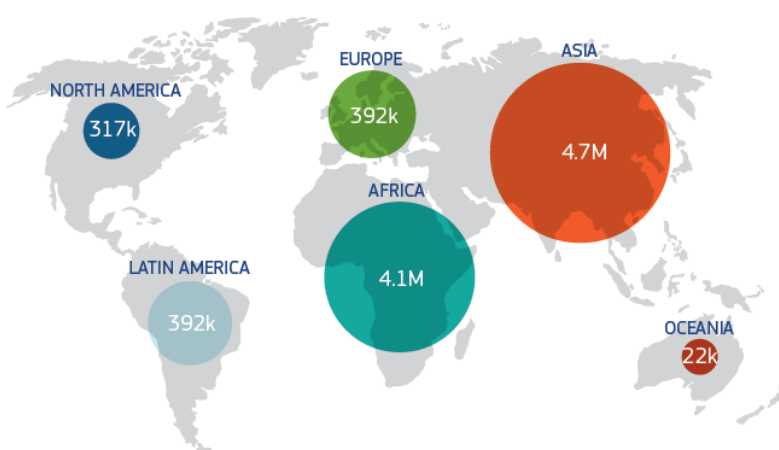


ROADMAP			
TITLE OF THE INITIATIVE	Commission's Communication on a One-Health Action Plan to support Member States in the fight against Antimicrobial Resistance (AMR)		
LEAD DG – RESPONSIBLE UNIT – AP NUMBER	SANTE – AMR TASK-FORCE (G4, D3, 01)	DATE OF ROADMAP	24/10/2016
LIKELY TYPE OF INITIATIVE	Inter-institutional non-legislative file: Communication from the Commission to the European Parliament and the Council		
INDICATIVE PLANNING	Adoption foreseen first semester 2017		
ADDITIONAL INFORMATION	-		
<p><b>This Roadmap aims to inform stakeholders about the Commission's work in order to allow them to provide feedback and to participate effectively in future consultation activities. Stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have. The Roadmap is provided for information purposes only and its content may change. This Roadmap does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content.</b></p>			

A. Context, Problem definition and Subsidiarity Check														
<p><b>Context</b> [max 10 lines]</p> <p>Antimicrobial resistance (AMR) describes a situation where microbes resist to antimicrobial medicines, making them ineffective. AMR is a growing global threat and a significant societal and economic challenge. The cost of inaction are projected to result in 10 million deaths globally per year and a cumulative loss of over EUR 88 trillion to the world economy by 2050. High political importance has been attached to the issue within the EU, the G7, the G20, the UN and international organisations in the recent past. The Council conclusions of 17 June 2016 on AMR call for a reinforced EU strategy against AMR and a new and comprehensive EU Action Plan (AP) on AMR based on the One-Health approach.</p> <p>The current Action Plan has been subject to an evaluation, which showed that the EU can bring added value in the fight against AMR, by: 1) supporting Member States, particularly in establishing, implementing and monitoring their National Action Plans; 2) bringing together EU funds and instruments, to promote innovation and research against AMR; and 3) helping to strengthen the EU's role in global fora, notably within the UN institutions and with major trade partners.</p> <p>The new AP should take the form of a Commission communication to the European Parliament and the Council.</p>														
 <table border="1"> <caption>Projected annual deaths attributable to AMR by 2050</caption> <thead> <tr> <th>Region</th> <th>Projected Annual Deaths</th> </tr> </thead> <tbody> <tr> <td>North America</td> <td>317k</td> </tr> <tr> <td>Latin America</td> <td>392k</td> </tr> <tr> <td>Europe</td> <td>392k</td> </tr> <tr> <td>Africa</td> <td>4.1M</td> </tr> <tr> <td>Asia</td> <td>4.7M</td> </tr> <tr> <td>Oceania</td> <td>22k</td> </tr> </tbody> </table>	Region	Projected Annual Deaths	North America	317k	Latin America	392k	Europe	392k	Africa	4.1M	Asia	4.7M	Oceania	22k
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<p><b>Projection for number of annual deaths attributable to AMR by 2050, (source: O'Neill AMR review<sup>1</sup>, May 2016)</b></p>														

