



New EU Action Plan against AMR: state of play of implementation

**One-Health Network on AMR
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AMR: HEALTH AND ECONOMIC COSTS

25 000 deaths

€1.5 billion economic loss

By 2050: **Economic damage** on par
with the 2008 financial crisis

2011-2016 EC AMR Action Plan evaluation

RECOMMENDATIONS

AMR problem persists and continued action is needed

Support and assist EU Member States as big differences still exist between them

Reinforce the One Health approach (incl. environment)

Pursue coordination and collaboration on research and innovation and boost the development of new antimicrobials, alternatives, vaccines and rapid diagnostic tests.

Enhance EU international cooperation





European
Commission



Adopted 29 June 2017

75 actions under 3 pillars

9 DGs involved



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

Open public consultation – Administrations, associations and other organisations

QUESTIONNAIRE FOR ADMINISTRATIONS, ASSOCIATIONS AND OTHER ORGANISATIONS

Public Consultation on possible activities under a 'Commission Communication on a One Health Action Plan to support Member States in the fight against Antimicrobial Resistance (AMR)'

Fields marked with * are mandatory.

INTRODUCTION

QUESTIONNAIRE FOR ADMINISTRATIONS^[1], ASSOCIATIONS AND OTHER ORGANISATIONS^[2]

GENERAL CONTEXT

This questionnaire is a working document prepared by the European Commission. This consultation aims to collect the views of administrations, associations and other organisations for the 'Commission communication on a One Health action plan to support Member States in the fight against antimicrobial resistance (AMR)'. The outcome of this public consultation will provide input to the currently ongoing process on proposals for the Commission communication. It is without prejudice to the final position of the European Commission.

The consultation builds on several already completed activities including:

- The public consultation on a roadmap for a 'Commission communication on a One Health action plan to support Member States in the fight against antimicrobial resistance (AMR)', published on October 2016
- The evaluation of the European Commission's 2011-2016 action plan against the rising threats from antimicrobial resistance, published on October 2016
- The Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance (10278/16) of 17 June 2016
- The Commission communication to the European Parliament and the Council on the action plan against the rising threats from antimicrobial resistance (AMR) (COM (2011) 748), published on November 2011

A SHORT INTRODUCTION ON ANTIMICROBIAL RESISTANCE

Antimicrobial resistance (AMR) describes a situation where microbes become resistant to antimicrobial medicines, making these medicines ineffective. AMR is a growing global threat and a significant societal and economic challenge. High political importance has been attached to the issue within the EU, the groups of 7 (G7) and 20 (G20) industrialised nations, the United Nations (UN) and international organisations such as the World Health Organization (WHO), the World Organisation for Animal Health (OIE) and the Food and Agriculture Organization of the United Nations (FAO). The Council conclusions of 17 June 2016 on AMR called for a reinforced EU strategy against AMR and a new and comprehensive EU action plan on AMR based on a One Health approach [3].

The European Commission's 2011-2016 action plan has been independently evaluated. The evaluation concluded that the EU can bring added value in the fight against AMR, by: 1) supporting Member States and making the EU a best practice region on AMR, 2) boosting research,

Consultation opened 27 January until 28 April 2017

Parallel consultation aimed at citizens

Objectives:

- Collect views on specific proposals under the three pillar approach
- Collect feedback from stakeholders on additional actions which could be of interest

Feedback received from 421 citizens and 163 stakeholders



MAKING THE EU A BEST PRACTICE REGION ON AMR

- Better evidence and awareness
- Better coordination and implementation of EU rules
- Better prevention and control
- Better addressing the role of the environment
- A stronger partnership against AMR and better availability of antimicrobials



BOOSTING RESEARCH, DEVELOPMENT AND INNOVATION ON AMR

- New economic models & incentives
- Better detection and control measures
- New antimicrobials, rapid diagnostic tests, vaccines & alternative therapies
- AMR in the environment



SHAPING THE GLOBAL AGENDA ON AMR

- Stronger EU global presence, partnering
- Stronger bilateral partnership for stronger cooperation
- Cooperating with developing countries
- Developing a global research agenda



MAKING THE EU A BEST PRACTICE REGION ON AMR

- 1. 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
- 2. 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
- 3. Better prevention and control of AMR**
 - Strengthen infection prevention and control measures
 - Promote the prudent use of antimicrobials
- 4. Better addressing the role of the environment**
- 5. A stronger partnership against AMR and better availability of antimicrobials**



Implementation of activities under pillar 1 (1/2)



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

One-Health AMR visits in Member States (June 2017)

Second JIACRA report (July 2017)

Inter-agency opinion on AMR indicators (September 2017)

Joint action AMR and HCAI (September 2017)

Implementation of activities under pillar 1 (2/2)



**AMR Training (BTSE) 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)**

**Trilogue negotiations on VMP/MF proposals
(January 2018)**



SHAPING THE GLOBAL AGENDA

1. Stronger EU global presence

- Contribute towards WHO, OIE, FAO, and Codex Alimentarius on development of international frameworks and standards/ norms/ guidelines/methodologies
- Sustain political attention and commitment to AMR action, including in the United Nations, G7 and the G20

2. Stronger bilateral partnerships for stronger cooperation

- Advocate EU standards and measures for tackling AMR in trade agreements
- Engage with major global players and strategic countries (Brazil, China, India)

3. Cooperating with developing countries

- Assist development of AMR strategies in food safety and animal health areas via regional training workshops (BTSF World)



Implementation of activities* under pillar 3 (1/2)

Signature letter of intent on AMR between FAO and EC (September 2017) for enhancing cooperation

SANTE participation in Codex Alimentarius Task force on AMR (November 2017)

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

*** : except RTD and DEVCO related activities**



Implementation of activities* under pillar 3 (2/2)



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)

*** : except RTD and DEVCO related activities**



Research Development and Innovation at the centre of the new Action plan

For making the EU a best practise region (pillar 1) and to shape the global agenda (pillar 3) we need to invest in novel knowledge, tools and solutions for which we rely on research

We will make use of different funding instruments under current and future framework programmes for research and innovation

We should make use of our brightest minds as well as use all the latest developments in technology, data handling and IT.



