

LARAS
LATIN AMERICAN
RISK ASSESSMENT
SYMPOSIUM



AMR as a global public health concern; European overview and initiatives

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European
Commission



**A European
One Health
Action Plan
against
Antimicrobial
Resistance
(AMR)**

NEW EU ONE HEALTH ACTION PLAN AGAINST AMR

Adopted 29 June 2017
75 actions under 3 pillars

https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf



1. MAKING THE EU A BEST PRACTICE REGION

A. Better evidence and awareness of the challenges of AMR

- Strengthen One Health surveillance and reporting of AMR and antimicrobial use
- Benefit from the best evidence-based analysis and data
- Increase awareness and understanding

B. Better coordination and implementation of EU rules to tackle AMR

- Improve the coordination of Member States' One Health responses to AMR
- Better implementation of EU rules

C. Better prevention and control of AMR

- Strengthen infection prevention and control measures
- Promote the prudent use of antimicrobials

D. Better addressing the role of the environment

E. A stronger partnership against AMR and better availability of antimicrobials



2. BOOSTING RESEARCH, DEVELOPMENT AND INNOVATION

- A. Improve knowledge on detection, effective infection control and surveillance**
- B. Develop new therapeutics and alternatives, preventive vaccines, diagnostics**
- C. Develop new preventive vaccines, diagnostics**
- D. Develop novel diagnostics**
- E. Develop new economic models and incentives**
- F. Close knowledge gaps on AMR in the environment and on how to prevent transmission**



3. SHAPING THE GLOBAL AGENDA

- A. Stronger EU global presence**
- B. Stronger bilateral partnerships for stronger cooperation**
- C. Cooperating with developing countries**
- D. Developing a global research agenda**



IMPLEMENTATION OF ACTIVITIES UNDER PILLAR 1

EU guidelines prudent use of antimicrobials in human (June 2017)

One-Health AMR network (2017)

Second JIACRA report (July 2017)

Inter-agency opinion on AMR indicators (September 2017)

Joint action AMR and HCAI (September 2017)

DG SANTE and ECDC AMR One Health Joint Country Visits

AMR Training (BTSF) for Competent Authorities (November 2017)

European Antibiotic Awareness Day (November 2017)

Audits of EU legislation on AMR monitoring in food/animals (ctd)

Fact-finding missions prudent use (vet med) in Member States (ctd)

Adoption of the new regulation VM and MF (January 2019)



IMPLEMENTATION OF ACTIVITIES UNDER PILLAR 3

Signature letter of intent on AMR between FAO and EU for enhancing cooperation

SANTE participation in Codex Alimentarius Task force on AMR

SANTE collaboration with FAO on a FAO manual on practical stepwise approaches to implementing prudent antimicrobial use guidelines

Joint paper of TATFAR partners on incentives for antibacterial drug development (October 2017)

AMR cooperation activities with India (VMP, November 2017) and South-American countries (ongoing)

Work with G20 and G7 (AMR in G7/G20 Health Minister Communique 2017, 2017 G7 CVO common approach on prudent use in vet medicine)



IMPLEMENTATION OF ACTIVITIES UNDER PILLAR 2

Investing in AMR R&D and innovation October

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

https://ec.europa.eu/health/amr/projects_en

The G20 (2017) called for a new international R&D Collaboration Hub on AMR .

Call topics include:

- data mining to enable early detection of infectious diseases threats and resistant pathogens.
- development of new antimicrobials and alternatives to antimicrobials.
- collaboration with the Russian Federation on HIV and TB research.

- to maximize the impact of existing and new anti-microbial basic and clinical research initiatives as well as product development.
- The Commission looks forward to further coordination and alignment of different initiatives in AMR research, which is in full alignment with the new European One health action plan

EU GUIDELINES PRUDENT USE OF ANTIMICROBIALS IN VETERINARY MEDICINE (SEPTEMBER 2015)

HOW IT WAS DONE?

11.9.2015

EN

Official Journal of the European Union

C 299/7

EU Antimicrobial Group VET. (AMGV)

representatives of all Member States
of the EU



Small subgroup appointed to support
EU network

Regular meetings in Brussels

Coordinated by EU



COMMISSION NOTICE

Guidelines for the prudent use of antimicrobials in veterinary medicine

(2015/C 299/04)

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Scope and purpose

11.9.2015

EN

Official Journal of the European Union

C 299/7

COMMISSION NOTICE

Guidelines for the prudent use of antimicrobials in veterinary medicine

(2015/C 299/04)

Purpose:

- Practical guidance by development of national strategies
- Promote prudent use AM in vet. sector
- Contribute /complement control AMR in humans

Use in conjunction with:

- National guidelines
- Stakeholder guidelines
- WHO, FAO, OIE standards/guidelines
- Council Recommendation 2002/77 on prudent use AB in humans



Guidelines → no legislation → additional to → not binding...



