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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)' (http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_176_action_plan_against_amr_en.pdf), published on October 2016
- The evaluation of the European Commission's 2011-2016 action plan against the rising threats from antimicrobial resistance (http://ec.europa.eu/dgs/health_food-safety/amr/docs/amr_evaluation_2011-16_evaluation-action-plan.pdf), published on October 2016
- The Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance (http://www.consilium.europa.eu/press-releases-pdf/2016/6/47244642809_en.pdf) (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 (http://ec.europa.eu/dgs/health_food-safety/docs/communication_amr_2011_748_en.pdf) (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 (http://www.rand.org/randeurope/research/projects/eu-action-plan-against-amr.html) 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 Molecular Biology Laboratory

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

With our headquarters and main laboratory in Heidelberg, EMBL is a geographically distributed intergovernmental research organisation with sites in Hinxton (UK), Grenoble (FR), Monterotondo (IT), , Hamburg (DE) and Barcelona (ES).

* 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)*:

max.eklund@embl.de

* 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)*:

Max Eklund

* 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 adminitration 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)*

Other *(please specify)*:

Text of 1 to 500 characters will be accepted

EMBL is Europe's flagship intergovernmental research organisation for the life sciences with more than 20 member states and one of the highest ranked scientific research organisations in the world.

* 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	○	◉	○	○	○
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	○	○	○	○	◉
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	○	○	○	○	◉
h) The European Commission should propose new EU initiatives in order to reduce antimicrobial use in people and the spread of AMR in humans	○	○	○	○	◉
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	○	○	○	○	◉
j) The European Commission should propose new EU initiatives to monitor antimicrobials and resistant microorganisms in the environment	○	◉	○	○	○
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	○	○	○	○	◉

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

EMBL shares the view that AMR is of global concern and that new antibiotics, diagnostic tools and risk mitigation policies are urgently required. We are however of the opinion that development of efficient interventional policies and practices for the health sector and agriculture are hindered by insufficient knowledge of the mechanisms underlying resistance development and transmission. To ensure a pioneering role in the fight against AMR, Europe should increase its efforts in funding basic research and public-private partnerships that provides mechanistic insights into AMR development and transmission, which can offer ways to bypass, mitigate or revert the AMR.

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
a) EU surveillance systems on **AMR in human medicine** [1] provide sufficient information to support actions aimed at preventing and controlling AMR in humans	○	○	○	○	◉
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	○	○	○	○	◉
c) EU surveillance systems on **AMR in animals** [3] provide sufficient information to support actions aimed at preventing and controlling AMR in animal husbandry	○	○	○	○	◉
d) EU surveillance systems on **antimicrobial consumption in animals** [4] provide sufficient information to support actions aimed at preventing and controlling AMR in animal husbandry	○	○	○	○	◉
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	○	○	○	○	◉

[1] European Antimicrobial Resistance Surveillance Network (EARS-Net (http://ecdc.europa.eu/en/healthtopics/antimicrobial-resistance-and-consumption/antimicrobial_resistance/EARS-Net/Pages/EARS-Net.aspx))

[2] European Surveillance of Antimicrobial Consumption Network (ESAC-Net (http://ecdc.europa.eu/en/healthtopics/antimicrobial-resistance-and-consumption/antimicrobial-consumption/ESAC-Net/Pages/ESAC-Net.aspx))

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

[4] European Surveillance of Veterinary Antimicrobial Consumption (ESVAC (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp))

[5] JIACRA report (http://ecdc.europa.eu/en/publications/publications/antimicrobial-resistance-jiacra-report.pdf)

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

Any future initiatives in collecting data on AMR should guarantee that collections of MDR strains and related data (such as whole genome sequencing, AMR characterization, 3D structural data) are made available freely to the global research community. Comprehensive surveillance procedures are to some extent already in practice in some European countries (e.g. Norway) and could serve as examples for other member states. Valuable information should not only include merely pathogenic isolates, but complete meta-data (mutation profile, resistance profile, metabolic protein catalogue, metabolite profile), including samples from the microbial community/context (microbiota) where the isolates where found. This latter information could facilitate future studies of horizontal AMR transmission, which is still a black box in our current understanding of AMR. Overall, such systematic surveillance policies could facilitate the development of intervention measures to limit or contain resistance transmission.

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**	○	○	○	○	◉
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)	○	○	○	○	◉
c) Limitation of the **use of sewage sludge and animal manure/slurry as soil amendments** unless subject to composting or similar measures	○	○	○	○	◉
d) **Monitoring** of antimicrobials and resistant microorganisms in the **environment**	◉	○	○	○	○
e) Other *(please specify)*	○	○	○	○	○

* 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

* 3.5. 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

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
a) Promote dialogue between stakeholders [1] to discuss human and animal **antimicrobial development challenges**	○	◉	○	○	○
b) Promote dialogue between stakeholders [1] to **accelerate vaccine development for pathogenic bacteria** which are resistant to a wide range of antimicrobial drugs	○	○	○	○	◉
c) Promote dialogue between stakeholders [1] to discuss on the **regulatory framework for alternatives** to the use of antimicrobial drugs	○	◉	○	○	○
d) Promote research on **new economic models** for the development of antimicrobial products	○	○	○	○	◉
f) Other *(please specify)*	◉	○	○	○	○