<sup>1</sup> <http://amr-review.org/>

### **Problem the initiative aims to tackle [max 25 lines]**

Antimicrobial Resistance (AMR) is a process whereby microbes evolve to resist the action of antimicrobial medicines, making them ineffective. AMR arises from the selection pressure that antimicrobials put on populations of microbes; selecting or allowing those microbes to survive and proliferate. This leads to antimicrobials becoming less effective over time and ultimately useless.

The levels of AMR are increasing in the EU and even more so globally, threatening our ability to cure even simple infections. Several cumulative factors explain this global trend, e.g.: the frequent overuse and misuse of antimicrobials both in human and veterinary medicine; the lack of new antimicrobial medicines available or in the development pipeline to challenge new resistant microbes; poor hygiene practices and insufficient prevention measures against infections.

With resistance to antimicrobials on the rise, there is a risk that in the EU progress gained in the last century may be lost. This includes: 1) the fight against life threatening infectious diseases such as pneumonia and tuberculosis; 2) the battle against conditions such as cancer and HIV/aids where antimicrobials are crucial; and 3) huge advances in surgical procedures like organ transplants, hip replacement and caesarean sections, which have become routine and relatively low risk if supported by effective and prudent antibiotic treatment.

The societal and economic impact of AMR in the EU is tangible already today: AMR claims over 25,000 deaths<sup>2</sup> a year and incurs over EUR 1.5 billion of healthcare costs and productivity losses. In the absence of interventions to slow the emergence of resistance, to increase the supply of new antimicrobials and to improve awareness across the board, the impact will be felt at fundamental levels, across our societies and healthcare systems.

### **Subsidiarity check [max 10 lines]**

Protection and improvement of human health is an area where the Union has competence to support, coordinate or supplement the actions of the Member States. In the veterinary and the phytosanitary fields, and as regards quality and safety of medicinal products, organs and substances of human origin, blood and blood derivatives, the Union has a broader competence and the co-legislators can adopt harmonised measures to meet common safety concerns.

As infectious diseases do not respect borders, Member States cannot succeed in the fight against AMR if they work in isolation. Furthermore, the scale and scope of the problem, covering both human medicine and animal health, with environmental and well as macro-economic implications, requires countries cooperating at EU and global level, and effective monitoring instruments to facilitate evidence-based policy-making.

Coordinated EU action against AMR is therefore justified. The EU can bring added value, in particular, by supporting Member States, by investing in research and development, and by bringing weight to the issue at international level.

## **B. What does the initiative aim to achieve and how [max 25 lines]**

In order to ensure that all relevant initiatives contributing to the fight against AMR are pursued within an efficient framework to maximise the impact of each action, the Commission intends to propose in 2017 a new Action Plan (AP) against AMR. The new AP will build on the evaluation of the current one (2011-2016), with a focus on activities with clear EU added value. The objective is to preserve the efficacy of antimicrobials for humans and animals and identify coherent action to that end. This AP should take the form of a Commission Communication to the European Parliament and the Council.

The AP against AMR will include a set of concrete measures, to be undertaken by the Member States and the Commission under 3 strategic pillars:

#### 1) Supporting Member States and making the EU a best-practice region on AMR, and by:

- Helping developing and/or consolidating national action plans against AMR covering both human and veterinary medicine. The Commission will help bringing together the necessary expertise into a forum where experts from different sectors exchange best practices, and provide peer reviews of their respective national action plans on AMR. This "One-Health network" was endorsed by Member States in the Council Conclusions of June 2016.
- Developing expertise on methodologies, indicators and instruments to monitor trends in resistant infections and antibiotics consumption, both in humans and animals.
- Improving knowledge about the contribution of the environment on AMR by analysing inter-alia the presence of antibiotics in the environment, their potentially harmful levels and their possible contribution to the development of AMR, and adopting appropriate monitoring measures.