PRINCIPLES FOR THE PRUDENT USE OF ANTIMICROBIALS

Use of Antimicrobials → conform legislation:

- According to authorization (SPC)
- Off-label use (cascade)
- Medicated premixes

Prudent use (appropriate/responsible) should result in:

- More **rational and targeted** use
- **Overall reduction** of use

Veterinary diagnostic, prescription and dispensation based on specific diagnosis: clinical examination, laboratory diagnosis, ST.

Metaphylaxis need for treatment, clinical findings of disease in flock/herd

Routine prophylaxis must be avoided. Prophylaxis must be reserved for exceptional cases

Antimicrobial treatment: **narrow spectrum, single substances, according vet. Prescription**

Special restrictions: use in food production animals, CIAs, off-label/cascade

Alternative disease control strategies



RESPONSIBILITIES

Multidisciplinary responsibility: authorities and stakeholders

1. Prescriber
2. Administrator of the antimicrobial
3. Pharmaceutical industry, pharmacists, retailers, wholesalers
4. Feed business operators
5. Food business operators
6. Veterinary faculties and agriculture schools
7. Veterinary professional associations
8. Industry stakeholder associations
9. Farmers' associations
10. Competent authorities
11. Laboratories



EU GUIDELINES FOR THE PRUDENT USE OF ANTIMICROBIALS IN HUMAN HEALTH (JUNE 2017)

Introduction



Provide guidance on generic **elements** of good practice on how to prudently and appropriately use antimicrobials in human medical practice:

- Measures to be considered by Member States
- Systems and processes when developing and implementing strategies

Target audience: actors responsible for, or play a role in, antimicrobial use

PRINCIPLES AND ELEMENTS INCLUDED IN THE GUIDELINES

- National, regional and local governments
- Healthcare facilities
- Clinical microbiologists
- Infectious disease specialists
- Prescribers
- Pharmacists
- Nurses
- Infection control practitioners
- Public/patients
- Professional associations and scientific societies
- Research funders
- Pharmaceutical/Diagnostic industry
- International collaboration



EU GUIDELINES PRUDENT USE OF ANTIMICROBIALS IN HUMAN (JUNE 2017)

NATIONAL, REGIONAL AND LOCAL GOVERNMENTS

Regulation of antimicrobials

Antimicrobial prescribing and **stewardship**

Education of health professionals



Antimicrobial prescribing and stewardship:

- Implementation of Antimicrobial stewardship programmes at all levels of care
- Qualitative and quantitative targets
- Availability of open data on antimicrobial consumption for benchmarking and on antimicrobial resistance for clinical guidance
- A mechanism for the development, implementation and monitoring of clinical guidance for infections

