



AMR **One Health Network**

Top suggestions for AMR actions



AUGUST 2022

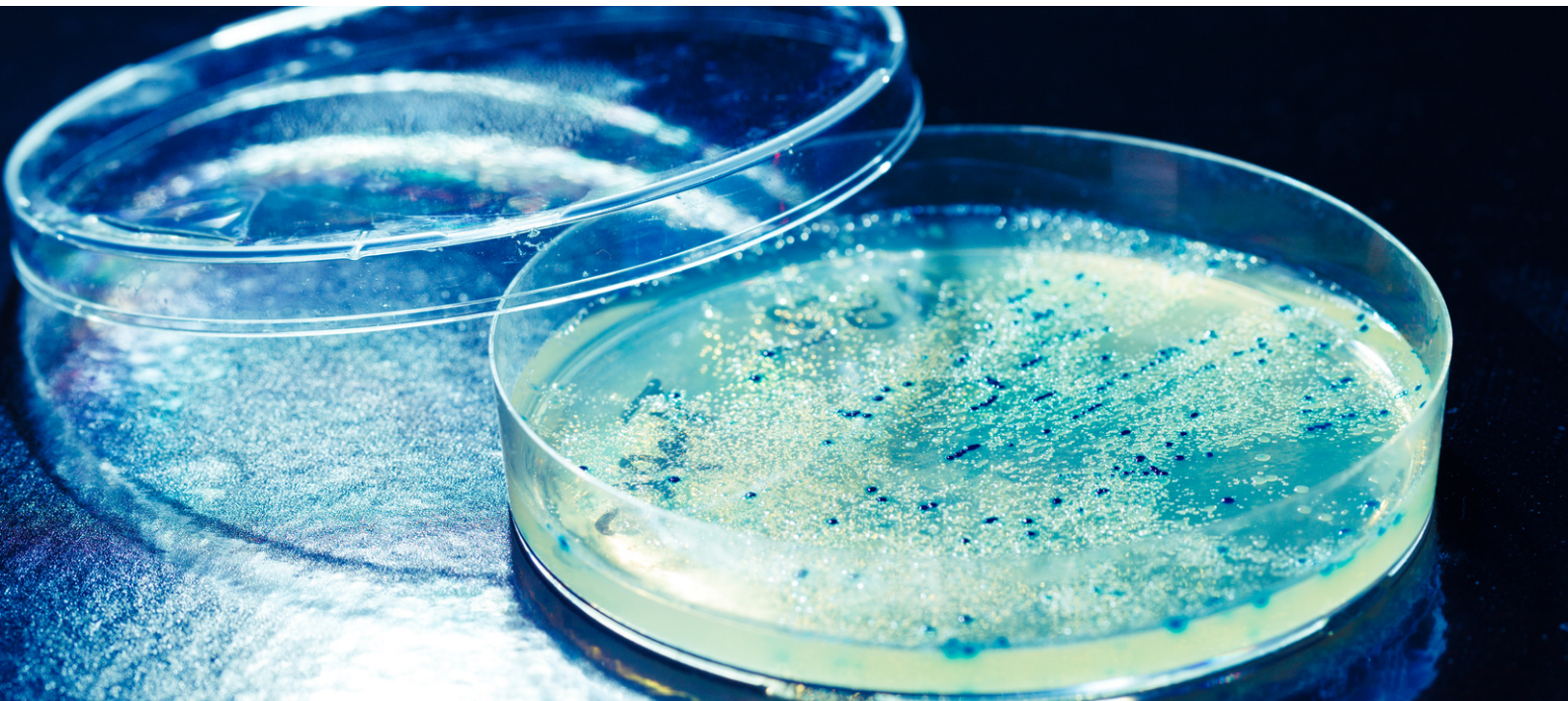
Prepared by the

Subgroup established under the EU AMR One Health Network to formulate suggestions for AMR actions

Outline

Introduction	3
Working method	5
Results	10
Top 10% suggestions	13
Conclusion	33
Annex	35

Introduction



The **AMR One Health Network** is an informal collaborative group coordinated by the European Commission that brings together human health, veterinary and environmental health experts from EU Member States, with the objective to improve the European Union (EU) efforts to fight against antimicrobial resistance (AMR).

During the AMR One Health Network meeting of January 2022, Commissioner for Health Stella Kyriakides announced a **new policy initiative on AMR from the European Commission** that will build on the implementation of the 2017 EU AMR Action Plan. By 2023, the Commission will adopt a proposal for Council Recommendations on AMR, and propose AMR provisions as part of the revision of the EU pharmaceutical legislation. Commissioner Kyriakides highlighted the need to take concrete coordinated actions in an integrated manner. The European Commission also decided to establish within the AMR One Health Network (OHN) a **temporary subgroup** with the objective to formulate suggestions from Member States to the European Commission in view of its new AMR policy initiative.

In this context, the French Presidency of the Council of the European Union hosted a [One Health Ministerial Conference on AMR](#) in Paris on 07 March 2022.

Top suggestions for AMR actions

1. SCOPE

The AMR OHN subgroup was tasked to **provide technical expertise and opinions from the EU 27 Member States** (MS), as a consultative step, to the Commission on needed concrete objectives and activities to strengthen EU and Member States action against antimicrobial resistance (AMR), in particular in the area of public health, animal health, plant health and the environment, taking into account the latest policy developments and the need to decrease antimicrobial resistance.

