

# Commission Regulation / AMR / Reservation of antimicrobials for humans

## Why do we need this Delegated Regulation (DR)?

- Antimicrobial resistance (AMR) is a 'silent' pandemic :
  - Each year, **700.000 people die of AMR worldwide, 33.000 in the EU alone.**
  - Without action, the death toll will rise even higher, to **as many as 10 million deaths annually by 2050.**
  - To save human lives we need to **preserve the efficacy of those antimicrobials that are the most crucial for human medicine**, those of last resort that cannot be substituted by any other antimicrobials or other treatments.
- We need a holistic 'One Health' approach.
  - **The EU Regulation on veterinary medicinal products that will apply as of January 2022 promotes prudent and responsible prescription and use of antimicrobials in animals.**
  - A key measure is to reserve certain antimicrobials for human medicine only, banning their use in veterinary medicine.
  - The EU is **shaping the global agenda** in the fight against AMR, **since this measure will also apply to imports into the EU.**
  - EMA (European Medicines Agency) provided scientific advice on this matter, based on the **joint expertise of physicians and veterinarians**, working as **national experts** or as **experts from EMA, EFSA, ECDC**, as well as **WHO and OIE<sup>1</sup>**.
- The timely **entry into force of this Delegated Regulation is paramount**, as the preparation and application of the subsequent list of antimicrobials reserved for humans, as well as rules to apply the ban to imports rely on it.

## What is this Delegated Regulation about exactly?

- It sets **three criteria to select antimicrobials that will be reserved for human medicine and banned for veterinary medicine.**
- These criteria are: 1) high importance to human health; 2) risk of transmission of resistance; 3) non-essential need for animal health.

1- EMA (European Medicines Agency), EFSA (European Food Safety Authority), ECDC (European Centre for Disease Prevention and Control), WHO (World Health Organization), OIE (World Organisation for Animal Health)

## Why is a criterion of non-essential for need animal health included?

- The preservation of human health relies on the preservation of animal health, notably by ensuring food safety, preventing the development and spread of zoonoses (animal diseases infecting humans), but also, by keeping animals healthy, we avoid undue animal suffering and ensure animal welfare.

## Will the criterion of non-essential need for animal health allow for sufficient antimicrobials to be reserved for humans?

Yes, the third criterion has been designed in a way that, when applied, the following antimicrobials could be included in the list reserved for human medicine:

- Antimicrobials for which there is **no robust evidence of their need in veterinary medicine**.
- Antimicrobials that are **used to treat serious life-threatening infections in animals with major impacts, but for which there are alternative treatments available**.
- Antimicrobials that are **used to treat serious life-threatening infections in animals that have limited impacts (e.g. few animals affected), even in the absence of alternative treatments available, when the public health interest indicates that they should not be used in animals**.

This criterion limits the number of antimicrobials which will still be available for use in animals to the **bare minimum that is critical for veterinary medicine**.

## Why not use the same criteria as those the World Health Organization (WHO) used to establish its list of Critically Important Antimicrobials ('WHO CIA list')?

- WHO recommends that its list of Critically Important Antimicrobials should be used in conjunction with the list of antimicrobials of critical veterinary importance established by the World Organisation for Animal Health (OIE).
- This is fully reflected in the three criteria in the Delegated Regulation.

## Is the measure of reserving certain antimicrobials to human medicine enough? What about the remaining antimicrobials that are not listed?

- The new EU Regulation on veterinary medicinal products includes measures to ban the preventive use of antibiotics in groups of animals and to tightly restrict metaphylactic use.
- Those measures will apply to all antimicrobials that will not be reserved for human medicine and will significantly decrease the use of these other antimicrobials.

## Shouldn't the European Commission rather take action to improve farming practices where significant amounts of antimicrobials are still being used?

- Improvements over the last decade have seen sales of veterinary antimicrobials reduced by nearly 34% in Europe.
- The **Farm to Fork Strategy** sets an ambitious target to reduce overall EU sales of antimicrobials by 50% by 2030 for farmed animals and in aquaculture.
- It aims to **develop more sustainable food-producing systems and foresees measures to improve animal welfare**.
- The new EU Regulation on veterinary medicinal products sets **a robust legal framework to ensure that antimicrobials are not applied routinely, nor used to compensate for poor hygiene or farm management**.
- In addition to setting very tight rules on prophylactic and metaphylactic use, it enlarges the scope of the 2006 legislation banning the use of antibiotics for growth promotion.
- The **appropriate implementation and enforcement of this new set of measures will significantly contribute to curbing AMR more efficiently and to improving farming practices**.



## Why not allow for the treatment of individual animals using antimicrobials reserved for human medicine?

- When antimicrobials are included on the list reserved for human medicine, they cannot be used at all.
- The new rules do not foresee any exceptions as they would clearly weaken the impact of this measure.

## There is no certainty as to what antimicrobials will be reserved for humans. How can the EP be sure that the list will be meaningful and relevant?

- The European Commission will be happy to **exchange views with the EP as the work for the implementing regulation on the list of antimicrobials to be reserved for human medicine is progressing.**
- The European Commission will monitor through audits, the implementation and enforcement of the ban on the use of those antimicrobials reserved to humans in veterinary medicine, as well as the correct use of those antimicrobials that have not been listed due to their essential need for animal health.
- This would allow to **assess whether the new measures in place are being effective** and would be facilitated by the obligation under the new EU Regulation on veterinary medicinal products for EU Member States to collect data not only on the sales of antimicrobials, but also on the use of antimicrobials per animal species.