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

Other *(please specify)*:

Text of 100 to 1500 characters will be accepted

Awareness and research of today's most threatening pathogens is necessary, but not sufficient. Due to the almost in finite combinations of pathogens, resistance mechanisms and disease patterns, made more diverse still through gene transfer, we urgently need to increase the efforts of producing new knowledge that forms the scientific foundation that drug development relies on. For example, a bacterium that is currently a "low risk" commensal might easily be come a threatening pathogen tomorrow via acquisition of resistance, as has been the case with MRSA, VRE, or ESBL in the recent past. In order to understand and ultimately combat development and transmission/spread of resistance, w e need to further enhance the global understanding of the interactions between bacteria and their environment (i.e. host, microbial community, chemical and physical surrounding).

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	◉	○	○	○	○
b) Lack of cooperation between publicly and privately funded research	○	◉	○	○	○
c) Lack of economic models incentivising R&D on AMR	○	○	○	○	◉
d) Challenging regulatory environment	○	○	◉	○	○
e) Lack of dialogue between R&D players, regulators, HTA bodies and payers	○	○	◉	○	○
f) Lack of coordination between Member States and the EU	○	○	○	○	◉
g) Other *(please specify)*	◉	○	○	○	○

Other *(please specify):*

Text of 100 to 1500 characters will be accepted

In identifying and developing novel antimicrobial compounds, major breakthroughs have been infrequent and progress is still limited by our reliance on the current 20-odd classes of antibiotics derived from fungi. Developing truly novel approaches in diagnostics and therapeutics on the long run requires further action and research funding. Thi s could also involve the funding of data resources that support scientific communities to easily access and use exi sting data to convert to new knowledge. Promising ways forward, for example, would be to put efforts into a search of new types of antibiotics, to expand our biochemical knowledge of virulence, resistance mechanisms, combined wit h research enhancing our understanding of host-microbiome and host-pathogen interactions. Discovering the molecular mechanisms underlying resistance gene transmission could offer new tools and approaches that can help contain/limi t resistance dissemination, not bound to the treatment of a single specific bacterium. In addition, funding to alte rnative drug discovery routes such as drug repurposing, combinatorial therapies, natural product searches, bacterio phage therapies, immunomodulatory treatments, probiotics and microbiome modulation has the potential of offering us new knowledge and the basis for new therapy discovery in the 2020s.

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 (https://ec.europa.eu/programmes/horizon2020/) grant schemes	◉	○	○	○	○
b) The SME instrument (https://ec.europa.eu/programmes/horizon2020/en/h2020-section/sme-instrument) under Horizon 2020	○	○	◉	○	○
c) Loan-based funding instruments like InnovFin Infectious Diseases (http://www.eib.org/products/blending/innovfin/products/infectious-diseases.htm) provided jointly by the EC and the European Investment Bank (EIB)	○	○	○	○	◉
d) Inducement Prizes (https://ec.europa.eu/research/horizonprize/index.cfm?pg=prizes)	○	○	○	○	◉

e) Public Procurement of Innovative Solutions (https://www.innovation-procurement.org/)	○	○	○	○	◉
f) R&D funding provided by EC's public-public partnership JPIAMR (http://www.jpiamr.eu)	○	◉	○	○	○
g) R&D funding provided by EC's public-private partnership IMI (http://www.imi.europa.eu/)	○	◉	○	○	○
h) R&D funding provided by the European & Developing Countries Clinical Trials Partnership (EDCTP (http://www.edctp.org/))	○	◉	○	○	○

* 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)	○	◉	○	○	○
b) Foster bilateral partnerships with key EU trading partners and major regional/ global players (e.g. USA, Canada, Brazil, China, India, South-Africa)	○	◉	○	○	○
c) Contribute towards AMR capacity building in developing countries (e.g. on surveillance and monitoring of AMR)	○	◉	○	○	○
d) Contribute towards AMR capacity building in candidate, potential candidate and neighbouring countries (e.g. on surveillance and monitoring of AMR)	○	◉	○	○	○
e) Other *(please specify)*	○	○	○	○	○

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	○	◉	○	○	○
b) Trade agreements or partnership agreements	○	○	○	○	◉
c) Capacity building	○	◉	○	○	○
d) Other *(please specify)*	○	○	○	○	◉

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	○	○	○	○	◉	○	○	○	○
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

AMR is of global concern and the European Commission and EU Member States should work closely with all major research institutes and parties (WHO, G7, G20) in all the listed regions in combating AMR, as only a coordinated international effort will enable for both continuous and sufficient coverage. In the short-term, due the ease of legal issues for sampling, material sharing and fast cross-border transfer, the EU could have greatest influence in the European Region (non-EU). Increasing efforts in rapidly developing regions with rampant growth of AMR and great sequencing centers could also prove fruitful.

Contact

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