



Better Training for Safer Food *Initiative*

Antimicrobial Resistance One Health approach

SUMMARY OF THE COURSE

BTSEF

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Food safety

Malaga, Spain – 25-28 November 2019

S1 – INTRODUCTION TO AMR

AMR Occurrence factors and general concepts.

- **Antimicrobial**
- **Antimicrobial resistance**
- **Inherent** (natural) resistance
- **Acquired resistance**
 - Mutational resistance
 - Vertical gene transfer
 - Horizontal gene transfer

Mechanisms of antibiotic resistance

Consequences of AMR

AMR Occurrence factors and general concepts. The “One Health”

'One Health' is an approach to designing and implementing programs, policies, legislation and research in which multiple sectors work together to achieve better public health outcomes.

The area of work in which a One Health approach is particularly relevant is combating antibiotic resistance

S2 – 2017 EU AMR ACTION PLAN

EU AMR Action Plan 2011-2016

5-year action plan, based on the holistic approach including 12 actions, divided in 7 areas, to be taken both from human and veterinary field.

It has been successful at stimulating action to tackle AMR within MS, EU and globally but action is still needed in all the sectors

EU AMR Strategy 2017: 3 strategic pillars



Commission's EU One Health Action Plan against AMR (JUNE 2017)

- Supporting Member States and making the EU a best-practice region on AMR
- Boosting research, development and innovation against AMR
- Shaping the global agenda on AMR

S2 – 2017 EU AMR ACTION PLAN

Implementation of activities under pillar 1

- EU guidelines prudent use of antimicrobials in human (June 2017)
- Adoption of the new regulation VM and MF (January 2019)

Implementation of activities under pillar 2

- October 2017 launch of Horizon 2020 work programme for 2018-20

Implementation of activities under pillar 3

- SANTE collaboration with FAO on a FAO manual on practical stepwise approaches to implementing prudent antimicrobial use guidelines (January 2018)

S3 - RELEVANT INTERNATIONAL INITIATIVES

International initiatives in relation to AMR - WHO, UN, FAO, OIE, Codex Alimentarius, GHSA, TATFAR, G7, G20, and UE initiatives (relations with China, Free trade agreements, DEVCO, etc.)

TATFAR: The Transatlantic Taskforce on Antimicrobial Resistance

GHSA: Global Health Security Agenda

CODEX ALIMENTARIUS

OIE

FAO

WHO

UN: United Nations

G7

G20

DEVCO



And several initiatives of EU and agreements with different countries

S4 - EU LEGISLATIVE FRAMEWORK

Overview of the EU legal AMR framework: General approach – H/V

HUMAN SECTOR

Directive 2001/83/EC on **medicinal products for human use**

Regulation (EC) No 726/2004 on **procedures for the authorisation and supervision of medicinal products** for human and veterinary use and establishing **EMA** (revision on-going, provisions on Vet. Medicines proposed to be moved to a new Regulation).

Decision No 1082/2013/EU on **serious cross-border threats to health**

VETERINARY SECTOR

New Regulation (EU) 2019/6 on veterinary medicinal products and 2019/4 on the manufacture, placing on the market and use of medicated feed.

S5 - EU AGENCIES AND THEIR COOPERATION

ECDC

Occurrence of resistance in humans: **EARS-Net** and **FWD-Net**

Consumption of antimicrobials in humans: **ESAC-Net** and **HAI-Net**

EFSA

Scientific Network for Zoonosis Monitoring Data: collects and analyse data on antimicrobial resistance in zoonotic and commensal indicator bacteria from food, food-producing animals and food

EMA: European Surveillance of Veterinary Antimicrobial Consumption: **ESVAC**

Interagency cooperation

RONAFA: **EFSA+EMA** opinion on the reduction of the need to use antimicrobials in animal husbandry

AMEG: Antimicrobial Advice Ad Hoc Expert Group (**EMA+ECDC+JIACRA**)

S6 – Source of data

- **Human field:** ESAC-Net includes wholesales data and reimbursement
- **Veterinary field:** MSs information from MAH and wholesalers

S7 – Measure units

- Units used in the Human field
- Units used in the Veterinary field

S8 – Categories

According to their risk for public health:

- **C1** - approved for use in animals
- **C2** - approved for use in food producing animals, where there is a higher potential for spread of resistance to humans.
- **C3** - Classes that are not approved for use in veterinary medicine

S9 – EU Guidelines on AMR:

- Commission guidance documents on prudent use of antimicrobials
- EU Guide for veterinary sector

MONITORING AND REPORTING OF ANTIMICROBIAL RESISTANCE

S10 – In human medicine

Four concepts:

- Antimicrobial susceptibility testing
- Minimal Inhibitory concentration (CMI)
- Clinical breakpoints
- Epidemiological cut off value (ECOFF)

S11 – In veterinary medicine

- Harmonised monitoring
- Prevalence of resistant microorganisms in food-producing animals and food
- Harmonised monitoring of the *Salmonella* spp., and *E. coli* producing the following enzymes: (a) Extended-Spectrum β -Lactamases (ESBL); (b) AmpC β -Lactamases (AmpC); (c) Carbapenemases
- Making the connection between antibiotic use and AMR

MONITORING AND REPORTING OF ANTIMICROBIAL RESISTANCE

S12 – Interpretation of results from breakpoints

- More information can be obtained with MICs than when only use clinical breakpoints
- Breakpoints can be modified by different committees over time (resistance rates can be reinterpreted when MICs are available)
- MICs avoids differences between different breakpoints
- Clinical breakpoints might be ineffective to detect resistance mechanisms and MICs are useful for this purpose
- MICs can simplify complex resistance mechanisms
- MICs are relevant when using molecular methods for surveillance

ROLE OF ENVIRONMENT IN SPREADING AMR

S13 – Introduction to environmental risks

- Environmental AMR and what are the major concerns around AMR in the environment
- Topics related to the emergence, drivers and perpetuation of AMR in the environment.

S14 – Relevance of AMR to Environment and related regulators

- Review of ERA guidelines
- Inclusion of ERA in risk-benefit analysis of medicines for human use
- Research needs and frameworks for implementation and minimization of the spread of AMR

S15 – JIACRA Report



- Relationship between AMC and AMR in animals and humans
- Conclusions and recommendations in a one-health perspective:
 - There is a link between consumption of antimicrobials in animals and humans and occurrence of resistance.
 - There are still important differences in the consumption of antimicrobials in animals and humans across EU countries.



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