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COMMISSION STAFF WORKING DOCUMENT

Synopsis report

Accompanying the document

Communication from the Commission to the Council and the European Parliament

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

{COM(2017) 339 final}

SYNOPSIS REPORT

1. INTRODUCTION

This report covers feedback and input from citizens and from administrations, associations and other organisations (hereinafter ‘stakeholders’) as regards a Commission Communication on a One Health action plan to support Member States in the fight against antimicrobial resistance (AMR) (hereinafter ‘the new One Health action plan’).

Stakeholders had the opportunity to provide their feedback on a Commission roadmap on a One Health action plan against AMR¹ from 24 October 2016 to 28 March 2017. In addition, an open public consultation (OPC)², targeting citizens and stakeholders, on the content for a new One Health action plan against AMR was open from 27 January to 28 April 2017³.

22 stakeholders submitted their feedback on the Commission roadmap. The OPC received replies from 584 participants: 421 citizens and 163 stakeholders. 16 of the 163 stakeholders had also provided comments on the Commission roadmap.

The stakeholders represented a great variety of sectors. Over a fifth of the respondents were public or private administrations, followed by non-governmental organisations (NGOs), pharmaceutical industry stakeholders and human healthcare providers. More than half of the respondents (52%) were umbrella organisations or associations representing the interests of stakeholders.

As for the citizens, 406 came from 22 Member States while 15 came from non-EU countries. The vast majority of the respondents were highly educated (87% had tertiary education), were employed in the human (39%) or animal (12%) healthcare sectors and admitted to being very well or well informed about AMR and its consequences (48% and 40% respectively), making the sample highly qualified to respond to the OPC.

The contributions received confirmed the strong support from citizens and stakeholders for a new One Health action plan, and the importance of a comprehensive approach. Contributions have been taken into account in defining concrete actions under the three main pillars of the new One Health action plan. Most of the contributions taken into account presented policy options which had a clear EU added value for Member States, which were relevant in terms of tackling AMR research and development (R&D) related challenges, or which would help ensure that the EU has a strong voice on AMR at international level. Contributions which went beyond the scope of EU competences were not taken into account.

A more detailed factual report on feedback received in the OPC will be published in parallel². It will offer a more comprehensive overview of the contributions received.

¹ http://ec.europa.eu/dgs/health_food-safety/amr/docs/communication_amr_2011_748_en.pdf

² http://ec.europa.eu/dgs/health_food-safety/amr/consultations/consultation_20170123_amr-new-action-plan_en.htm

³ The cut-off date is 28 April 2017. Contributions received by the European Commission after that date could not be taken into account in preparing this report.

2. MAKING THE EU A BEST PRACTICE REGION

Almost half of the citizens (46%) attributed equal importance to conducting actions against AMR in the human health, animal health and environmental sectors and more than a quarter (27%) were in favour of actions in both the human health and animal health sectors. The views expressed by the stakeholders also corresponded to a One Health approach addressing actions in all three sectors (human health, animal health, and environmental sectors).

2.1. Better evidence and awareness of the challenges of AMR

Stakeholders familiar with the EU surveillance systems considered that more improvements are needed on data collection in the animal health side than in the human health side. They pointed to the following possibilities to improve surveillance in the EU, which will be further explored in the implementation phase of the new One Health action plan:

- Moving towards a standardised system of data collection in order to reduce disparities in the quality of national data;
- For antimicrobial consumption data:
 - In the human health sector, more granularity in the collection of data (e.g. collection at regional, sub-regional, or even local level; stratified by healthcare sector; age/gender specific);
 - In the animal health sector, consumption data by species; by target population (e.g. fattening pigs or breeding sows and boars rather than all pigs); by farming system (e.g. intensive farming) and to start collecting data on antimicrobial use in companion animals (e.g. cats and dogs);
 - In both sectors, collecting data on the diagnoses or reasons for prescription;
- For antimicrobial resistance data, stakeholders called for broadening the scope of the surveillance systems to cover more pathogens in the human health sector. In both sectors they advocated for a database of resistance genes and for the use of genetic methods to improve data quality.

