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From: General Secretariat of the Council
To: Council

Subject: **Employment, Social Policy, Health and Consumer Affairs Council**
meeting on 8 December 2017
Outcome of the High Level Meeting "AMR: One Health Action Plan and
evidence-based policy-making" (Brussels, 23 November 2017)
– *Information from the Presidency*
(Any Other Business item)

Delegations will find in Annex an information note from the Presidency on the above-mentioned subject to be raised under "Any Other Business" at the session of the Council (EPSCO) on 8 December 2017.

Outcome of the High Level Meeting

“AMR: One Health Action Plan and evidence-based policy-making”

23 November 2017, Brussels

Antimicrobial resistance (AMR) is a multisectoral problem. Tackling AMR needs collaboration and a comprehensive approach of a variety of actors from different sectors like health, agriculture and the environment. In 2016, the WHO Member States endorsed a global action plan (GAP) on antimicrobial resistance. In June 2017, the European Commission adopted the new EU One Health Action Plan against AMR (*hereinafter EU Action Plan*) in line with GAP, which contains concrete actions with EU added value and assumes close cooperation of all three sectors – health, agriculture and the environment. One Health is a term used to describe a principle, which recognises that human and animal health are interconnected, that diseases are transmitted from humans to animals and vice versa and have to be therefore tackled jointly. The One Health approach also encompasses the environment, another link between humans and animals and likewise a source of new resistant microorganisms¹.

The Estonian Presidency of the Council of the European Union decided to organise in collaboration with the European Commission the high level meeting on AMR with the aim to accelerate discussion and implementation of the One Health Action Plan on AMR and promote evidence based policymaking on antimicrobial resistance. The invitees were ministers and high level experts from the health, agriculture and environment sectors from all EU Member States. In total, 122 participants took part of this event. The event started with opening speeches by the Estonian Secretary General for Rural Affairs, Mr Illar Lemetti and by the EU Commissioner for Health and Food Safety, Dr Vytenis Andriukaitis. The two discussion panels focussed on the challenges and opportunities at Member State, EU and global level in the implementation of the One Health Action Plan and on effective evidence-based policy making. A more detailed summary of the discussions is provided in Annex I.

¹ https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf

Main outcomes and conclusions

Some key issues emerged from the High Level Meeting discussion:

The need for a One Health approach at all levels

Many drivers of AMR lie outside of the health sector. We must also engage crop and livestock farming and environmental experts. There is potential to collaborate with the pharmaceutical industry as well.

The need to mobilize political will at all levels of governance

One important element of tackling AMR is raising the awareness and commitment of high level persons and politicians responsible for shaping policies in the sectors of health, agriculture and the environment at all levels of governance.

The need to acknowledge the economic burden of AMR

AMR costs money. Small investments to tackle AMR can lead to bigger gains, not only for health but also for the economy.

The need for innovation

Although prudent use and infection prevention are cornerstones of the fight against AMR, we will still need new antimicrobials as well as vaccines. Particularly when it comes to the former, new business models, including push and pull incentives are needed to promote research and development.

The need to learn from country examples and bridge gaps within Europe

Though Europe is a successful region for AMR control, wide differences exist between countries. Platforms to share positive examples are welcome.

The need for healthcare workforce education

The healthcare workforce is at the forefront of the fight against AMR and they need better skills in treating, as well as managing and guiding their patients.

The need to further promote infection prevention and control

Particularly, hand hygiene was highlighted as a highly cost-effective method to combat AMR.

The need to act on AMR in the environment

Although more research is welcome, there is a more urgent need to act on pre-existing knowledge, particularly when it comes to the resistance caused by emissions from pharmaceutical manufacturing in certain parts of the world.

The need for behavioural change in healthcare providers, veterinarians and the general public

It is not enough to only raise awareness, we need to transform the knowledge and awareness into behavioural change.

The importance and challenge of measuring AMR

AMR data is of vital importance but having multiple monitoring mechanisms runs the risk of duplication. There is a clear need for greater coordination to ensure coherence and comparability of data. This includes the need for joint indicators. The data presented should also cover HCAI and IPC and be engaging and easily understandable. Initiatives, such as the joint indicators developed by EMA, EFSA and ECDC, could be a way forward. Better data needs to lead to evidence based policy making.

