EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Consultation meeting with stakeholders

Request from the European Commission for advice on the impact on public and animal health of the use of antibiotics in animals – Question 2

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# The EC has requested the European Medicines Agency to provide:

Advice on classes or groups of antibiotics ranked according to their relative **importance for their use in human** medicine, in particular considering whether these antibiotics are essential to treat multi-resistant infections in humans in the EU. The Agency should take into account the existing **work of the WHO on critical antibiotics** and consider the need, advantages, disadvantages and feasibility of **categorising** antibiotics as for example first line, second line or last resort antibiotics.

# Where is the link?

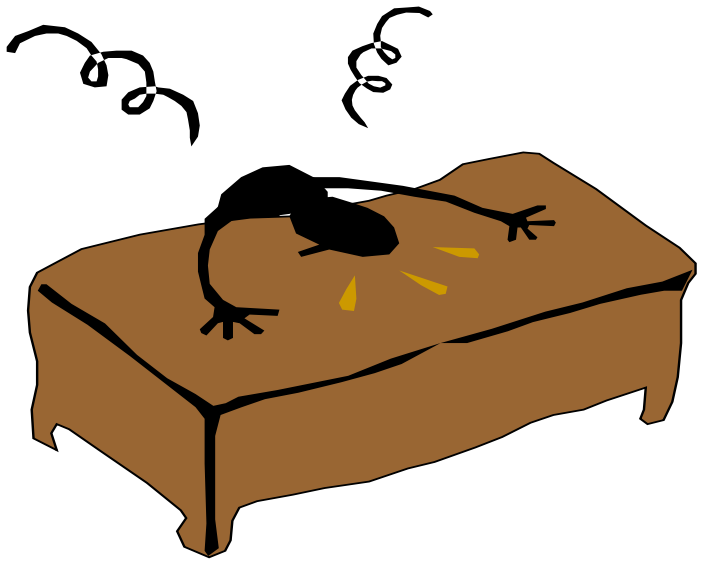
It may be critically important in human medicine without an animal reservoir or with low risk of transfer of resistance…

Penicillins and carbapenems are both classes of CIAs…

Conclusions should be based on risk analysis!

# The link is present but elusive…

1. Use of antimicrobial agent in animals
2. Selection pressure leading to increased number of resistant bacteria in the animal biota
3. Possibility of spread of resistant bacteria to humans
4. Possibility of colonisation of resistant bacteria (same clone) or horizontal transfer of resistance to other bacteria in the human biota
5. Possibility of treatment failure due to resistant infection in humans



# WHO first criteria

Antimicrobial agent is used as sole therapy or one of few alternatives to treat serious human disease.

- Globally relevant
- Minor amendments to comply with EU
- Still a long list…

# The second criteria needs to be specified

The aspects of evolution and organisation of the resistance mechanisms describing the likelihood of spread:

- Presence of stable mutations
- Organisation of resistance genes into horizontally transferable elements
- Presence of a cluster of resistance genes enabling efficient spread by co-selection
- Foodborne pathways

# List of CIA

Aminoglycosides

Carbapenems

3rd and 4th G cephalosporines

Cyclic esters

Fluoroquinolones

Glycopeptides

Glycylcyclines

Lipopeptides

Macrolides

Monobactams

Oxazolidinones

Penicillins

Polymyxins

Rifamycins

Tuberculosis medicines

Drugs not yet listed…

# No new risk assessments

Risk profiles on colistin and glycylcyclines made by AWP

AWP currently work on aminogycosides

Not feasible to make new risk assessments in AMEG but the presentation will be based on available information

# Other factors to consider when working with treatment guidelines

- Not only importance for human and likelihood of spread
- Need in animals (what is used instead?)
- Production forms
- Local disease situation
- Local resistance situation
- **Treatment guidelines must be locally defined and locally implemented!**

# Summary

The EC has requested the European Me ovide:

Advice on classes or groups of antibiotics ranked according to their relative **importance for their use in human** medicine, in pa er these antibiotics are essential to tre ns in humans in the EU. The Agency sh existing **work of the WHO on critical antibiotics** and consider the need, advantages, disad f **categorising** antibiotics as for exam or last resort antibiotics.

Important factor when setting priorities for risk analysis but not the sole factor of importance for risk management

WHO criterium 1 valid for EU but criterium 2 further developed

Must consider also various other factors which are determined locally