

Q1) Limiting factors are:

Not enough **alternative treatments**

Use of antibiotics is not prudent

No **holistic approach**

Key actions: These three points

Others (communication, education, etc.)

Q2) Information & Training: Learn from the MS that have experience in this.

Guidelines at different levels:

- global
- European
- national
- local

Q3) Restriction of use of cephalosporin in poultry in USA and not in the rest of the world is a good example. No clear conclusion can be drawn and need to be further investigated.



Q5) It is necessary that human beings have access to life-saving antimicrobials but we cannot forget animal health and production. Certain antimicrobials are necessary in livestock, poultry, etc.

Q 4) Can risk assessment only provide the basis for the decision whether a marketing authorisation of antimicrobials can be granted, restricted or withdrawn? Or specific circumstances or factors exist that risk managers have to adopt appropriate measures in cases with scientific uncertainty.

The current marketing authorisation legislation allows for the benefit-risk assessment of a given product to be considered only according to its own merit.

However, there is a need for an extended benefit-risk assessment which explicitly describes the importance of benefits and risks in the specific AMR issues context.

Provision should be made to develop a specific benefit-risk assessment to include critical factors. The idea would be to improve transparency, consistency and communication.



JOINT CONFERENCE ON AMR: STATE OF PLAY OF THE 5 YEAR ACTION PLAN

1) *Benefit-Risk Assessments are a key tool that we can use to manage AMR*

2) *Clear message of the opportunities and restrictions in the development of new antimicrobials*

3) *Importance of the benefit /risk assessment which is basic in the decision to either authorise or restrict the use of an AM*

4) *Consider available data on antimicrobial resistance (AMR) inside and outside the dossier and give adequate AMR related risks*

5) *Risk management measures in line with evidence-based principles in order to ensure that the measures taken reflect the real risk*