

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, development and innovation against AMR; and 3) shaping the global agenda on AMR.

REPLIES TO THE QUESTIONNAIRE

We invite administrations, associations and other organisations to take part in this consultation. A separate consultation has been launched for citizens.

This consultation includes questions on human health, animal health and the environment, following a One Health approach.

We invite administrations at national or subnational (e.g. regional) level to coordinate their replies with all appropriate services dealing with human health, animal health and the environment in order to submit one single reply.

In the case of organisations and other associations, some of the questions might be out of your policy scope. As answers to the entire questionnaire are mandatory, we have reserved the option 'I do not know / Not applicable (NA)' for such cases.

The questionnaire should take about 30 minutes to complete and there are opportunities to make written recommendations.

[1] For the purpose of this survey, administrations refer to both public administrations and private administrations with public service obligations.

[2] For the purpose of this survey, associations and other organisations refer to trade associations, professional associations, academia and scientific societies and organisations representing the interests of specific stakeholders.

[3] The One Health concept recognises that the health of people is connected to the health of animals and the environment.

1. INFORMATION ABOUT THE RESPONDENT

Please provide the following data on your organisation/association/administration:

- * 1.1. Please indicate the name of your organisation/association/administration:

European Association of Urology (EAU)

- * 1.2. Please enter the country where your organisation/association/administration is based:

The Netherlands

- * 1.3. Please indicate whether your organisation/association/administration is listed in the Transparency Register*:

- ☒ Yes
☐ No

* In the interest of transparency, organisations and associations have been invited to provide the public with relevant information about themselves by registering in Transparency Register and subscribing to its Code of Conduct. If the organisation or association is not registered, the submission will be published separately from the registered organisations/associations.

- * 1.4. Please enter your e-mail address (*this data will not be made public*):

Information removed

- * 1.5. Please indicate the name of a contact person *(please note that the name will not be made public and is meant for follow-up clarification only)*:

Information removed

- * 1.6. Do you consent to the Commission publishing your replies?

- ☒ a) Yes *(On behalf of my organisation/association/administration I consent to the publication of our replies and any other information provided, and declare that none of it is subject to copyright restrictions that prevent publication)*
- ☐ b) Yes, only anonymously *(The replies of my organisation/association/administration can be published, but not any information identifying it as respondent)*
- ☐ c) No *(The replies provided by my of my organisation/association/administration will not be published but may be used internally within the Commission. Note that even if this option is chosen, your contribution may still be subject to 'access to documents' requests)**

* As set out in Regulation (EC) No 1049/2001, any EU citizen, natural, or legal person has a right of access to documents of the EU institutions, including those which they receive, subject to the principles, conditions and limits defined in this Regulation.

2. IDENTIFICATION OF RESPONDENT

- * 2.1. Main sector of the responding organisation/association/administration *(one answer possible)*:

- ☐ Public administration or private administration with public service obligations (other than payers)
- ☐ Payer (irrespective of status, i.e. public or private)
- ☐ Human healthcare provider
- ☐ Veterinary healthcare provider
- ☐ Patients and consumers
- ☐ Farmers and animal keepers
- ☐ Pharmaceutical industry
- ☐ Food industry
- ☒ Academia or scientific society
- ☐ NGO
- ☐ Other *(please specify)*

- * 2.1.1 Are you an umbrella organisation/association representing the interests of the stakeholders mentioned in question 2.1.? *(one answer possible)*:

- ☒ Yes
- ☐ No

* 2.2. Please specify the geographic coverage of your organisation/association/administration (*one answer possible*):


























- ☒ International
- ☐ European
- ☐ National
- ☐ Sub-national/local

3. PILLAR I: SUPPORTING MEMBER STATES AND MAKING THE EU A BEST PRACTICE REGION ON AMR

3.1. In order to ensure greater coherence and help Member States' efforts to fight AMR, a number of activities are listed in the table below.

Please rate the helpfulness of the following EU facilitated activities:

	Very helpful	Helpful	Less helpful	Not helpful	I do not know / NA
*a) Member States should hold regular discussions on AMR within a dedicated network on AMR (One Health network), gathering experts from the public health, animal health and environmental sectors	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*b) Member States should conduct voluntary peer-to-peer reviews of their respective national action plans against AMR and discuss the results within the One Health network	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*c) Member States should define measurable goals to reduce infections in humans and animals, the use of antimicrobials in the human and veterinary sector and antimicrobial resistance in all domains					
*d) The European Commission should coordinate and facilitate the sharing of best practices and exchange of information on national action plans of Member States on AMR					
*e) EU funds should be used to complement and help Member States in developing and implementing their national action plans against AMR					
*f) The European Commission should complement awareness raising activities of Member States on AMR					
*g) The European Commission should implement training programmes on AMR for Member States' competent authorities					

<p>*h) The European Commission should propose new EU initiatives in order to reduce antimicrobial use in people and the spread of AMR in humans</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>*i) The European Commission should propose new EU initiatives to reduce antimicrobial use in animals and agriculture and spread of AMR in/from these sources</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>*j) The European Commission should propose new EU initiatives to monitor antimicrobials and resistant microorganisms in the environment</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>*k) The European Commission should ensure stricter implementation by Member States' competent authorities of existing EU rules and measures that are designed to reduce the development and spread of AMR</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3.1.1. Please specify other concrete actions that could be helpful in ensuring greater coherence and fight against AMR.