In order to strengthen the evidence base, another stakeholders' proposal that was put into concrete action in the Communication on the new One Health action plan, is helping Member States in assessing the economic and health burden of AMR.

Other stakeholders' proposals require further consideration and were not translated into concrete actions in the new One Health action plan. These include assessing the economic and health impact of vaccines against major infectious diseases in humans and the effectiveness of vaccination schemes, infection control measures, farming systems and nutrition practices in animals.

In terms of awareness, stakeholders were very positive about the Commission complementing Member States' AMR awareness-raising activities. Almost four times as many (79%) rated the Commission's efforts as helpful or very helpful compared to those who found these to be less helpful (21%).

Stakeholders mainly called for initiatives driven by Member States which would be country-specific, tailor-made and as targeted as possible to citizens and consumers, but also to pharmacists, doctors, dentists, patients, veterinarians, and farmers. These national campaigns are outside of the scope of the new One Health action plan.

2.2. Better coordination and implementation of EU rules to tackle AMR

To improve coordination of Member States' action on AMR, stakeholders considered important holding regular discussions within a One Health dedicated network on AMR, gathering experts from the human health, animal health and environmental sectors. They also called on the Commission to coordinate and facilitate the sharing of best practices and exchange of information on Member States' national action plans (NAPs) against AMR. The Commission addressed positively this request in the new One Health action plan.

87% of the stakeholders considered that it would be either very helpful or helpful for Member States to define measurable goals to reduce infections in humans and animals, the use of antimicrobials in the human health and animal health sectors and AMR in all three sectors. Concrete actions to support Member States in implementing their NAPs against AMR were included in the new One Health action plan.

2.3. Better prevention and control of AMR

To reduce antimicrobial use and prevent the spread of AMR, stakeholders favoured new Commission initiatives in humans, followed by new Commission initiatives in animals and agriculture.

Stakeholders strongly called for EU initiatives on infection prevention and control and on prudent use of antimicrobials. The following proposals were translated into concrete actions in the new One Health action plan:

- Supporting activities in the human health sector, e.g. including training and policies on healthcare-associated infection (HAI) control for all healthcare professionals;
- Promoting antimicrobial stewardship teams in hospitals and healthcare facilities and enhancing antimicrobial stewardship policies for all clinicians in primary healthcare and hospitals;
- Supporting Member States in producing treatment guidelines and decision-support tools;
- Promoting initiatives in the animal health sector aiming to improve animal husbandry practices for infection prevention and control;
- Promoting feeding and animal nutrition strategies developed by national authorities in collaboration with feed industry experts.

Stakeholders also suggested proposals concerning actions under Member State competences. The Commission did not include them in the new One Health action plan. These included:

- Member States to develop clear national vaccination programmes in the human health sector with vaccination goals, which acknowledge the role of vaccines in the fight against AMR and to identify and address key barriers to the introduction and roll-out of national vaccination schedules;
- Member States to establish national vaccination programmes in the animal health sector that reflect the diversity in livestock species and husbandry conditions;
- Member States to include vaccination schedules in their NAPs against AMR;
- Member States to encourage prescribers' access to rapid diagnostics in order to help them in their decision-making and to set up measures targeting human and animal health providers to promote the use of rapid diagnostics;
- Member States to include the use of rapid diagnostics in educational, training and antimicrobial stewardship programmes.

Finally, some stakeholders in the homeopathic and alternative medicine sectors called for the promotion of homeopathic and alternative medicinal products (traditional, complementary and alternative medicine) in the fight against AMR. These proposals were not addressed by the Commission in the new One Health action plan due to the lack of clear evidence.

2.4. Better addressing the role of the environment

Stakeholders expressed strong support for initiatives aiming to monitor antimicrobials and resistant microorganisms in the environment. A few stakeholders pointed out that health and economic impact studies should be conducted before defining limitations on antimicrobial discharges to the environment.