This consultative step among MS is one of the several elements based on which the Commission will develop its policy initiative. Other elements include inter alia: an AMR future proofing study, a Eurobarometer on AMR, work on AMR by the expert panel on effective ways of investing in health, the Commission review of Member States AMR One Health National Action Plans, recommendations from the 2018-2021 Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI) and the new Joint Action launched in 2022, as well as relevant scientific opinions and reports of EFSA, EMA and ECDC.

2. OBJECTIVE

The objective of this MS subgroup was to develop conclusions summarising actions which Member States experts identify as relevant to consider for the above-mentioned policy initiative. Such actions should be as specific and concrete as possible, and **focus on unmet needs and priority areas where the EU level can be an added value**, either via **actions undertaken at EU level or national actions undertaken in a coordinated manner within the EU**.

The conclusions of the subgroup were adopted in August 2022.

Working method



1. SUBGROUP COMPOSITION

All 27 EU Member States representatives of the AMR One Health Network were invited to participate in the subgroup. Member States are represented by experts of the public health, veterinary and environmental sectors. The Commission was invited as observer.

2. STEERING COMMITTEE

The subgroup was chaired by the French representatives of the EU AMR One Health Network. A Steering Committee composed of representatives from three Member States (**France, Spain and Sweden**) facilitated the work of the subgroup, prepared the discussions and reviewed the meeting documents as well as the draft prepared by the French representatives for the subgroup conclusions. The Steering Committee met during one hour every two weeks from end of February to early July 2022.

Top suggestions for AMR actions

3. PROPOSALS

On 25 March 2022, all Member States were invited to formulate action proposals in the human, animal and/or environmental health sectors, if possible **in a "One Health" approach**. In order to make these proposals as specific and applicable as possible, MS were asked to use the "SMART" methodology (i.e. to devise proposals that are **Specific, Measurable, Attainable, Relevant and Time-bound**). Member States had until 15 April to send their proposals to the French representatives, who grouped and sorted them by sector. Overall, 19 out of 27 MS provided suggestions.

This document was then forwarded to the participating MS, who were given time to review their proposals, ask clarifying questions and answer comments on their suggestions. These exchanges were done through the French representatives to preserve the anonymity of the MS proposals.

All proposals were taken into account without being modified, except if the title and description were exactly similar, in which case they were merged. Each MS choice of applicable sectors was also respected. For example, if a Member State chose to consider its proposal as applicable to the human sector only, it was placed only in that sector.

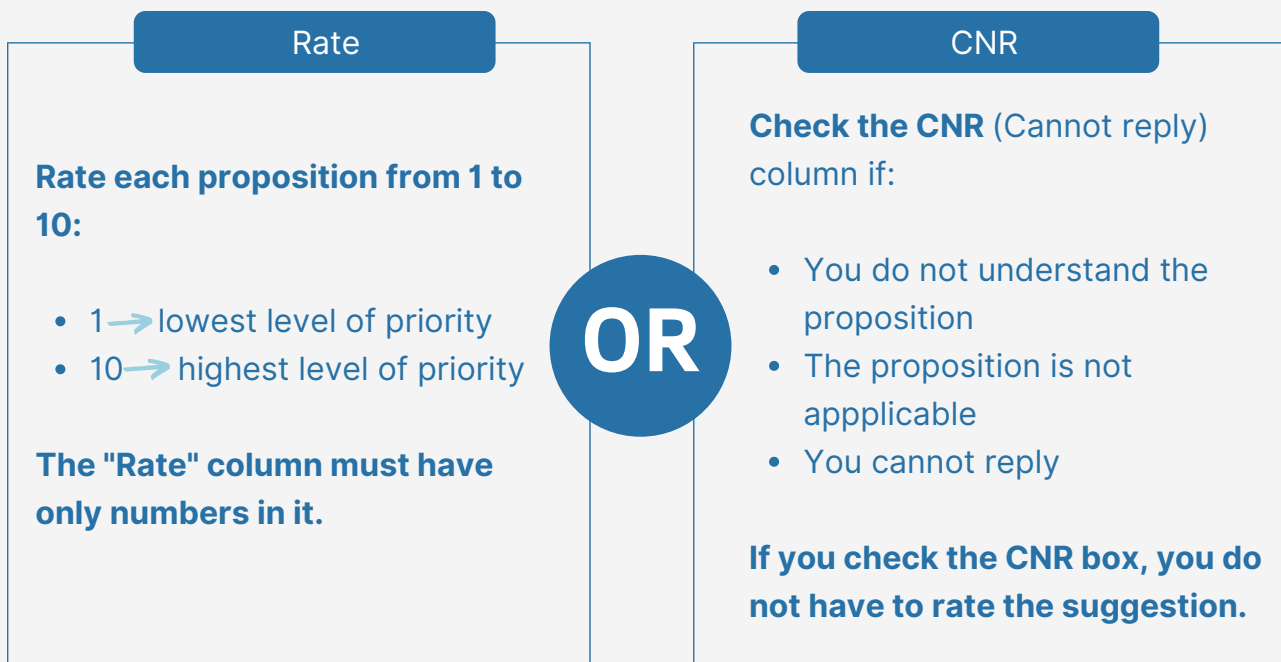
4. QUESTIONNAIRE

Once the document containing all the MS proposals was approved, Member States were asked to grade each proposal by **priority level**, they had until the 29 of May.



