and remain available should you wish to engage in any further discussion on the subject.

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