Stakeholders familiar with antimicrobial discharge pathways to the environment had the opinion that action should be taken to limit antimicrobial discharges from the pharmaceutical manufacturing process. Several stakeholders urged the Commission to adopt an EU strategic approach to pharmaceuticals in the environment. This action was included in the new One Health action plan, and will be followed, where appropriate, by proposals for measures. A range of options could be considered in the strategic approach, e.g. in relation to manufacturing effluents and collection of unused antimicrobials. As outlined in its Communication, the Commission intends to maximise the use of data from existing monitoring systems to improve knowledge of the occurrence of AMR and the spread of antimicrobials in the environment and thus better inform policy measures.

2.5. A stronger partnership against AMR and better availability of antimicrobials

Success against AMR depends on efforts from all levels of governance and multitude of societal actors. Stakeholders considered that the promotion of dialogue between all relevant stakeholders is crucial in order to discuss human and animal antimicrobial development challenges, the regulatory framework for alternatives to the use of antimicrobials, and to accelerate vaccine development for multidrug-resistant pathogenic bacteria.

To optimise development plans, pharmaceutical industry stakeholders strongly advocated for early and continuous dialogue with all relevant stakeholders throughout the entire product development cycle. They particularly called for dialogue on a regulatory framework that prioritises the development of antimicrobial medicines, vaccines and diagnostic tests; further enables efficient pathways for medicinal product development; and accelerates review pathways for antimicrobial medicinal products targeting serious and life-threatening infections. Stakeholders in the animal health sector asked for dialogue to properly differentiate in the development phase which new antimicrobials are intended for human use and for use in animals.

In line with these comments and suggestions, and as indicated in its Communication on the new One Health action plan, the Commission included initiatives to promote regular dialogues among stakeholders and to encourage them to develop and share their strategies against AMR.

Stakeholders had multiple constructive suggestions on how to guarantee the availability of effective antimicrobials (e.g. safeguarding of Internet sales and improving and reformulating older antimicrobials in order to be kept longer on the market). The Commission carefully considered these suggestions and addressed them in the new One Health action plan.

3. BOOSTING RESEARCH, DEVELOPMENT AND INNOVATION ON AMR

Research, development and innovation are essential strategic pieces in the fight against AMR. Stakeholders familiar with medicinal product development indicated as the main obstacles to bringing new antimicrobials to patients in Europe the lack of funding in R&D on AMR, followed by the lack of economic models incentivising R&D on AMR and a challenging regulatory environment.

3.1. Improve knowledge on detection, effective infection control and surveillance

Stakeholders involved in R&D called for funding of basic research, but also for research on communication, behavioural sciences and methods to promote a change in how antimicrobials are used. As indicated in its Communication on the new One Health action plan, the Commission remains committed to supporting research to better understand epidemiology, resistance mechanisms or AMR-related challenges and to improve early detection of disease outbreaks.

3.2. Develop new therapeutics and alternatives

In view of prioritising research, 76% of the stakeholders agreed that the EU should develop a list of R&D priorities for resistant pathogens, i.e. a priority pathogens list. This option will be further explored in the implementation phase of the new One Health action plan.

In addition, views and proposals from stakeholders called for supporting scientific communities to easily access, share resources and use existing data to convert into new knowledge and for supporting scientific research on novel alternatives to antimicrobials (e.g. medicinal product repurposing). This input will be translated into policy options to facilitate efforts in the development of new antimicrobials and novel alternatives and to address scientific challenges.

3.3. Develop new preventive vaccines

In order to select the appropriate pathogens for the development of new vaccines against AMR pathogens and HAIs, stakeholders considered that it would be beneficial to clearly define priorities and to establish the necessary tools to support this development. In the new One Health action plan, the Commission indicated its commitment to supporting the development of new effective preventive vaccines.

3.4. Develop novel diagnostics

Stakeholders considered rapid diagnostic tests essential to inform prescribing and therefore to use antimicrobials appropriately in the human and animal health sectors. They also called for supporting and funding targeted research for innovative, rapid and more mobile technologies in order to facilitate and accelerate the detection and identification of pathogens.

