



## ENVI committee 28 June exchange Delegated Act on criteria for identifying antimicrobial medicines reserved for treating humans

Dear Member of the European Parliament,

**EPRUMA calls for your support to endorse the draft Commission delegated regulation (DEA 2021/2718) on “Criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans” scheduled to be discussed in the ENVI Committee on Monday 28 June 2021.**

**Our call for support is based on the following 5 arguments:**

### 1. Science based decision making

The proposed delegated act is a prime example of a ‘One Health’ approach, being based on the scientific advice report from the European Medicines Agency (EMA) which takes into account expert opinions from both the human health side and the animal health side. The advice also took into account input from the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) as well as from the World Health Organisation (WHO) and the World Organisation for Animal Health (OIE). The WHO lists all antimicrobials important in humans and as WHO itself recommends this advice should be used in combination with the OIE list, which categorises all antimicrobials important for animals.

The European Medicines Agency scientific advice takes into account both the WHO and the OIE, but importantly also has adapted advice to the European health and resistance situation. The Delegated act is based on EMA’s scientific advice and should not be challenged.

### 2. Proportionality

In this Delegated Act, legislators have taken great care to find the correct balance between protecting human and animal health, and further building on and aligning with global efforts by the WHO, OIE and FAO Tripartite. In fact, the Delegated Act clearly gives priority to public health, by providing the option to reserve an antimicrobial for human use if there is an overriding public health interest.

Banning antimicrobials for animal use is the most severe risk management measure and should be avoided as much as possible. Whereas all antimicrobials listed on the reserved list will be totally prohibited for use in animals, under any circumstances, the implications on the health of both food producing and companion animals as well as to human health should be very carefully considered.

Therefore, banning authorised antimicrobials for animals without any scientific argument and science-based reasons is counter-productive and increases potential risks.

#### **EPRUMA**

168 Avenue de Tervueren, box 8, 5th floor  
1150 Brussels, Belgium  
email : [info@epruma.eu](mailto:info@epruma.eu)

Tel. : +32 2 542 7564  
Twitter : [@epruma1](https://twitter.com/epruma1)  
[www.epruma.eu](http://www.epruma.eu)

### 3. Responsible use

The ultimate target is the reduction of levels of antimicrobial resistance. By ensuring prudent and responsible use, by using antimicrobials by bacterial culture as often as possible and using antibacterial susceptibility testing (AST), and by focusing on the prevention of disease to reduce the need for treatment by e.g. good housing, good nutrition and hygiene measures, the aim is to minimise the need for using more antimicrobials.

The animal health sector has shown that it takes prudent use seriously, having reduced antibiotic sales by 34% between 2011 and 2018. This is the result of more than a decade of efforts in the animal health sector to increase disease prevention and improve animal health management through better hygiene practices, biosecurity measures, vaccine use and nutrition.

It is important to emphasise that regardless of the husbandry system, biosecurity measures, or other agricultural practices, animals can become sick and require treatment with antimicrobials. Antimicrobials are only used to treat animals that have been diagnosed by a veterinarian as requiring antimicrobial treatment.

It needs to be reiterated that the ultimate target is the reduction of levels of antimicrobial resistance.

### 4. Animal health and welfare

The new Regulation on Veterinary Medicines (Regulation 2019/6) which is planned to come into force in January 2022 will introduce important further measures to ensure responsible and prudent use, e.g. banning regular and group preventive treatments, promoting responsible prescribing by a veterinarian, and introducing the monitoring of use per species. These measures envisage a further reduction to the amount of antimicrobials used in animals, in line with the Farm to Fork Strategy.

Banning certain antibiotics for use in animals will have little effect on the human antimicrobial resistance burden. This is acknowledged by many scientific bodies and authorities, which have stated that about 75% of the total burden of infections with antibiotic-resistant bacteria in EU and EEA countries are associated with human patients and healthcare settings. In addition, the number of different antibiotics classes available for use in animals is very low compared to what is available in human medicine. To keep a range of different antibiotics allows effective treatment with the appropriate antibiotic when necessary ('right drug for the right bug') and prevents the building up of resistance.

As recognised by the EU Treaty, animals are sentient beings and deserve treatment too. The inability to treat susceptible infection has serious implications for animal health and animal welfare, and potentially for public health. Protection of human health often relies on proper prevention and treatment of disease in animals (zoonotic pathogens can be bacterial, viral, or fungal, and they represent 70% of all human diseases).

Imposing additional restrictions without robust scientific arguments and going beyond the defined criteria in the delegated act, will cause significant animal health and welfare problems as certain bacterial infections would no longer be able to be treated.

This will endanger public health and also have detrimental economic and social impacts for animal owners, such as for European farmers, who will have to destroy herds when diseases can no longer be treated, but it will also cause certain distress for European pet owners. And this while the EU is without doubt taking a leadership role in the fight against AMR and already has the strictest on a global level.

### 5. One health

Reservation of antimicrobials for humans only must be based on sound scientific criteria, based on a true "One Health" approach.

Antimicrobial resistance is threatening public health and our society. To combat it, a 'One Health' approach is needed as human health, animal health and the environment are all interlinked. Actions in one sector alone cannot solve this problem, as recognised also by the 'EC One Health AMR Action Plan'.

---

#### About EPRUMA

EPRUMA, the European Platform for the Responsible Use of Medicines in Animals, EPRUMA is a multi-stakeholder platform linking best practice with animal health and public health. It aims to promote the responsible use of medicines in animals in the EU. For further details, visit [www.epruma.eu](http://www.epruma.eu)