Top suggestions for AMR actions

They were given the following instructions:



MS were reminded that all received proposals will be sent to the Commission, and that the objective of the rating survey was to **identify which actions Member States believe are most urgent to prioritize at the EU level.**

Representatives were also informed that only one answer per MS would be accepted, thus each MS had to coordinate internally between the human health, veterinary and environmental health sectors, in a “One Health” approach. The deadline for submitting replies was end of May 2022. On the whole, 22 out of 27 MS participated in the voting procedure.

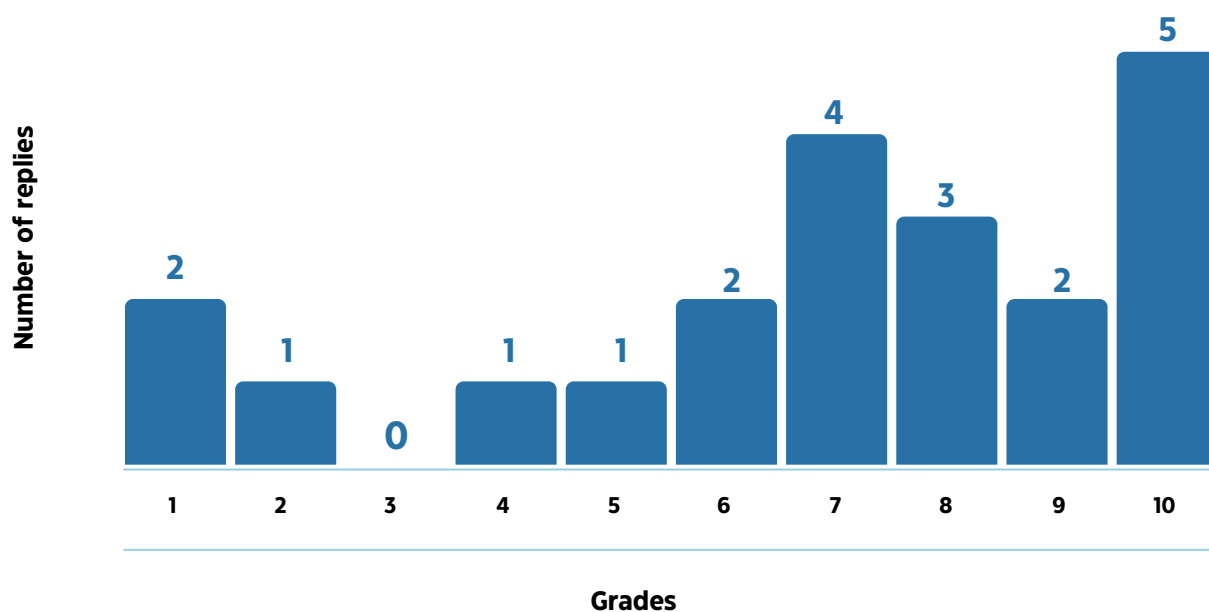
5. METHODOLOGY FOR THE SURVEY AND THE PRESENTATION OF RESULTS

The results present the mean, the median, the distribution of replies, the number of “CNR” (cannot reply) as well as the missing data. All replies were compiled by the French team in an Excel® spreadsheet, with rows for each proposal, a column for each mean, median, distribution of replies, CNRs, missing data, number of replies received and the replies of each MS. All calculations were done thanks to Excel® formulas.

Top suggestions for AMR actions

The “CNR” replies were not taken into account as “0”. “CNR” indeed does not necessarily imply a lower degree of prioritisation of a proposal, as some Member States may have picked “CNR” for proposals that were outside their scope, not understood, or on which they could not reach an agreement. Therefore counting them as “0” could bias the results of the mean and the median.

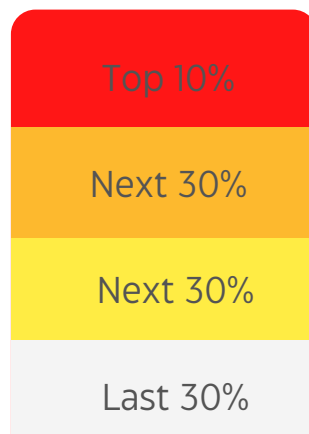
The distribution presents how many times each grade was chosen in the replies, as illustrated in the example below.



For the proposals classified as “Communication” and “One Health”, i.e. the first 100 proposals, Member States were given the opportunity to precise for which sector they believed this proposal was “best applied to” among the human health, animal health and environmental health sectors. The calculation for these results were also completed using Excel®. If all three boxes were ticked, or if none were ticked, this was considered as a suggestion best applied in a “One Health” perspective.

To sort out where each proposal ranked, the SC decided to use the mean, as these data were more discriminating. The proposals were then colour coded according to where they rank, with chosen colours illustrated below. The choice of red for the Top 10% of proposals was made to highlight that these were considered the **most urgent to prioritize**.

Top suggestions for AMR actions



The results are presented by sector in the final report, in the initial order they were voted on. Only the Top 10% of proposals are ranked in the following section. To sort out the Top 10% proposals, the means were used. To classify the proposals with the same mean, the number of replies and “CNR” were taken into account, as well as the distribution of replies. The results of the survey were shared with the subgroup in June 2022. Member States had the opportunity to provide comments should they wish to do so. The conclusions of the subgroup were then adopted in August 2022.