Please limit your answer to 1500 characters:

Text of 100 to 1500 characters will be accepted

3.2. Please indicate your opinion on the following statements regarding EU surveillance systems:

	Strongly agree	Agree	Disagree	Strongly disagree	I do not know / NA
<p>*a) EU surveillance systems on AMR in human medicine [1] provide sufficient information to support actions aimed at preventing and controlling AMR in humans</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>*b) EU surveillance systems on antimicrobial consumption in human medicine [2] provide sufficient information to support actions aimed at preventing and controlling AMR in humans</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>*c) EU surveillance systems on AMR in animals [3] provide sufficient information to support actions aimed at preventing and controlling AMR in animal husbandry</p>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

<p>*d) EU surveillance systems on antimicrobial consumption in animals</p> <p>[4] provide sufficient information to support actions aimed at preventing and controlling AMR in animal husbandry</p>					
<p>*e) The integrated analysis [5] of the existing AMR and antimicrobial consumption data at EU level provides all the necessary information to support actions aimed at preventing and controlling AMR with a One Health approach</p>					

[1] European Antimicrobial Resistance Surveillance Network ([EARS-Net](#))

[2] European Surveillance of Antimicrobial Consumption Network ([ESAC-Net](#))

[3] Surveillance on zoonotic bacteria in animals and food by the European Food Safety Authority

[4] European Surveillance of Veterinary Antimicrobial Consumption ([ESVAC](#))

[5] [JIACRA report](#)

3.2.1. Please provide concrete examples of further data not currently collected within the EU and which collection could be helpful in the fight against AMR. Please justify your rationale for collecting this data and limit your answer to 1500 characters:

Text of 100 to 1500 characters will be accepted

3.3. The 2011-2016 action plan against the rising threats from antimicrobial resistance focused mainly on actions in human medicine and veterinary medicine. There may be a need to propose further EU actions to tackle AMR in the environment.

Several possible actions are listed in the table below. For each of these please provide your opinion on their usefulness by ticking the appropriate box:

	Very useful	Useful	Less useful	Not useful	I do not know / NA
*a) Limitation of antimicrobial discharges to the environment from the pharmaceutical manufacturing process	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*b) Limitation of antimicrobial and resistant microorganisms discharges to the environment from other possible hotspots (e.g. urban wastewater treatment plants, hospitals, manure and slurry stores)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*c) Limitation of the use of sewage sludge and animal manure/slurry as soil amendments unless subject to composting or similar measures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*d) Monitoring of antimicrobials and resistant microorganisms in the environment	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e) Other (<i>please specify</i>)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

- * 3.4. Vaccination against infectious disease represents one way to reduce the need to use antimicrobials. Different actors could play a useful role in promoting vaccination in humans and animals.

Please choose whether you want to reply to this question for the human health sector, the animal health sector, both or it is not applicable to your association/organisation:

- ☒ Human health
- ☐ Animal health
- ☐ Not applicable

3.4.1. Human Health

In the following tables actors that could play a useful role in promoting vaccination are listed.

Please rank your choice from 1 to 7, with 1 being the MOST important and 7 being the LEAST important actor in promoting the uptake / use of vaccination:

	(1) Most important	(2)	(3)	(4)	(5)	(6)	(7) Least important
*a) International organisations (e.g. WHO)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*b) European Commission	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*c) Member States	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*d) Pharmaceutical industry	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*e) Human healthcare providers (e.g. doctors, nurses, pharmacists)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*f) Non-Governmental Organisations (NGOs)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*g) Patients	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3.4.1.1. For the choice where you attributed the ranking (1) please give further details on what your expectations from this actor are and why this actor is preferred above the other actors. If your preferred actor is not listed in the table above, please specify it.

Please limit your answer to 1500 characters:

Text of 100 to 1500 characters will be accepted

It should be a responsibility of governments to promote vaccinations through widely promoted national programmes

* 3.5. The use of rapid diagnostics should help ensure that only antimicrobials which are effective are used to treat infectious disease. Different actors could play a useful role in promoting the uptake / use of rapid diagnostics in humans and animals.

Please choose whether you want to reply to this question for the human health sector, the animal health sector, both or it is not applicable to your association/organisation:

- ☒ Human health
- ☐ Animal health
- ☐ Not applicable

3.5.1. Human Health

In the following tables actors that could play a useful role in promoting rapid diagnostics' use are listed. Please rank your choice from 1 to 7, with 1 being the MOST important and 7 being the LEAST important actor in promoting the uptake / use of rapid diagnostics in the human health and animal health sectors:

	(1) Most important	(2)	(3)	(4)	(5)	(6)	(7) Least important
*a) International organisations (e.g. WHO)							
*b) European Commission							
*c) Member States							
*d) Pharmaceutical industry							
*e) Human healthcare providers (e.g. doctors, nurses, pharmacists)							
*f) Non-Governmental Organisations (NGOs)							
*g) Patients							

3.5.1.1. For the choice where you attributed the ranking (1) please give further details on what your expectations from this actor are and why this actor is preferred above the other actors. If your preferred actor is not listed in the table above, please specify it.
Please limit your answer to 1500 characters:

Text of 100 to 1500 characters will be accepted

Human healthcare providers are the most important actors concerning the rapid diagnosis of patients – they are in the best position to determine treatment.