Other options addressed by stakeholders fall under Member State competences and include promoting alternative reimbursement systems for rapid diagnostics and encouraging the uptake of rapid diagnostics in the human and animal health sectors.

3.5. Develop new economic models and incentives

Stakeholders widely supported the development of new funding and business models for improved access to innovative technological solutions to prevent and control AMR and HAIs.

In terms of incentives, stakeholders familiar with funding instruments expressed considerable enthusiasm for funding possibilities under the European Framework Programme Horizon 2020 (95% considered it very important or important), followed by funding provided by the

Innovative Medicines Initiative (IMI) public-private partnership (92% considered it very important or important).

But whereas these push mechanisms were very well regarded, pharmaceutical industry stakeholders advocated for complementing them with pull mechanisms rewarding innovation earlier in the product life cycle and reducing the proportion of manufacturer revenue derived from antimicrobial sales volume in order to align with stewardship principles. These options will be explored in the implementation phase of the new One Health action plan.

3.6. Close knowledge gaps on AMR in the environment and how to prevent transmission

Stakeholders agreed that a clear understanding of the transmission dynamics between AMR in the environment and humans, animals, and food is lacking. In their contributions stakeholders consistently pointed to funding research on the impact of antimicrobial discharges into the environment and the mitigation of the risk that this may pose.

4. SHAPING THE GLOBAL AGENDA

The challenges of AMR are globally shared and due to travel and trade, the spread of AMR can be further facilitated.

Citizens expressed strong support for both EU-centred and worldwide action on AMR, which is in line with the actions presented in sections 2 and 4 of this report. Stakeholders considered global coordinated action crucial and expressed a preference for EU efforts in the non-EU European region, followed by the South Asian region and the North African region. These preferences were reflected in the new One Health action plan, with capacity building activities foreseen in EU candidate and potential candidate countries and neighbouring countries (including those where the European Neighbourhood Policy applies), which applies to certain non-EU European and North African countries. Further, activities with the South Asian region are also foreseen under the Better Training for Safer Food (BTSF) initiative.

4.1. A stronger EU global presence

Stakeholders expressed clear support for reinforcing cooperation with normative international organisations (e.g. WHO, OIE, FAO⁴, and Codex Alimentarius) to tackle AMR. Stakeholders additionally pointed to international actions including that imports to the EU (e.g. food) should meet EU standards and that the Commission should support the establishment of international databases on the monitoring of antimicrobial use and occurrence of resistances. Stakeholder suggestions relating to advocating EU standards and measures on AMR and reinforcing technical cooperation in areas covered by the WHO Global Action Plan on AMR were reflected in the new One Health action plan.

A few stakeholders also urged for action to address discharges to the environment from the pharmaceutical industry by enforcing on-site inspections and amending rules under the Good Manufacturing Practices to include environmental and waste management criteria. In its Communication, the Commission underlined its support for efforts to manage pharmaceutical manufacturing effluents effectively. Enforcing on-site inspections on environmental matters in countries outside of the EU would be beyond the mandate of the Commission.

⁴ WHO: World Health Organisation, OIE: World Organisation for Animal Health, FAO: Food and Agriculture Organisation of the United Nations.

4.2. Stronger bilateral partnerships for stronger corporation

Stakeholders perceived positively fostering bilateral partnerships with key EU trading partners and major regional and global players (e.g. USA, Canada, Brazil, China, India, and South-Africa). The Commission is committed to working with strategic partners in the new One Health action plan. Capacity building, trade and partnership agreements, as well as non-binding cooperation were endorsed by stakeholders. Several stakeholders called for stronger action with countries that export large volumes of antimicrobials to Europe, yet proposals that encroached on national sovereignty were disregarded.

4.3. Cooperating with developing countries

In their comments, stakeholders asked for international actions including raising awareness of AMR globally and assisting countries that most require support through surveillance and stewardship capacity building. While the EU can raise political awareness in international forums (e.g. United Nations), public awareness-raising activities in third countries are beyond the capacity of the Commission, hence any proposals for activities relating to the Commission directly launching public awareness-raising campaigns in third countries were dismissed.