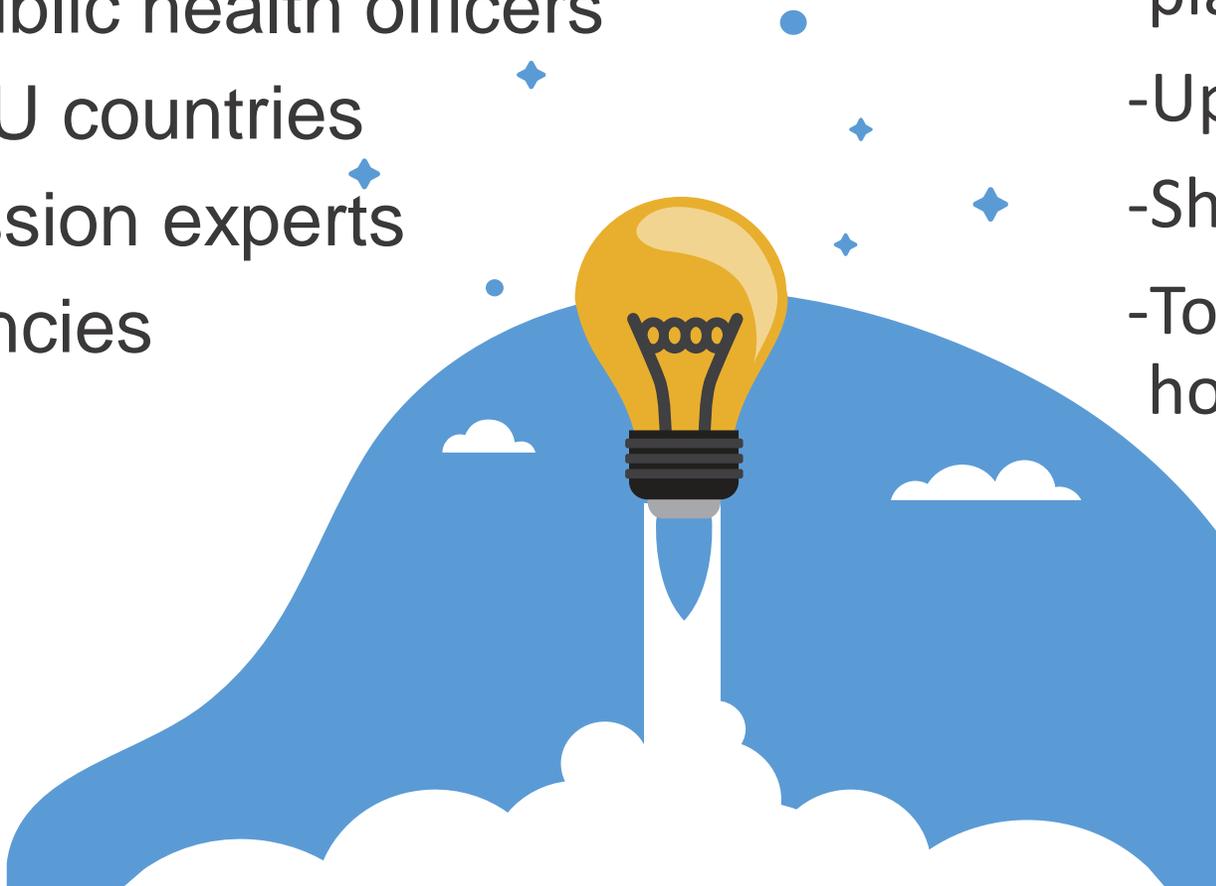
ONE-HEALTH AMR NETWORK (2017)

Representatives:

- Chief veterinary officers
- Chief public health officers
- All 28 EU countries
- Commission experts
- EU agencies

Networking platform:

- to present national action plans
- Up to date on progress
- Share best practices
- To discuss policy options and how to enhance coordination



SECOND JIACRA REPORT (JULY 2017)

JOINT INTERAGENCY ANTIMICROBIAL CONSUMPTION AND RESISTANCE ANALYSIS (JIACRA) REPORT

- Interagency collaboration
- Analysis of the relationships, in humans/animals, between:
 - Antimicrobial Consumption (AMC) vs. Antimicrobial Resistance (AMR)
- To cover the years 2013, 2014 and 2015



JIACRA REPORT CONCLUSIONS



important differences exist in the amounts of antibiotics people and animals consume in different EU countries

in different EU countries



an **increase in antibiotics use** = increase in **resistant bacteria**

resistant

There is a **link** between **consumption** of antimicrobials in animals and humans and **occurrence of resistance**.

Added value of linking AMC and AMR data

Added value of a synthetic view of the AMC and AMR situation through limited number of consistent indicators to follow up the situation over time

Higher is the AMC, higher is the risk of AMR!

There is a need to **promote responsible use** of antibiotics in both humans and animals.

P.-A. Belœil (EFSA). ECDC/EFSA/EMA second joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food producing animals

INTER-AGENCY OPINION ON AMR INDICATORS (SEPTEMBER 2017)

EC evaluation of 2011 5-year AMR action plan...
'called **for** further **strengthening of monitoring and surveillance** of AMR and AMR-related activities [...] **developing indicators** and instruments to monitor trends in resistant infections and antimicrobial consumption'



Council conclusions June 2016... 'call upon MS to have in place before mid-2017 national action plans against AMR based on the **'One Health'** approach and including **measurable goals** to reduce infections in humans and animals, the use of antimicrobials in the human and veterinary sectors and antimicrobials resistance in all domains'

INTER-AGENCY OPINION ON AMR INDICATORS (SEPTEMBER 2017)