<sup>2</sup> [http://ecdc.europa.eu/en/publications/Publications/0909\\_TER\\_The\\_Bacterial\\_Challenge\\_Time\\_to\\_React.pdf](http://ecdc.europa.eu/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf)

- Implementing national measures for the prudent use of antimicrobials and the prevention of infections. The Commission aims to develop and update voluntary EU guidelines at the service of health and veterinary stakeholders.
- Increasing awareness on AMR, notably among health professionals, through targeted actions such as the European Antibiotic Awareness Day, and monitoring progress about public usage of and knowledge on antibiotics through periodic surveys.
- Ensuring that the regulatory instruments that contribute to the fight against AMR are used to their full potential, notably via the adoption of legislation on veterinary medicines, on medicated feed and implementing legislation on animal health.
- Strengthening cooperation with the relevant EU regulatory agencies (EMA, EFSA, ECDC), with the pharmaceutical industry and with other stakeholders, to provide better pathways for the authorisation of new antimicrobials, and better incentives for a limitation of antimicrobial use and for a wider use of diagnostic tests and vaccines.

#### 2) Boosting research, development and innovation against AMR, by:

- Using EU funding to stimulate research on new antimicrobial medicines, and the development of rapid-diagnostic tests, vaccines and alternatives to antibiotics.
- Promoting collaborative research for a better understanding of the mechanisms causing resistance.
- Driving research on development of new economic models to incentivise antimicrobial discovery and development activities while safeguarding the efficacy of antimicrobials.

#### 3) Shaping the global agenda on AMR, by:

- Strengthening the EU role within international organisations (WHO, notably, but also FAO/Codex and OIE) to promote a stronger global governance on AMR.
- Helping Member States with the implementation of the WHO Global Action Plan on AMR, and raise AMR in the context of the UN General Assembly and other international institutions such as G7 and G20.
- Promoting EU best-practices bi-laterally and helping raising awareness and building technical capacities in non-EU countries, including the main EU trade partners (e.g. through the Transatlantic Taskforce on AMR<sup>3</sup>), and low and middle-income countries.

### C. Better regulation

#### Consultation strategy [max 10 lines]

A comprehensive consultation exercise of Member States and stakeholders has been conducted in the framework of the evaluation of the current EC Action Plan against AMR, including on prospective aspects of this file and new elements that should be included in any new EU initiative against AMR. This consultation exercise already gives a very good overview and feedback on the various positions of the different stakeholders. In addition the Commission intends to consult further during the preparation of the new AP through joint meetings to be organised and gathering Member States experts and relevant stakeholders belonging to both the veterinary and the human health fields.

#### Impact assessment [max 10 lines]

No impact assessment is needed for this initiative. The actions envisaged in the foreseen initiative are either non-legislative, or are part of the regulatory agenda of the Commission already in place or planned, and will undergo impact assessments whenever relevant. These actions aim mainly at helping Member States in the implementation of their national AMR policies (e.g. by developing guidelines and indicators, organising exchange of best practices, and preparing the necessary elements for periodic monitoring and evaluation of AMR trends), the coordination of their research efforts to increase the supply of new and innovative medicines and the development of their influence on the global scene. These actions will be based on the results of the recent evaluation which showed the relevance of providing more support to Member States to tackle AMR.

#### Evaluations and fitness checks [max 5 lines]

The 2011 Action Plan has just been evaluated. The evaluation objectives were to analyse whether the actions set out in the Plan were the most appropriate ones to be taken to combat AMR, and which elements worked well or not. The final evaluation and its accompanying Staff Working Document can be found here: [http://ec.europa.eu/dgs/health\\_food-safety/amr/docs/amr\\_evaluation\\_2011-16\\_evaluation-action-plan.pdf](http://ec.europa.eu/dgs/health_food-safety/amr/docs/amr_evaluation_2011-16_evaluation-action-plan.pdf)

<sup>3</sup> <http://www.cdc.gov/drugresistance/tatfar>