4.4. Developing a global research agenda

Stakeholders expressed favourable opinions on research coordination. In terms of international action, they advocated for improving mapping and coordination of global R&D efforts, and globally supporting R&D efforts, particularly regarding the WHO list of R&D priorities on AMR and addressing multidrug-resistant tuberculosis.

5. CONCLUSION

Overall, citizens and stakeholders expressed through their replies very strong support for a new Commission Communication on a One Health action plan to support Member States in the fight against antimicrobial resistance (AMR). They believed that AMR is a major public health issue in which the EU can bring real added value and propose concrete measures.

The feedback provided on the Commission roadmap was used to inform policy-making in the area of AMR and to define the action areas under the three main pillars of the new One Health action plan. The open public consultation results confirmed the input received on the roadmap and provided additional insights. The contributions mentioned in this report have to a great extent been translated into concrete actions in the new One Health action plan or are being further analysed to be put into possible actions during the implementation phase.

In order to make the EU a best practice region, stakeholders acknowledged the importance of developing sound monitoring and surveillance systems at EU level in order to inform policies. Although stakeholders rated positively the information collected by current EU surveillance systems on AMR and antimicrobial consumption, they particularly called for the collection of antimicrobial consumption data amongst individual species in the animal health sector. To strengthen the evidence base they also advocated for generating evidence through health economics and evaluation studies which show the value of policies or interventions.

Stakeholders were also very vocal on the relevance of slowing down the emergence of AMR by developing infection prevention and control measures, antimicrobial stewardship programmes and prudent use policies. Stakeholders in the human health sector called for priority actions on infection prevention and patient safety in hospital environments. They also called for the promotion of vaccination, in particular at Member State level, as an effective public health measure to prevent infections and consequently reduce the need for using antimicrobials. In turn, stakeholders in the animal health sector asked for new initiatives on

infection prevention, animal husbandry practices and best practice feeding regimes, and expressed their concern over the reduced availability of existing antimicrobials and the poor availability of vaccines in certain markets.

Stakeholders strongly supported initiatives aiming to monitor antimicrobials and AMR in the environment, provided these are backed by a sound science-driven evidence base. They urged the Commission to adopt an EU strategic approach to pharmaceuticals in the environment.

In terms of research, development (R&D) and innovation on AMR, stakeholders were largely in favour of developing a list of priority pathogens at EU level to prioritise R&D and direct pharmaceutical industry R&D investment to the greatest threats. Pharmaceutical industry stakeholders strongly advocated for early and continuous dialogue with all relevant stakeholders throughout the entire product development cycle, and for a regulatory framework that prioritises the development of new antimicrobials, alternatives, vaccines and diagnostic tests. Stakeholders involved in R&D also asked for increased sharing of resources and better use of existing data. As regards the development of new diagnostics, stakeholders asked for targeted funding for innovative, rapid technologies but most prominently for actions to encourage their uptake and include them in antimicrobial stewardship programmes.

Stakeholders expressed support towards the development of new funding and business models to encourage the development of new antimicrobials, alternatives, vaccines and rapid diagnostics in order to prevent and control resistant infections and in particular HAIs. They conveyed great importance to push mechanisms such as the European Framework Programme 2020 and the Innovative Medicines Initiatives, but pharmaceutical industry stakeholders also advocated for pull mechanisms rewarding innovation earlier in the product life cycle.

At international level, stakeholders were largely in favour of reinforcing cooperation with international organisations to tackle AMR and fostering bilateral partnerships with key EU trading partners and major regional and global players. Stakeholders indicated preference for capacity building and cooperation in the non-EU European region, but also called for stronger partnerships with China and India, given their role in antimicrobial manufacturing and as major exporters of food products to the EU. Finally, stakeholders called for more capacity development and cooperation activities in low- and middle-income countries.