Results

Top 10% suggestions

It is interesting to note that the recommended actions that ranked in the Top 10% of the means mostly relate to the veterinary sector. Indeed, 12 out of the 28 proposals target the veterinary sector, i.e. almost 43% of proposals. An additional 4 are classified as “Human & Animal Health” and 2 are considered “One Health”. Therefore, 16 out of 28 proposals relate to animal health, which represent 57% of these proposals. There are 6 recommended actions in the environmental health sector and 4 classified as “Human Health”.

Additionally, the Top 10% highlight four key categories of priorities. First, the need to **strengthen data collection and AMR surveillance systems** is mentioned in all sectors (7 proposals). Second, actions to **ensure the availability and accessibility of antimicrobials** are deemed priorities, including access to “old” narrow-spectrum antimicrobials

Top suggestions for AMR actions

and antimicrobials that lack commercial interest (6 proposals). Third, 7 proposals relate to the need to **develop guidelines, biosecurity measures and tools to help prevent the development and spread of infectious diseases in animals** and to support farmers in improving animal welfare as well as access diagnostic tools. Finally, 5 proposals are linked to the development of **EU guidelines and regulations to control (through a harmonised surveillance) and manage environmental pollution from wastewater treatment plants and manufacturing sites**. This includes the idea to develop environmental monographs. The remaining 3 proposals relate to including environmental goals in National Action Plans, the update of dosage information on leaflets and postgraduate education of veterinary practitioners.

However, it is important to keep in mind that this analysis only takes into account the top 28 proposals. Member States indeed suggested a total of **287 proposals** to improve the EU action against AMR.



Results at a glance

A European consultation process



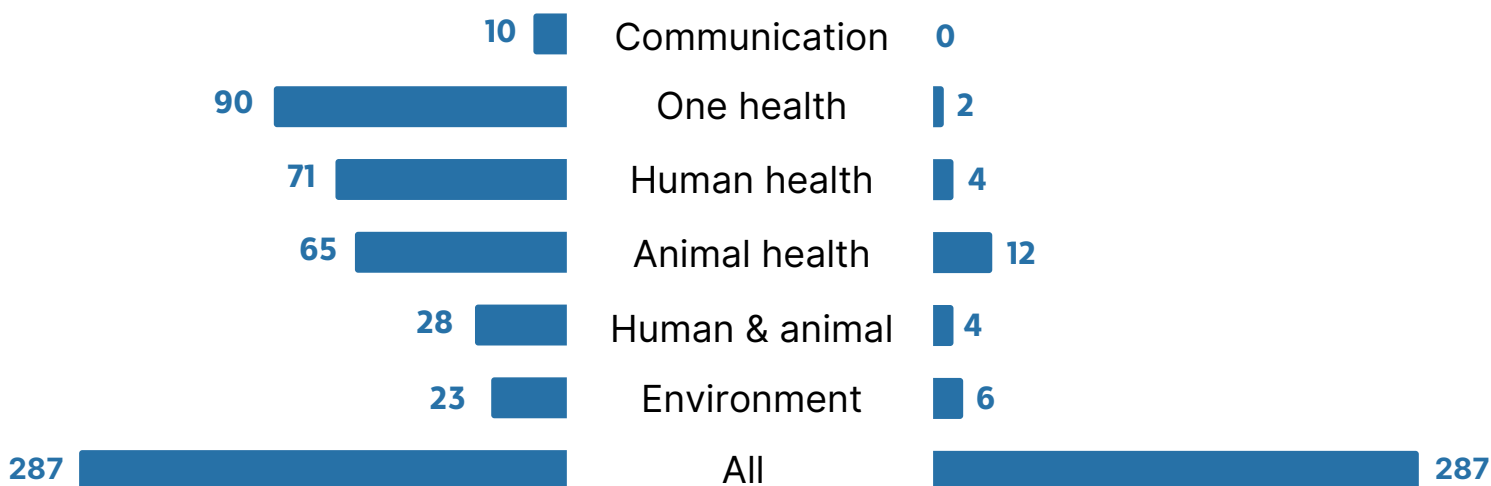
The baseline

287 suggestions
from EU Member States



The top 10% suggestions

28 proposals
following a grading process



81 % 19 MS sent their suggestions

90 % 22 MS participated in the voting process to select top priorities

Top 10% suggestions

You will find below the 28 proposals that ranked in the Top 10%. The numbers before the proposals refer to the numbers they are given in the final report containing all received recommendations.

1 273. Provide EU guidelines and regulation regarding production of pharmaceuticals and wastewater management

Provide guidance and regulation for sustainable and clean production of antimicrobials both in- and outside the EU, including criteria for wastewater management to avoid antimicrobial production contributing to antimicrobial resistance in the environment.

Sector



Environment



Mean
8.58



Median
9.00

CNR	Missing data	Number of replies
2	1	21

2 201. Preventing development and spread of infectious diseases

Healthy animals to reduce the need for antibiotics, by improving biosecurity at farm level, by vaccine uptake, and by improved nutrition & breeding.

- Establish a subgroup to develop specific biosecurity measures to be implemented at farm level. These measures should be distributed to all Member States as a best practice catalogue;
- Implement specific biosafety measures in all holdings in EU to ensure healthy animals;
- Include selected biosecurity measures in EU legislation step by step to ensure that the measures are feasible for Member State despite their different production systems and types of holdings.