The need to support countries in AMR monitoring

We are still missing AMR data from a number of European countries, who for various reasons lack the capacity to monitor.

The need for the EU to be a global actor on AMR

The EU can use its influence to change practices outside of the union. One potential way is to use trade measures such as trade agreements that contain clauses on AMR.

The need for a systematic approach

We must avoid overly simplistic solutions and take the potential repercussions of our policies and measures into account.

Discussion panel I: The New EU One Health Action Plan Challenges and Opportunities at Member State, EU and global level

The first discussion panel focused on the challenges and opportunities for Member States, the EU and the rest of the world. The panellists were **Ms Karin Kadenbach** (MEP European Parliament), **Mr Zbigniew J. Król, PhD, M.D** (Deputy Minister of Health, Poland), **Mr Niclas Jacobson** (Deputy Director-General/Head of the Division for EU and International Affairs at Swedish Ministry for Health and Social Affairs, Sweden), **Mr Jean-François Heymans** (Director of the Directorate Animal Health & Safety of Animal Products at DG Control Policy of FASFC, Belgian Chief Veterinary Officer (CVO), Delegate of Belgium to OIE), **Prof Christian Brun-Buisson** (Ministerial delegate on AMR from the French Ministry of Health, EU JAMRAI), **Mr Mark Pearson** (Deputy Director of Employment, Labour and Social Affairs, OECD), **Ms Nathalie Moll** (Director general of EFPIA) and **Dr Danilo Lo Fo Wong** (Programme Manager for Control of Antimicrobial Resistance, WHO).

The first discussion panel was moderated by **Mr Xavier Prats Monné** (Director-General for Health and Food Safety).

A key challenge, according to WHO, is that many of the drivers of AMR lie outside of the health sector. This highlights the need for a multisectoral approach. Member State representatives from Poland, Sweden and Belgium introduced their national actions, which have proven that measurable results can be achieved with concerted action across sectors. For example, Belgium reported a 53% reduction in the use of critical antibiotics in the animal sector. Nordic countries have achieved good outcomes as a result of long-time stewardship and proper AMR management.

The need to learn from successful examples and to bridge the gap between EU member states was voiced. One way to address this is through the EU Joint Action on AMR, which connects 44 partners from 28 countries in an effort to strengthen national actions in areas such as policy making, research and the prudent use of antimicrobials. The EU-JAMRAI furthermore seeks to ensure coherence between the objectives of the EU and the WHO, which is to continue as the leading actor in the global fight against AMR.

Several speakers highlighted that AMR is not only challenging for health systems, but also for the economy. It is estimated that by 2050, every year 10 million people may die due to AMR, while costing the global economy around 1 trillion dollars according to the World Bank. Taking action on AMR, therefore, has clear economic value. According to OECD models, every dollar spent on hand hygiene to prevent infection, would result in a 5 dollar return for hospitals alone. Other effective methods of fighting AMR, such as antimicrobial stewardship programmes and improved environmental hygiene would cost more for hospitals, but the gains would be felt in society. Mass media campaigns – while relatively cheap to carry out – also carry the least benefit. Several speakers nevertheless pointed out the need for education and awareness raising in order to achieve the necessary behavioural change and overcome resistance among end-users. Particularly, healthcare workers need both knowledge on AMR and communication skills to tackle the issue and to treat and inform patients appropriately.

In addition to preventing AMR, the need for new medicines was pointed out by several speakers, both to treat infections and to prevent them. In particular, the importance of vaccination and the lack of vaccine coverage was highlighted. New business models as well as push and pull incentives are needed for the development of new antimicrobials. The representatives of the pharmaceutical industry expressed their commitment to advance R&D for new antimicrobials and to improve the efficacy of vaccines. This work is carried out for example through the IMI public-private partnership programme "New drugs for bad bugs". The industry also sees the need to be engaged in the One Health Network, to work together with public authorities as partners in One Health.

There was overwhelming consensus that proper monitoring of AMR is crucial to curbing it. The challenge is balancing the need to monitor with having a reasonable reporting burden. Furthermore, the knowledge needs to be translated into actual behaviour change and to guide policy decisions. The WHO has provided tools and templates to assist policy makers in this regard. More intervention research is needed, however, on what works or not.

