

Council of the European Union

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NOTE	
From:	General Secretariat of the Council
То:	Council
Subject:	Presidency conferences
	- Information from the Presidency

Delegations will find in <u>Annex</u> an information note from the Presidency on the above mentioned subject to be raised under "Any other business" at the meeting of the EPSCO Council (Health) on 13 June 2023.

Information on the conferences and high-level meetings organised by the Swedish Presidency of the Council of the European Union in the area of health

The main health priorities during the Swedish Presidency of the Council of the European Union are access to pharmaceutical products, implementing Europe's Beating Cancer Plan and antimicrobial resistance (AMR), in addition to files subject to negotiations in the Council.

<u>High-level conference: Equity, excellence, and innovation – modern cancer care for all,</u> <u>Stockholm, 31 January–1 February 2023</u>

Thanks to the constant advancements in the field of cancer care, more and more people today survive a cancer diagnosis. Yet if nothing is done, cancer is on pace to be Europe's leading cause of death by 2035. To prevent this development, Member States must take further action against the disease. Europe's Beating Cancer Plan offers an important framework and a clear direction for how this can be done. At the end of January, the Swedish Presidency and the European Commission jointly held a high-level conference on cancer, continuing the important work of the Czech and French Presidencies. As the title of the conference, Equity, excellence, and innovation – modern cancer care for all, suggests, the aim was to advance the implementation of Europe's Beating Cancer Plan and to share knowledge on how to ensure equal cancer care for all.¹

The first part of the meeting was dedicated to patient testimonials. The testimonials demonstrated the differences in care both between and within Member States and urged the participants to ensure the inclusion of patients' perspectives in the further development of cancer care.

¹ To access the final version of the agenda, please see <u>Official Website of the Swedish Presidency of the</u> <u>Council of the European Union</u>

In the subsequent session, the importance of – and new perspectives on – prevention offered by precision health were emphasised. Topics included the use of digital tools to increase public awareness of key risk factors and the recently published inequalities registry, which provides sound and reliable data on Member States' cancer prevention.

The discussion on prevention was followed by a session on the importance of early detection. The session highlighted, amongst other things, the importance of cancer screening for equal access to early detection and the important step that was taken towards equal access to screening thanks to the updated Council recommendation adopted in late 2022. The conference also highlighted the possibilities to further advance early detection methods that lie within the use of biomarkers.

The final theme of the conference was health data as a key to modern and equitable cancer care. Examples considered included the European Health Data Space (EHDS) and artificial intelligencebased precision health innovations. The secondary use of health could facilitate a paradigm shift in cancer care by allowing each affected individual to be both diagnosed and treated more efficiently. Lest these types of innovations lead to health care gaps, however, it is vital that we ensure that these advancements are made available to all.

Throughout the meeting, panels reinforced the urgent need for a holistic perspective on cancer care and the development thereof. To make withstanding and notable changes in cancer care, the entire disease pathway must be considered. As up to 40 per cent of all cancer cases within the EU are estimated to be preventable, resources must be allowed to be invested in long-term prevention efforts. As a patient's prognosis is strongly affected by the stage in which a cancer is discovered, it is also urgent that we continue the work in advancing access to – and methods for – early detection. Once a person has been diagnosed with cancer, they must be able to feel safe knowing that they are being offered the best possible care. To enable this, continued and further exchanges between Member States are of utmost importance. Equally important is the constant involvement of patient voices, as it is them that we are here for.

High-level meeting on antimicrobial resistance (AMR), Stockholm, 6-7 March 2023

The meeting aimed to stimulate reflection and dialogue and to explore how the EU, through its Member States and institutions, can leverage progress in tackling AMR. Taking a One Health approach, the meeting centred around the human health perspective with a two-fold focused on EU-contribution to a reinforced global response to AMR and sustainable access to existing and stimulation of the development of new antibiotics.

The high-level meeting was attended by participants from EU and EEA countries, and key international organisations, ranging from ministers, state secretaries to senior advisors and experts.²

During the meeting, the speakers *reinforced* that AMR is a political priority for EU Member States. EU action is a powerful tool to enhance the response to AMR, within the Union, nationally and globally. Being a part of the global community, the EU has an obligation to play a leading role and has an opportunity to utilise and guide the conversation at global level in delivering better health for all. The EU Global Health Strategy, which has a strong focus on AMR, is a steppingstone for playing a leading role in the work against AMR.

JAMRAI-2 will constitute a significant platform for taking some of the required action on EU level further, particularly since all EU Member States are involved as are four neighbouring countries and key EU institutions. Research and innovation relating to all aspects of AMR are supported within the Horizon Europe framework. The One Health AMR Partnership, co-funded by the Commission and EU Member States and which is currently being established could coordinate funding and facilitate coherence to effectively close knowledge gaps on AMR and provide new solutions to identified challenges.

² To access the final version of the agenda, please see <u>Official Website of the Swedish Presidency of the</u> <u>Council of the European Union</u>.

The speakers further *expressed* that the EU can help to pave the way for strong global governance and commitments through the pandemic treaty and the political declaration of the high-level meeting on AMR in the UN General Assembly in 2024. There are additional regional and global fora with the potential of highlighting the urgency of a strong AMR response – such as upcoming UNGA high-level meetings in 2023 on universal health coverage, tuberculosis and pandemic prevention, preparedness, and response.

