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Stella Kyriakides
Commissioner for Health and Food Safety

Implementing act on critically important antimicrobials

Dear Commissioner Kyriakides,

with this letter I wish to enquire about the state of affairs of the list on critically important antimicrobials to be reserved for human use.

As you are well aware, from today the new Regulation on Veterinary Medicinal Products (VMP) applies. This regulation has the potential to considerably contribute to the fight against antimicrobial resistance. Essential in this context is the list of antimicrobials to be reserved for treatment of certain infections in humans. This list is to be established by means of implementing acts and to be based on scientific advice by the European Medicines Agency (EMA). To the present date this list does not exist.

Even though the VMP Regulation does not foresee a deadline by which the implementing acts under Article 107(6) are to be adopted, the European Commission had made it clear in its mandate to EMA that the list should be established by January 28 2022. It had therefore asked for EMA's scientific advice on this list by end of February 2021¹:

I am fully aware that the current global pandemic comes with enormous challenges for EMA. I am nevertheless concerned by the non-existence of the list of critically important microbials to be reserved for human use. I consider it of utmost importance that as quickly as possible the most valuable antibiotics are to be forbidden in group treatment of animals. The long-awaited list hopefully offers to do so.

You know that I had strong concerns about the Commission's delegated regulation of 26 May 2021 on the establishment of the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans. Rather than banning whole groups of antibiotics completely I would favour an approach that allows for considerate treatment of individual animals. The European Commission assured us in September 2021 that *'the number of antimicrobials which will still be available for use in animals will be limited to the bare*



minimum that is critical for veterinary medicineⁱⁱ. We are more than eager to see this promise put into practice.

I would also like to use this opportunity to recall that the European Commission had offered to exchange views with the European Parliament as the work for the implementing regulation on the list is progressing. To the present date such exchange of views has not taken place.

Commissioner, I know that I am speaking for many when I enquire about an update on the state of affairs on the list of antimicrobials to be reserved for human use. I would appreciate if your services could update me on the matter and am looking forward to soon exchanging with you in the European Parliament.

I look forward to your favourable reply.

Martin Häusling

ⁱ https://ec.europa.eu/food/system/files/2020-02/ah_vet-med_imp-reg-2019-06_mandate_art-107-6.pdf

ⁱⁱ https://martin-haeusling.eu/images/Veterinary_medicines_factsheet_EU_commission_sep21.pdf