REQUIREMENTS

MAXIMUM 15
INDICATORS, DIVIDED
IN: **PRIMARY
INDICATORS**
(MONITORING
ESSENTIAL POINTS)
AND **SECONDARY
INDICATORS**
(MONITORING HIGHLY
RECOMMENDED
POINTS TO ASSESS
PROGRESS MADE IN
MEMBER STATES'
PLANS)

01

SUITABLE TO ESTIMATE
PROGRESS MADE IN
REDUCING AMR TO KEY AMS IN
ACCORDANCE WITH WHO,
AMEG AND OIE DEFINITIONS

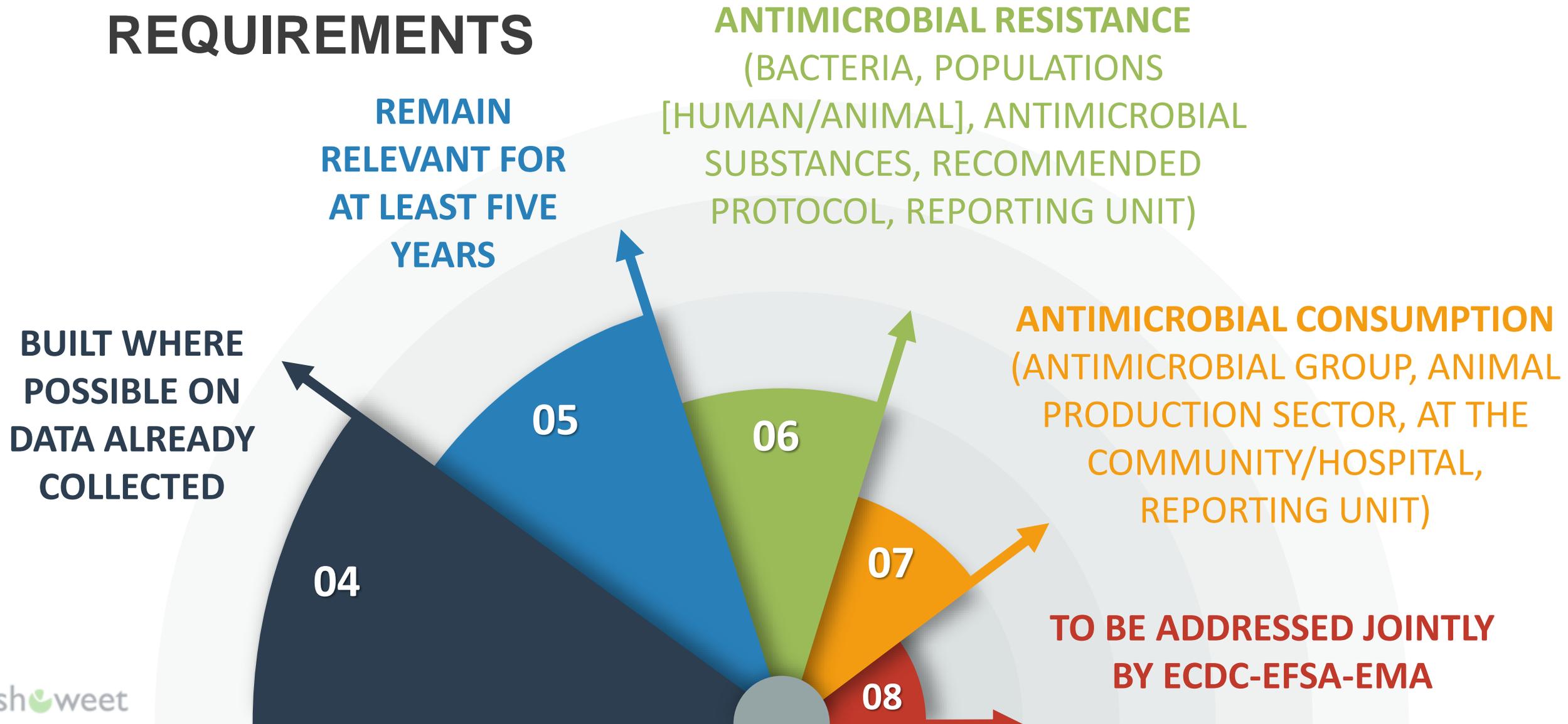
02

ROBUST, TAKE INTO
ACCOUNT '**ONE HEALTH**'
APPROACH TO TRACK
AND COMPARE
IMPROVEMENTS IN
HUMAN/VET SECTORS

03

INTER-AGENCY OPINION ON AMR INDICATORS (SEPTEMBER 2017)