Sector



Veterinary



Mean
8.50



Median
8.50

CNR	Missing data	Number of replies
2	0	22

Top 10% suggestions

3 28. Ensure continued availability and accessibility of 'old', narrow-spectrum antimicrobials

Support a stable supply chain of older, narrow-spectrum antimicrobials (such as penicillin and 1st generation cephalosporin) including pediatric formulations, e.g. by encouraging pharmaceutical industries to continue production, perhaps with private/public funding. Different types of penicillin and 1st generation cephalosporin are drugs recommended for treatment of major common bacterial infections. Many European countries have in recent years experienced shortages in delivery of these antimicrobials and some products are no longer available on the market. This makes it difficult to maintain the recommended use of narrow-spectrum antimicrobials and drives the usage towards a choice of broader-spectrum products, which contributes to maintaining a high level of AMR

Sector



One Health



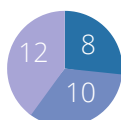
Mean
8.41



Median
9.00

CNR	Missing data	Number of replies
0	0	22

Best apply to :



■ One Health

■ Animal

■ Human

□ Environment

Top 10% suggestions

4 184. Surveillance of antibiotic resistance in bacterial pathogens important for animal health

Surveillance of antibiotic resistance in bacterial pathogens important for animal health in EARS-vet.

Sector



Veterinary



Mean
8.25



Median
9.00

CNR	Missing data	Number of replies
1	1	21

5 247. Work on the availability of antibiotics, both for human and animals, especially when there is a lack of commercial interest

EMA already has a proactive policy regarding this matter, but new incentives and levers need to be added, especially in veterinary medicine.

Sector



Human & Animal



Mean
8.23



Median
9.00

CNR	Missing data	Number of replies
0	0	22

6 284. Environment in EU and NAP

Fully include environment (water, manure, sewage, and use in plants/crops) in the EU Action plan and in NAPs, in line with the One Health approach (e.g. surveillance).

Sector



Environment



Mean
8.19



Median
9.00

CNR	Missing data	Number of replies
1	0	22

Top 10% suggestions

7 246. Ensure the availability of antibiotics

This should be a priority at EU level. Include the topic of securing supply of antibiotics in the upcoming international instrument on pandemics.

Sector



Human & Animal



Mean
8.19



Median
8.00

CNR	Missing data	Number of replies
1	0	22

8 140. Preventing development and spread of infectious disease

Improve infection prevention and control (IPC) in human health. The knowledge gained from the covid-19 pandemic should be used to improve general IPC measures, particularly at all levels of healthcare, in hospitals as well as in long-term care facilities and home care, where patients and residents are particularly vulnerable to infections, including resistant infections. In addition, basic hygiene should be promoted also in community settings. Common EU standards, guidelines, or if possible legislation, should be developed regarding:

- Common definitions of minimum criteria for training within medical specialties responsible for IPC;
- Common standards for utilization of IPC specialists in non-hospital facilities, e.g. long-term care facilities;
- Mandatory surveys and reporting of health care-associated infections in long-term care facilities and similar settings.

Sector



Human



Mean
8.18



Median
8.00

CNR	Missing data	Number of replies
0	0	22

Top 10% suggestions

9 216. Accessible and affordable rapid diagnostic tools and rapid antibiograms for animal health professionals

Develop accessible and affordable rapid diagnostic tools and rapid antibiograms for animal health professionals.

→ Medical diagnostics industry involvement in One Health concept.

Sector



Veterinary



Mean
8.15



Median
9.00

CNR	Missing data	Number of replies
2	0	22

10 267. Strengthen data collection and surveillance systems

Clarify the purpose of environmental monitoring in relation to how and where the results should be applied. Clarify and harmonize methods to conduct environmental monitoring, to ensure that Member States provide comparable results. Clarify whether there is a need for development within the area.

Sector



Environment



Mean
8.09



Median
8.00

CNR	Missing data	Number of replies
0	0	22

Top 10% suggestions

11 44. Design and implement a One Health monitoring and surveillance systems for antimicrobial use and AMR

Build these monitoring and surveillance systems for antimicrobial use and AMR on the WHO guidelines, OIE standards, the Codex alimentarius standards as well as the regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and Regulation (EU) 2016/429 of the European parliament and of the Council of 9 march 2016 on transmissible animal diseases. Ensure that these monitoring and surveillance systems are analysed in a cross-sectorial manner. The EU agencies should contribute further to the harmonization and interoperability of national and regional systems, in support of the European Commission and the Member States.

→ European agencies such as ECDC, EMA and EFSA should be mandated by European Commission to work on this topic.

→ The EU4Health program might also help support this action.

Sector



One Health



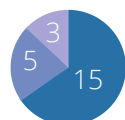
Mean
8.06



Median
8.00

CNR	Missing data	Number of replies
4	0	22

Best apply to :



■ One Health

■ Animal

■ Human

□ Environment

Top 10% suggestions

12 210. Support farmers in order to improve animal welfare as well as husbandry via the Common Agricultural Policy

Support farmers to improve husbandry and animal welfare through the Common Agricultural Policy.

→ Introduce financial and regulation incentives in the next CAP for farmers to ameliorate husbandry practices linked to deteriorated animal welfare. The goal is to focus on practices that have an impact on the infection rate of animals, and thus the consumption of antimicrobials;

→ Those suggestions should be discussed during the meetings with the DG AGRI on the new CAP.

