



Best use of medicines legislation to bring new antibiotics to patients and combat the resistance problem



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AMR a public health priority

***2011 Commission adopted AMR Action Plan
Further action needed !***

AMR Action Plan

Holistic / global approach
(human+veterinary/food) → in line
with “**One Health**” principle

The 12 actions

Human

Veterinary

1. Appropriate
use

4. Prevention of
infections

6. New
antibiotics

9. Surveillance

8. International
cooperation

11. Research &
Innovation

12.
Communication,
education

2 & 3. Appropriate
use & legal changes

5. Prevention of
infections

7. Need for new
antibiotics,
alternatives

10. Surveillance

My views on today's event

'Best use of medicines legislation to bring new antibiotics to patients and combat the resistance problem'

SMEs – a key role

Specific policies

Source of innovation

Session 1: Approval of new antibacterials

Action 6 AMR Action Plan

Bringing new antibacterials to patients

Action 8 AMR Action Plan

Multilateral and bilateral commitments

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Session 1: Approval of new antibacterials

- Clarity
- Flexibility
- Length of marketing authorisation procedure
- Risk-benefit
- International cooperation

Session 2: Encouraging appropriate use of antibacterials

Action 1 AMR Action Plan

**Strengthening the promotion of the
appropriate use of antibacterials**

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Session 2: Encouraging appropriate use of antibacterials

- Responsibility of all actors
- Authorities a key role
- Preparatory action

Session 2: Encouraging appropriate use of antibacterials

- Guidance
- Role of health professionals and authorities
- Competing priorities, need to involve all stakeholders

Session 2: Encouraging appropriate use of antibacterials

- The importance of surveillance data
- Summary of Product Characteristics

Session 3: Research and development

Action 6 AMR Action Plan

Bringing new antibacterials to patients

Action 11 AMR Action Plan

Reinforcing and coordinating research efforts

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Session 3: Research and development

- The basis for science-based policies and measures
- To provide new tools for diagnosis and new antibacterials

This event an important step in addressing AMR



http://ec.europa.eu/dgs/health_consumer/index_en.htm

Joint Procurement of Medical countermeasures

- Article 5 of Decision 1082/2013/EU on serious cross-border threats provides for the organisation and implementation of a joint procurement of medical countermeasures (entered into force on 6/11/2013).
- The Joint Procurement Agreement will now have to be approved, signed and ratified by each Member State according to the national approval process.
- The first joint procurement will be to procure pandemic vaccines.
- Currently, 27 EU Member States intend to sign the Joint procurement agreement and 24 Member States intend to procure pandemic vaccines.