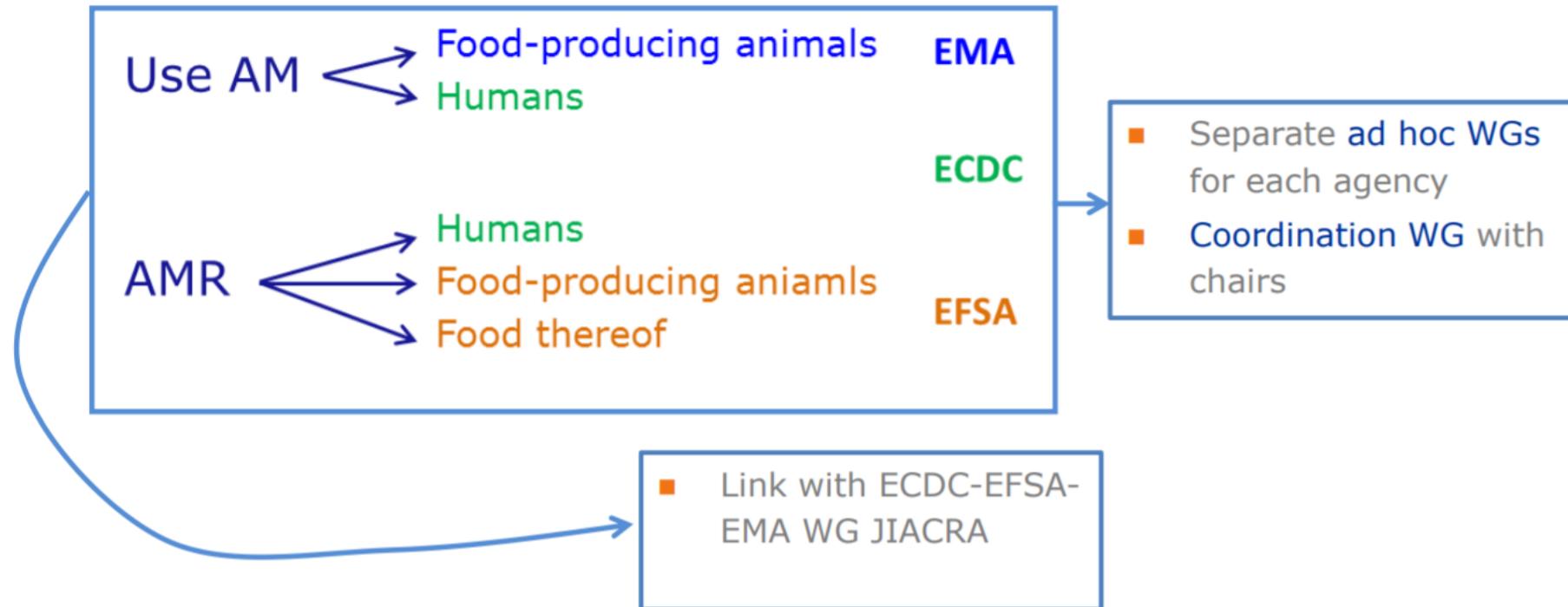
REQUIREMENTS



INTER-AGENCY OPINION ON AMR INDICATORS (SEPTEMBER 2017)

REQUIREMENTS

- Adoption by respective bodies of the Agencies



INTER-AGENCY OPINION ON AMR INDICATORS (SEPTEMBER 2017)

REQUIREMENTS

AMC in Humans

One primary indicator: **Total consumption of all antimicrobials for systemic use** (DDD per 1,000 inhabitants per day)

Two secondary indicators

AMR in Humans

One primary indicator: **Proportion of methicillin-resistant *Staphylococcus aureus* (MRSA) and proportion of *E. coli* resistant to 3rd-generation cephalosporins (3GCR *E. coli*)**

Three secondary indicators



AMC in food animals

One primary indicator: **Overall sales of AM in mg/PCU**

Three secondary indicators

AMR in food animals

One primary indicator: **Proportion of *E. coli* completely susceptible to antimicrobials tested in the EU monitoring***

Three secondary indicators

EU-JAMRAI: THE PLACE TO BE TO TACKLE AMR!