Sector



Veterinary



Mean
8.00



Median
8.50

CNR	Missing data	Number of replies
2	0	22

13 190. Better monitoring of AMR

Development of a European Antimicrobial Resistance Surveillance network in Veterinary medicine (EARS-Vet), in order to fill the current surveillance gap in diseased animals in Europe and complement the existing EFSA and EARS-Net monitoring. Among others, EARS-Vet would help: i) to support the development of evidence-based guidelines for antimicrobial stewardship in veterinary medicine, ii) to better characterize links between AMC and AMR in animals and iii) to support risk assessment of AMR transmission from animals to humans via non foodborne related routes. Overall, EARS-Vet would contribute to a much stronger One Health strategy for AMR surveillance in Europe.

Sector



Veterinary



Mean
8.00



Median
8.00

CNR	Missing data	Number of replies
0	0	22

Top 10% suggestions

14 102. Develop and strengthen real-time surveillance tools and common European indicators

Develop real time surveillance tools in order to collect high quality data on the use of antimicrobials (both quantity and appropriateness) and resistance to antimicrobials in human health.

The EU4Health programme could support this action. Data generated by those surveillance tools should be analyzed in a cross-sectorial way, when relevant.

The 2017 ECDC, EMA and EFSA common indicators on AMR and antimicrobial use should also be updated and expanded, and their active use should be ensured at national level. Those indicators should be associated with targets (relevant to the different national contexts).

→ A subgroup of the AMR OHN should be created to specifically discuss the topic and make concrete recommendations, together with EMA, EFSA and ECDC to develop the common indicators on AMR and antimicrobial use. The 2017 ECDC, EMA and EFSA common indicators should be used as the basis for discussion.

Sector



Human



Mean
8.00



Median
8.00

CNR	Missing data	Number of replies
0	0	22

Top 10% suggestions

15 188. Promote harmonized monitoring of AMR of animal pathogens at EU level

There is an urgent need for harmonized and coordinated approach for AMR surveillance in bacterial pathogens of animals across Europe.

→ Provide European guidance for developing surveillance system of AMR in animals;

→ Provide financial support to Member States for implementing this monitoring;

This action could be supported through the establishment of EARS-Vet.

Sector



Veterinary



Mean
8.00



Median
8.00

CNR	Missing data	Number of replies
0	0	22

16 250. Improve the availability of old/narrow spectrum antibiotics

Dress a list of antibiotics of special medical value that must be safeguarded, both for human and veterinary medicine.

→ Enter into EU-wide agreement with pharmaceutical companies to ensure continuous availability of such antibiotics;

→ Secure the supply.

This action could be part of the Pharmaceutical Strategy for Europe and HERA.

Sector



Human & Animal



Mean
8.00



Median
8.00

CNR	Missing data	Number of replies
1	0	22

Top 10% suggestions

17 245. Increase long-term and sustainable access and availability of antibiotics to preserve effective treatment of bacterial infections

Access to both new and older antibiotics need to be guaranteed. This issue is highly relevant for all patients in the EU to ensure optimal treatment, including for the society since it aims to curb AMR.

Availability problems include both when products are not launched and when established products are withdrawn from markets as well as more or less temporary shortages. Due to increasing AMR and scarcity of new agents, the antibiotics that already exist must be used responsibly. However, older but still effective antibiotics run the risk of being taken off the market due to small volumes and limited revenues for these. Even if there are some ongoing national, EU and global initiatives to strengthen availability, a coordinated EU initiative would greatly contribute and give added value.

The aim should be to create a diverse portfolio and stable supply chains to secure the best treatment and to minimize resistance development. Methods to increase access include different push and pull incentives and can be related to economic incentives, procurements, legal and regulatory aspects, as well as increasing transparency to assure effective early warning systems. For some aspects, more research is required. One way to achieve this could be through a strategy implemented by HERA. It may be monitored by measuring changes in the number of products introduced and taken off the market in the EU or in individual MS, and also by measuring changes in serious shortages of antibiotic products.

Sector



Human & Animal



Mean
8.00



Median
8.00

CNR	Missing data	Number of replies
1	0	22

Top 10% suggestions

18 181. Examine issues with availability of first-line antimicrobials

Examine how the pharmaceutical industry can be incentivized to licence and produce lower priority antimicrobials in all necessary formulations to ensure prescribing vets have options to treat infections that are expected to respond to category D AMs (AMEG) with first line products rather than selecting AMs from a higher priority category due to lack of treatment options:

- Products can be discontinued if the cost-benefit analysis is unfavourable;
- Market supports may be necessary to keep certain products/formulations on the market.

Sector



Veterinary



Mean
7.95



Median
9.00

CNR	Missing data	Number of replies
0	0	22

Top 10% suggestions

19 106. Strengthen data collection and surveillance systems

Strengthen data collection and surveillance systems at EU level for AMR in hospital-acquired infections (HAI) and in the community through current funding programs. Continue improving data reporting and quality of data to EARS-Net and develop model for continuous monitoring and annual reporting of HAI and AMR in HAI (move from Point Prevalence Surveys every other to third year to stable, continuous reporting via ECDC). Continue to support the development and implementation of data collection and surveillance systems at EU level of antimicrobial use, including at more detailed level (hospital, department, and specialty) through current funding programs and ESAC-Net. Granular, high quality data pave the way for future integrated monitoring systems that can combine emergence and spread of resistant bacteria with usage per “compartment”. This will also enable setting more specific reduction targets for antimicrobial use in specific settings.