4. PILLAR II: BOOSTING RESEARCH, DEVELOPMENT AND INNOVATION

4.1. The table below lists actions which could help to reduce barriers to the development of new antimicrobial medicines, vaccines, diagnostic tests and alternative therapies.
For each option, please indicate your opinion on the potential benefits of the actions by ticking the appropriate box:

	High benefits	Medium benefits	Low benefits	I do not consider this a potential benefit	I do not know / NA
<p>*a) Promote dialogue between stakeholders [1] to discuss human and animal antimicrobial development challenges</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>*b) Promote dialogue between stakeholders [1] to accelerate vaccine development for pathogenic bacteria which are resistant to a wide range of antimicrobial drugs</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>*c) Promote dialogue between stakeholders [1] to discuss on the regulatory framework for alternatives to the use of antimicrobial drugs</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>*d) Promote research on new economic models for the development of antimicrobial products</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>f) Other (<i>please specify</i>)</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

[1] E.g. regulators, health technology assessment (HTA) bodies, pharmaceutical industry, healthcare payers, etc.

4.2. In your opinion, what are the main obstacles to bringing new antimicrobials to patients in Europe?

Please rate the importance of the listed obstacles:

	Very important	Important	Less important	Not important	I do not know / NA
*a) Lack of funding in AMR R&D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*b) Lack of cooperation between publicly and privately funded research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*c) Lack of economic models incentivising R&D on AMR	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*d) Challenging regulatory environment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*e) Lack of dialogue between R&D players, regulators, HTA bodies and payers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*f) Lack of coordination between Member States and the EU	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g) Other (<i>please specify</i>)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4.3. In your view, which funding instruments could be important to stimulate R&D in AMR?
Please rate the importance of the listed funding instruments.

	Very important	Important	Less important	Not important	I do not know / NA
*a) Funding via EU Framework Programme Horizon 2020 grant schemes	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*b) The SME instrument under Horizon 2020	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*c) Loan-based funding instruments like InnovFin Infectious Diseases provided jointly by the EC and the European Investment Bank (EIB)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*d) Inducement Prizes	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*e) Public Procurement of Innovative Solutions	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*f) R&D funding provided by EC's public-public partnership JPIAMR	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

<p>*g) R&D funding provided by EC's public-private partnership IMI</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>*h) R&D funding provided by the European & Developing Countries Clinical Trials Partnership (EDCTP)</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

* 4.4. In your view, should the EU develop a list of R&D priorities for resistant pathogens (as done on a global level by WHO)? *(one answer possible):*

- ☒ Yes
- ☐ No
- ☐ No opinion

5. PILLAR 3: SHAPING THE GLOBAL AGENDA ON AMR

5.1. The table below lists international actions / activities through which the European Commission could help to tackle AMR internationally.

Please rate the usefulness of these actions / activities:

	Very useful	Useful	Less useful	Not useful	I do not know / NA
*a) Reinforced cooperation and advocacy of EU AMR policies with normative international organisations (WHO, OIE, FAO/Codex Alimentarius) and international fora (e.g. G7, G20, UN)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*b) Foster bilateral partnerships with key EU trading partners and major regional/ global players (e.g. USA, Canada, Brazil, China, India, South-Africa)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*c) Contribute towards AMR capacity building in developing countries (e.g. on surveillance and monitoring of AMR)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*d) Contribute towards AMR capacity building in candidate, potential candidate and neighbouring countries (e.g. on surveillance and monitoring of AMR)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
e) Other (<i>please specify</i>)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5.2. The table below lists a number of mechanisms which the European Commission could use to tackle AMR internationally.

Please rate the usefulness of each of these actions / activities:

	Very useful	Useful	Less useful	Not useful	I do not know / NA
*a) Non-binding cooperation	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*b) Trade agreements or partnership agreements	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*c) Capacity building	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
d) Other (<i>please specify</i>)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5.3. The European Commission and the EU Member States have an opportunity to help tackle the development of AMR at a global level.

In the table below a number of regions are listed. Based on your opinion and knowledge, in which of these do you think the EU would have the greatest influence and should focus its efforts?

Please rank your choice from 1 to 9, with 1 being the MOST preferred and 9 being the LEAST preferred:

	(1) Most preferred	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9) Least preferred
*a) North African region	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*b) Sub Saharan African region									
*c) North American region									
*d) Central & South American region									
*e) North Asian region									
*f) Central Asian Region									
*g) South Asian Region									
*h) Pacific Region									
*i) European Region (non-EU)									

5.3.1. For the choice where you attributed the ranking (1) please give further details and elaborate on your key criteria for this decision.

Please limit your answer to 1500 characters:

Text of 100 to 1500 characters will be accepted

Contact

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