Tackle AMR

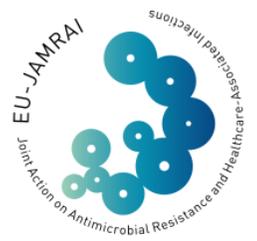


Stop working *in silo*

EU-JAMRAI

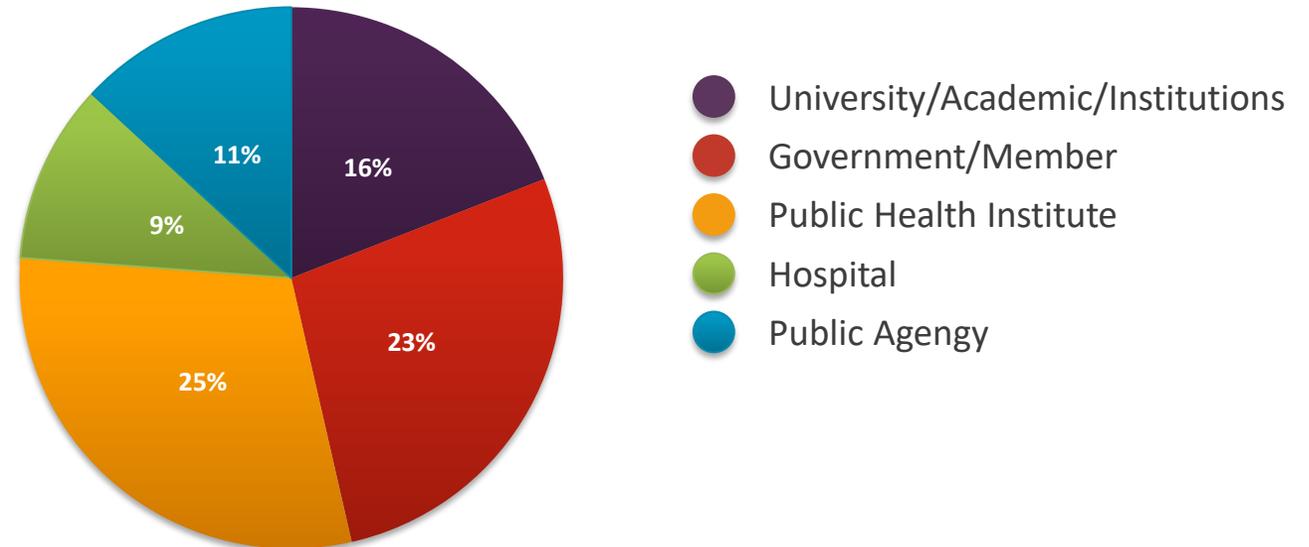
A unique place gathering MS and all stakeholders

All key actors working together to fight AMR and reduce HCAI



27 countries

44 participating partners

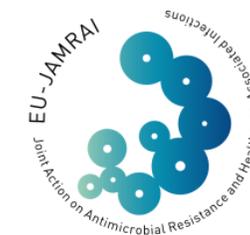


40 international stakeholders

- International organisations
- Civil society
- Industries
- Professionals of human and animal sectors



Bridge the gap between declarations and actions!



YESTERDAY

--- Strategic ---

DECLARATIONS

&

----- Strong -----

Political Will

EU-JAMRAI



Healthcare professional



*Hospital/
veterinary clinic*



Patient

TOMORROW

-- To implement --

CONCRETE ACTIONS

at **Operational Level**



**Reduction of
AMR Burden**

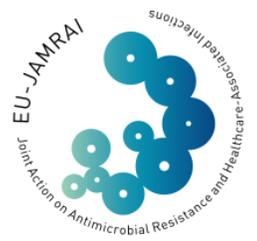


Animal health



Environment

MAKE OUR DREAMS COME TRUE: take-home messages



EU-JAMRAI is a small step forward
DOWN THE ROAD of **AMR reduction**
contributing to:

AMR REDUCTION

1- Decrease
consumption
of antibiotics
in humans and
animals



2- Test wide
implementa-
tion of
programs to
prevent HCAI

3- Analyse
gaps in
national
action plans



4- Propose
incentives for
the
development
of antibiotics
and diagnostic
tools

5- Improve
surveillance
in human and
animal



6- Increase
awareness on
AMR

AMR TRAINING (BTSF) FOR COMPETENT AUTHORITIES (NOVEMBER 2017)

Commission training initiative covering food and feed law, animal health and welfare and plant health rules.
"Train the trainers" principle

Prevention and control of AMR in the context of an overall **One Health** approach

Participants are involved at central level in monitoring, surveillance, reporting and control activities



Objectives

Spreading knowledge on methods of prevention and control of AMR in the veterinary and human medicine sectors with a "One health" approach;

Further **harmonising** Member States' approaches and sharing best practices in the field of use of antimicrobials;

Increasing the **efficacy** of the **competent authority** in the field of AMR monitoring, reporting and control;

Increasing the **compatibility** of procedures and practices between public health authorities and veterinary/food safety authorities **across the EU**.