Sector



Human



Mean
7.95



Median
8.00

CNR	Missing data	Number of replies
0	0	22

Top 10% suggestions

20 203. Biosecurity and implementation of sanitary measures to prevent or minimize the risk of transmission of infectious diseases in farm animals

Encourage the operators to improve animal husbandry processes as regards to management and biosecurity by advisory support and through the CAP.

Support vaccination campaigns to improve animal health. Organize promotion actions towards encouraging vaccinations.

Sector



Veterinary



Mean
7.95



Median
8.00

CNR	Missing data	Number of replies
1	0	22

21 204. Provide biosecurity information and benchmark tools for farmers and veterinarians

Farmers, together with veterinarians, need to be able to evaluate their own biosecurity status, to identify gaps in biosecurity and to develop a plan of action based on processed information on biosecurity measures (effectiveness, economics, legal obligation, etc.). Suitable tools are needed for this purpose.

Sector



Veterinary



Mean
7.95



Median
8.00

CNR	Missing data	Number of replies
1	0	22

Top 10% suggestions

22 214. Update in the leaflet the dosage information and duration of treatment of old/narrow spectrum antibiotics

Encourage the pharmaceutical sector to update in the leaflet the dosage information and duration of treatment of old/narrow spectrum antibiotics.

Sector



Veterinary



Mean
7.95



Median
8.00

CNR	Missing data	Number of replies
2	0	22

Top 10% suggestions

23 131. Consider pharmaceutical pollution, including AMR, in upcoming revisions of EU legislation

In order to contain AMR in the environment, emissions to the environment should be minimized. There is now a window of opportunity to address this in upcoming revisions of several EU legislative acts. The upcoming revision of the legislation on medicinal products for human use provides an opportunity to enhance the regulation of environmental aspects of medicinal products, including the spread and development of AMR in the environment. For example, the environmental effects should be considered in the risk-benefit analysis in the authorisation process, without compromising the patient's health. The upcoming revision of the Industrial Emissions Directive and the Urban Wastewater Directive could be used to take action against pharmaceutical pollution, including from AMR, within the European Union. Further, in order to tackle emissions from production in third countries, the introduction of environmental requirements with respect to antimicrobials in the legislations related to production of active substances and medicinal products for human use and the Good Manufacturing Practices (GMPs) should be considered, taking into account potential effects on availability. This would enable to set emission and discharge limit values for production.

Sector



Human



Mean
7.90



Median
8.00

CNR	Missing data	Number of replies
1	0	22

Top 10% suggestions

24 275. Provide EU guidelines and regulation regarding production of pharmaceuticals and wastewater management

The most cost-effective measures including legal measures to mitigate the effects of pharmaceuticals in the environment including the fight against AMR should be assessed based on the report “Communication from the Commission to the European Parliament, the council and the European Economic and Social Committee European Union Strategic Approach to Pharmaceuticals in the Environment”. The communication provides 6 areas of initiatives and specific measures including;

- Support the development of pharmaceuticals intrinsically less harmful for the environment and promote greener manufacturing.
- Improve environmental risk assessment and its review.
- Reduce wastage and improve the management of waste.
- Expand environmental monitoring and fill other knowledge gaps.

Sector



Environment



Mean
7.90



Median
8.00

CNR	Missing data	Number of replies
1	0	22

Top 10% suggestions

25 234. Post-graduate education for veterinary practitioners on AMR and responsible use of antimicrobials

Support farmers to improve biosecurity and animal welfare through the common agricultural policy (CAP).

Sector



Veterinary



Mean
7.86



Median
8.00

CNR	Missing data	Number of replies
1	0	22

26 206. Support farmers – pursuing better biosecurity and Animal Welfare

Develop lifelong learning and up to date status of knowledge representing materials for veterinary practitioners focusing on responsible use of antimicrobials, AMR control, and One Health concept (in collaboration with FVE).

Sector



Veterinary



Mean
7.85



Median
8.50

CNR	Missing data	Number of replies
2	0	22

Top 10% suggestions

27 270. Identify major sources and pathways of emissions of antibiotic residues and antimicrobial resistance to the environment by joint screening efforts among EU 27

Background: The knowledge on sources, pathways and magnitudes of emissions needs to increase on an EU level in order to develop effective actions and policies to limit the development and spread of antimicrobial resistance. Since the problem picture is diverse, several EU initiatives and actions are needed.

Action: Include AMR in Horizon Europe Programmes and other relevant research initiatives. Screening efforts could e.g. be included in Horizon Europe Partnership on Risk Assessment of Chemicals (PARC).

Deliverable: Mapping emissions of antibiotic residues and antimicrobial resistance from relevant sources among EU 27 MS. Joint screening efforts measuring levels of antibiotic residues and antimicrobial resistance in e.g. wastewater treatment plants, industry effluents and farming facilities within EU.

Beneficiaries: EU and national and local authorities.

Effect: Building monitoring capacity and enable more MS to screen emissions due to the co-financing procedure under e.g. Horizon Europe. A baseline to enable development of effective policies and measures in relevant EU initiatives, strategies, and EU environmental and pharmaceutical legislation to limit the development and spread of antimicrobial resistance. Among the EU legislation there are several directives with policy relevance e.g. connected to wastewater plants (including use of water and sludge), water frame directive, industrial emissions directive, and pharmaceutical directive for humans etc. Might in the long run be a useful indicator to follow up efficiency on implemented policies and measures.