Investing in AMR R&D and innovation

October 2017 launch of Horizon 2020 work programme for 2018-20 with around €192 million committed to AMR

€143 under Societal challenge 1 (health demographic change and wellbeing) and €49 million under Societal challenge 2 (Food Security, Sustainable Agriculture, Forestry, Marine, Water Research and the Bioeconomy)

- *Call topics include:*
 - data mining to enable early detection of infectious diseases threats and resistant pathogens (budget for this €30 million)
 - development of new antimicrobials and alternatives to antimicrobials (€95 million)
 - collaboration with the Russian Federation on HIV and TB research (€10 million)





Investing in AMR R&D and innovation

The new Horizon 2020 work programme for 2018-20 also supports optimizing the development of antimicrobials

- we will fund developing a business plan for a Europe-wide clinical research network (with €3 million)
- such a network can potentially reduce the cost and time of clinical trials in infectious diseases, make medicine development more attractive,
- and bring more new products to the market.





Investing in AMR R&D and innovation

In November 2017, the Innovative Medicines Initiative launched a call for proposals to understand, demonstrate and quantify the value of diagnostics as tools to optimise antibiotic use and tackle antibiotic resistance.

- *budget €13.6 million*
- *expanding IMI's New Drugs for Bad Bugs programme that has already invested heavily in AMR*

In January 2018 the final report of the IMI project DRIVE AB published its findings on how to revitalize the antibiotic pipeline





Investing in AMR R&D and innovation

Supporting One Health research and addressing AMR in the environment

In January 2018 the One Health European Joint Programming started to create a sustainable European One Health framework

- to integrate and align medical, veterinary and food institutes through joint programming of research agendas matching the needs of European and national policy makers and stakeholders

In 2017 a Roadmap to a strategic approach to pharmaceuticals in the environment was launched

- to identify knowledge gaps, present possible solutions and explore how to protect the environment (and human health via the environment) while safeguarding access to medicines





Investing in AMR R&D and innovation

InnovFin Infectious Diseases (InnovFin ID), established jointly by the European Investment Bank and the European Commission provides loans for R&D in the area of ID

- €7.5m to €75m to innovative players active in developing vaccines, drugs, medical and diagnostic devices, and research infrastructures
- 7 operations signed to date (EUR 125 m) + active pipeline

Company	Contribution to fighting AMR
• Da Volterra	• Protection of gut microbiota when taking antibiotics, preventing C-diff and the proliferation of resistant bacteria
• Mobidiag	• Early detection of most relevant carbapenemase and vancomycin resistance markers
• AntibioTx	• A new class of antibiotics against various resistance strains such as MRSA and Streptococcus



Shaping the global agenda

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2. Stronger bilateral partnerships for stronger cooperation

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3. Cooperating with developing countries

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4. Developing a global research agenda

- improve global coordination of research



Developing a global research agenda

Supporting Member States joining forces in AMR research via the Joint Programming Initiative on AMR (JPIAMR)

- in 2017 the JPIAMR expanded globally with Egypt, India and South-Africa joining as new members
- in the first half of 2018 it aims to launch a Virtual Research Institute, providing a global platform for scientific interaction and research capacity building
- in January 2018 it issued a call for the identification and validation of new targets, the development of new therapies, and new tools for new treatments against pathogens on the WHO priority list



Developing a global research agenda

Supporting Member States joining forces in AMR research via the European and Developing Countries Clinical Trial Partnership (EDCTP)

- supports collaborative research with sub-Saharan Africa, in particular in relation to TB, HIV, malaria and NID
- European and Developing Countries Clinical Trials Partnership (EDCTP2) is a partnership between 14 European and 14 African countries
- has funded several new research projects, including four projects on clinical trials for the development of new TB vaccines. These projects that have started at the end of 2017 and in February 2018 with a total budget of €37 million





G20 on AMR



G20 GERMANY 2017
HAMBURG

The G20 (2017) called for a new international R&D Collaboration Hub on AMR to maximise the impact of existing and new anti-microbial basic and clinical research initiatives as well as product development. All interested countries and partners can join this new initiative.

- The Commission has agreed to join the interim phase preceding the official launch in the 1st half of 2018
- 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
- It sees the JPIAMR as an important stakeholder in the hub, as it already gathers 26 countries funding AMR related research



The fight against AMR: one challenge, many instruments

Collaborative projects



Public-private partnership with big pharma



Public-public partnerships with EU Member States & beyond

GLPID-R

One health EJP



Blue sky research



Grants for small businesses



Loans for small and big R&I companies



Knowledge triangle: Higher education, business, R&I

Research and Innovation



These deliverables are

- further strengthening the EU as a best practice region for AMR
- boosting research development and innovation, addressing knowledge gaps and enabling a comprehensive effort of both public and private research efforts
- allowing the EU to lead in shaping the global agenda



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Commission



**Thank you for your
attention**