NEW VETERINARY REGULATION

7.1.2019

EN

Official Journal of the European Union

L 4/43

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

on veterinary medicinal products and repealing Directive 2001/82/EC

(Text with EEA relevance)

Definitions of AMR

Scientific risk-benefit analysis for granting of marketing authorisations for veterinary antimicrobials

The prudent use of antimicrobials.

A legal tool to preserve certain antimicrobials for human use

Provide incentives for the development and marketing of new medicines

ADDRESSING AMR

All antimicrobial products shall be subject to veterinary prescription

Possibility to require post-authorisation studies from marketing authorisation holders

Specific information (conditions/restrictions on the use) to be included in the SPC

To improve the operation of the cascade (restriction off-label use) the Commission may establish a list of products which cannot be used off-label or can only be used subject to certain conditions

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

on veterinary medicinal products and repealing Directive 2001/82/EC

(Text with EEA relevance)

ARTICLE 107

USE OF ANTIMICROBIALS

Antimicrobial medicinal products **shall not be applied:**

- ✓ routinely to compensate for poor hygiene, inadequate animal husbandry or lack of care or to compensate for poor farm management.
- ✓ in animals for the purpose of **promoting growth** nor to increase yield.
- ✓ for prophylaxis other than in exceptional cases, for the administration to an individual animal or a restricted number of animals when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe.
- ✓ the use of antibiotic medicinal products for prophylaxis shall be limited to the administration to an individual animal only.

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 11 December 2018
on veterinary medicinal products and repealing Directive 2001/82/EC
(Text with EEA relevance)

ARTICLE 107

USE OF ANTIMICROBIALS

Antimicrobial medicinal products **shall be used for metaphylaxis only** :

- a) when the risk of spread of an infection or of an infectious disease in the group of animals is high and where **no other appropriate alternatives are available**.

- b) Member States may provide guidance regarding such other **appropriate alternatives** and shall actively support the development and application of guidelines which promote the understanding of **risk factors associated with metaphylaxis and include criteria for its initiation**.

PROPOSAL FOR A REGULATION ON MEDICATED FEED

Measures to fight the misuse of antimicrobials:

- Ban on the use in medicated feed for preventive treatment or as a growth promoter.
- Requirement for diagnosis of a disease prior to the mandatory prescription for medicated feed.
- Limitation of the duration of a treatment and of the validity of the prescription.
- EU-wide residue limit for veterinary medicines in ordinary feed.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2019/4 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC

A

- **NO USAR**
- Carbapenemes, fosfomicina, Cefalosporinas de última generación, Glicopéptidos,
- Glicilciclinas, Lipopéptidos, Monobactams, Oxazolidinonas, Riminofenazinas, Sulfonas,
- Tratamientos para tuberculosis y otras micobacterias

B

- **RESTRINGIDA**
- Cefalosporinas de 3ª y 4ª generación,
- Fluoroquinolonas y otras quinolonas,
- Polimixinas

C

- **CAUTELA**
- Aminoglicosidos and aminocyclitol, Aminopenicillins in combination with β -lactamase inhibitors (e.g. amoxicillin-clavulanic acid, co-amoxiclav), Amphenicols (florfenicol & thiamphenicol), Cephalosporins, 1st- and 2nd-generation and ephamycins, Macrolidos, Lincosamidas, Pleuromutilins, Rifamycins

D

- **PRUDENCIA**
- Aminopenicillins, without β -lactamase inhibitors, Cyclic polypeptides (bacitracin), Nitrofurantoin derivatives (e.g. nitrofurantoin), Nitroimidazoles, Penicillins: Anti-staphylococcal penicillins (β -lactamase-resistant penicillins), Penicillins: Natural, narrow spectrum penicillins (β -lactamase-sensitive penicillins), Steroid antibacterials (fusidic acid), Sulfonamides, dihydrofolate reductase inhibitors and combinations, Tetracyclines

¡Muchas gracias!



www.resistenciaantibioticos.es



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