Sector



Environment



Mean
7.82



Median
8.00

CNR	Missing data	Number of replies
0	0	22

Top 10% suggestions

28 280. Environmental monographs

Support the principle of environmental monographs for veterinary medicines and extend it to antimicrobials in human medicines.

→ Harmonized environmental information by active substance in the monographs would make it possible to identify the molecule most present in the environment and to give indications as to the biospheres to be investigated in the context of their monitoring.

→ To have a better understanding of the environment as a reservoir and interface in the transmission of resistance with the human population and with animals.

Rationale: During the marketing authorisation process for medicinal products for human or veterinary use, an analysis of the impact of these medicinal products and/or their major metabolites on the environment is requested. This analysis can be summarized as follows: the assessment is carried out in several phases. The first phase, which is theoretical, consists of estimating the exposure of the environment to the active substance: at the level of surface water for medicinal products for human use (PEC surface water < 10 ng/L) and at the level of soil for medicinal products for veterinary use (PECsoil < 100 µg/kg). According to the "Guideline on the environmental risk assessment of medicinal products for human use", for active substance with an antibacterial mode of action, and no other known pharmacological targets, a targeted effect assessment should be performed for the aquatic compartment. The second phase of the analysis consists of determining the physico-chemical properties of these molecules as well as their fate and ecotoxicity. The description of the transformation of these active substances in the environment, their degradation and their effects at aquatic or terrestrial level could help in understanding the environment as a reservoir and as an interface in the transmission of resistance with the human population and with animals.

Top 10% suggestions

28

Many medicines, including antimicrobials, were authorized before October 2005 for veterinary medicines and before December 2006 for human medicines, when this assessment was not required. Therefore, they were not assessed. An active substance administered according to the same route of administration, dosage and indication will have the same ecotoxicological impact whatever the name of the product. Pooling the available data of high quality would allow the ecotoxicological profile per substance to be described in a monograph and would provide more information on the active substances or metabolites to be monitored and the biospheres to be investigated. Such an initiative has already been launched for monographs for veterinary medicines (not restricted to antimicrobials). In January 2022, the European Commission presented to the European Parliament the results of a feasibility study for such monographs. The initiative is strongly supported by many National Competent Authorities. To date, the decision on whether or not to implement these monographs is still unknown.

Sector



Environment



Mean
7.82



Median
8.00

CNR	Missing data	Number of replies
5	0	22

Conclusion

The subgroup established in 2022 under the EU AMR One Health Network to formulate suggestions for AMR actions came up with almost 300 proposals, that may provide the European Commission with a **useful “toolbox” with numerous and detailed proposals for concrete actions** that could be taken or coordinated at EU level to fight the growing public health threat that is AMR. These suggestions are accompanied by **additional information** to indicate how consensual these proposals are amongst MS, and which ones are deemed most important to prioritize. The subgroup believes these proposals will be helpful for the announced AMR policy initiative and beyond, as the EU cooperation on AMR deepens. They may also suggest ideas that could be integrated in the upcoming EU Joint Action on AMR.

The full report with all received proposals will be made available by the European Commission. For more information, please visit health.ec.europa.eu/antimicrobial-resistance_en.

The efforts invested by Member States highlight that MS are keen to collaborate with the European Commission and all relevant EU institutions and agencies to strengthen the fight against AMR at EU and global level. At the same time, the exercise also pointed out capacity limits from MS. The time and resources required by MS should be considered in planning any further activities.



Top suggestions for AMR actions

It is important to note that this subgroup was set up to be consultative, and that a deeper study of which measures can and should be implemented is needed.

The subgroup wishes to highlight the four key categories of priorities making up the Top 10% of proposals, namely:

- Strengthen data collection and AMR surveillance systems;
- Ensure the availability and accessibility of antimicrobials;
- Develop guidelines, biosecurity measures and tools to help prevent the development and spread of infectious diseases in animals and support farmers in improving animal welfare as well as access to diagnostic tools;
- Develop EU guidelines and regulations to control (through a harmonised surveillance) and manage environmental pollution, notably from wastewater treatment plants and manufacturing sites.

The 28 initiatives that make up the Top 10 % suggestions should serve as an inspiration when proceeding with these four key categories.

The SC asked to receive feedback on the process. Some MS acknowledged the huge task solved by the subgroup in a very short time, but also highlighted that it made it difficult for MS to deliver well-prepared “One Health” contributions. Additionally, the MS stressed that it could have been useful for the received suggestions to be pooled and edited as this would have made the subsequent feedback and rating easier, and as it could cause bias in the final ranking of proposals – with many proposals being very similar. The SC would have benefited from technical support on the feasibility of proposed measures and to identify the ones already in place.

The Steering Committee wishes to sincerely thank all participating Member States and their representatives for their hard work under a tight schedule, and for efficiently coordinating their positions between the human, animal and environmental sector in a “One Health” perspective.

Annex

Voting Member States

Member States that participated (22 out of 27)		Member States that did not participate (5 out of 27)
Austria	Ireland	Croatia
Belgium	Italy	Greece
Bulgaria	Latvia	Malta
Cyprus	Lithuania	Romania
Czech Republic	Luxembourg	Slovenia
Denmark	Netherlands	
Estonia	Poland	
Finland	Portugal	
France	Slovakia	
Germany	Spain	
Hungary	Sweden	

Contact

SANTE-AMR-ONE-HEALTH@ec.europa.eu