In terms of the EU Action Plan objective to intensify EU efforts worldwide, several speakers in the room put forward the idea that the EU could use trade measures e.g. trade deals to demand better practices related to AMR from other countries.

Finally, the need to avoid overly simplistic solutions was stressed. Although it makes sense to limit the use of antibiotics of critical importance to humans in the animal health sector, we cannot ban them entirely. Albeit trade measures could be used against AMR, in doing so, the EU should avoid creating unnecessary technical barriers to trade.

Discussion Panel II: Effective evidence based policy making on AMR: science, surveillance and policy-making decisions. How to put evidence into practice and achieve effective policy making on AMR at the national, EU and global level

The second discussion panel focused mainly on the environmental aspects of AMR as well as on how to measure antimicrobial resistance and consumption. The panellists were **Dr Line Matthiessen** (Acting Director of the Health Directorate, Directorate General on Research and Innovation, European Commission), **Mr Jordi Torren Edo** (Head of Service of Veterinary Risk and Surveillance, Veterinary Medicines Department, EMA), **Mr Pietro Stella** (Biological Hazards (BIOHAZ) Team Leader and Panel Coordinator, Unit on Biological Hazards and Contaminants, EFSA), **Dr Diamantis Plachouras** (Senior Expert, Antimicrobial Resistance and Healthcare associated Infections, ECDC), **Prof Dr Lothar Wieler** (President of the Robert-Koch-Institute; representing also G20), **Dr Danilo Lo Fo Wong** (Programme Manager, Control of Antimicrobial Resistance, WHO), **Dr Matthew Stone** (Deputy Director General on International Standards and Science, OIE), **Prof Joakim Larsson** (Professor in Environmental Pharmacology, Director of the Centre for Antibiotic Resistance) and **Prof Kåre Mølbak** (Executive vice-president at Statens Serum Institut, Denmark).

The panel was moderated by **Prof Dame Sally Davies**.

Professor Joakim Larsson gave an overview of AMR in the environment, which illustrated that although we were still missing evidence in some areas, in others we have plenty of data to act upon – a fact also acknowledged by the pharmaceutical industry. In areas of India, major discharges from the manufacture of medicinal products have resulted in environmental antibiotic levels that are higher than in patients (30 mg/L). Novel resistance genes are found in industry areas that could easily be transferable to common infectious agents such as *E. coli*. The following actions were proposed:

- include emissions from production and risks for resistance selection in the Environmental Risk Assessment guidelines for pharmaceuticals in the EU;
- make the relevant parts of the European registration dossiers for pharmaceuticals public to illustrate where they come from;
- create economic incentives for cleaner production;
- implement discharge limits for antibiotics within the EU;
- put pressure also on non-EU manufacturers.

The room was in agreement about the need to take action on AMR in the environment, but it was unclear who should take the lead, as specialized agencies, for example, are bound by legislation.

The need for comparable global antimicrobial resistance data was stressed in the second half of the panel. A variety of databases already exist, which governments report to, but coordination is needed to avoid duplication. To this end, three EU agencies (EFSA, ECDC, EMA) recently generated a set of indicators to measure progress on AMR. These indicators address both human and animal health and are based on data that is already being collected. There was broad support for the indicators in the room. In addition, several participants voiced the need for measurable health care associated infections (HCAI) and infection prevention and control (IPC) indicators, which, according to the ECDC, have already been developed. Furthermore, several panellists raised the issue that getting people to look at data is just as important as collection, highlighting the importance of presenting data in an engaging manner.

At the same time it was acknowledged that several countries faced difficulties in providing data. Dr Matthew Stone particularly stressed the difficulty of measuring antimicrobial consumption in veterinary practice. There was consensus that more support was needed to ensure good monitoring practices. WHO is setting up such a support program (CAESAR) for Central Asian and Eastern European countries. ECDC is making weekly country visits on request. In addition, cooperation within networks of national public health institutes was considered important to improve monitoring capacity in tackling AMR.

Additionally, the second panel briefly touched upon the issue of whether veterinarians should be prohibited from profiting from the sale of antimicrobials. The benefits of such a measure were acknowledged but only when applied in tandem with the provision of alternative means to earn an income.
