Question for written answer E-000986/2022 to the Commission Rule 138 Joanna Kopcińska (ECR)

Subject: Criteria for antimicrobial labeling advice

The misuse and abuse of antimicrobials has led to the growing problem of antimicrobial resistance, which has been identified as one of the top ten global public health threats facing humanity.

The EMA/CVMP/678496/2021 working document of 16 February on advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans outlined three main criteria that will be formally defined in Commission Delegated Regulation (EU) 2021/1760.

Given that the Commission has welcomed the EMA's advice:

- 1. What action will the Commission take regarding the list and the criteria, and to what extent do the three criteria take into account the opinion of Member States and the concerns of epidemiological surveillance authorities regarding the advice presented?
- 2. With regard to a future delegated act, how could the list of proposed measures be updated procedurally after possible consultation with Member States?
- 3. What methodology will the Commission use to ensure that it can monitor the application of the designated criterion for the evaluation of certain substances and other veterinary medicines, in particular in relation to criterion C, and specifically antimicrobials that are not essential for animal health and whose selection may be of highly relative value?