There is a need for global financing of implementation of national action plans and antibiotic research and development, as well as a need for support for building local manufacturing capacity for antibiotics and vaccines. Investment in counteracting AMR needs to be put in relation to the current EUR €1.5 billion in expenditures in the EU, and the expected increasing costs for global inaction. Support to countries should not be limited to funding but must include technical expertise and health systems strengthening and always be adapted to the local context.

In order to ensure sustainable access to existing and new antibiotics, an end-to-end approach needs to be applied to the fragmented "Research & Development and Access Chain". A comprehensive combination of suggested solutions to the fragmented "Research and development and access chain" could include coordinated research prioritisation; investments in young scientists; an EU structure for technical and regulatory support and advice; expansion of clinical trial networks; milestone rewards; waived registration fees; joint procurement; revenue guarantees and virtual stockpiling. Diversified sourcing and increased production capacity are also required at national, EU and global level.

Strategies are needed to clarify public health priorities to guide industry and to enable partnerships, commitments, and tangible deliverables. There is a need for a number of potential payment models, and the Swedish pilot on a partially de-linked reimbursement model to secure access to antibiotics of special medical value was highlighted. This revenue guarantee solution serves as a model for upcoming pilots in other countries. Ensuring access must always be complemented by measures to steward responsible use of antibiotics along with infection prevention and control implementation.

Finally, the participants *concluded* that the meeting offered an opportunity to contribute to the preparations for the upcoming EU negotiations on the pharma legislation and the Council recommendations on AMR. The meeting also served as a forum to initiate dialogue and exchange on the road leading up to the high-level meeting on AMR in the UN General Assembly in 2024.

There is a need for the implementation of a comprehensive combination of sustainable push and pull incentives that secure access to new and existing antibiotics. These incentives should be designed to consider the multiple causes behind and contexts contributing to the development of resistance and to the weak availability. Various initiatives to stimulate innovation and improve access to antibiotics are being developed in different regional and national contexts, requiring EU and global coordination and concomitant up-scaling.

The EU should speak with one voice in the work leading up to and during UNGA 2024 to drive the collective ambition and work forward, striving for bold commitments and the accountability of heads of state and government of all UN Member States. The European Union, through its Members States and institutions is ready to take the next necessary steps to leverage global progress on AMR together with partner countries and organisations. Global action is urgent. By working together within the EU and with international partners and countries, we can accelerate the collective response to AMR.

<u>High-level meeting on combatting loneliness – policy options to combat loneliness and</u> <u>strengthening mental health in the EU, Stockholm, 20–21 April 2023</u>

In mid-April, the Swedish Presidency arranged a high-level meeting on loneliness – policy options to combat loneliness and strengthening mental health in the EU. The meeting was the first of its kind and aimed to bring attention to the issue, and build synergies with the Commission's new initiative on mental health.³

³ To access the final version of the agenda, please see <u>Official Website of the Swedish Presidency of the</u> <u>Council of the European Union</u>

The meeting, attended by researchers, stakeholders, the Commission and Member State representatives, started with a panel on health-related aspects on a global level. The purpose was to define the causes, consequences for individuals and society at large, and how to forecast loneliness in the future. Culture and societal norms' effects on loneliness in different countries was introduced, and how solutions need to be adapted to the circumstances was discussed. Participants expressed that loneliness is not only prominent in the West but also in other parts of the world. Furthermore, participants agreed on the need to gather more and better targeted group-specific data to obtain a better understanding and prediction of loneliness. New initiatives to gather data and evidence for the purpose of supporting policy-makers were introduced during the meeting.

Moreover, the connection between loneliness and mental health was discussed – more specifically, identifying the most successful therapeutic approaches to help individuals suffering from mental ill health and loneliness. Participants expressed the need to categorise loneliness as different from social isolation and depression. At the same time, individuals who are lonely for a longer time have an increased risk of suffering from depression later in life. Therefore, continuity in mental health care and loneliness intervention is important.

Afterwards, Member State representatives shared learnings from national strategies on loneliness in a panel. The COVID-19 pandemic's effects on loneliness and mental health were a recurring theme during the discussion. Young people were hit particularly hard by social distancing measures, leading to an increased reported share of people between 18 and 25 feeling lonely. Mental health and social relationships are crucial pre-conditions for all young people to have good living conditions and a healthy life. Furthermore, the panellists emphasised that measures against loneliness should be considered investments in public health. It is clear that loneliness causes damage on an individual, community and national level. Well-functioning communities, societies and economies rest on the foundation of social connections between people. Participants also agreed on the importance of improving communication to convey information about loneliness and its effect to citizens. Existing measures around communication that Member States considered successful included information campaigns and helplines. The session aimed to contribute to a better-informed citizen and preventing self-diagnosis.

Lastly, pathways to preventing loneliness in collaboration with civil society were introduced by actors such as religious communities, sports organisations, youth and pensioner organisations, which will be an important part of the work in preventing loneliness. One agreed-upon outcome was that the role of different local stakeholders should be emphasised, with the primary purpose of enhancing social relationships and better identifying vulnerable groups. Here, it is important to keep in mind that young people with disabilities tend to experience feelings of loneliness to a higher extent than people without disabilities. This requires broad efforts in several policy areas, where social inclusion is key.

Throughout the meeting, participants agreed on the need to raise awareness about loneliness and recognise the stigma around it. Improved communication between patients and mental health clinics is a large part of reducing the stigma. There is also a need to accelerate the adoption of evidence-based solutions to reduce social isolation and loneliness, including adoption of tools for identification of different types of loneliness. Furthermore, a national loneliness strategy should work together with the Commission's existing initiative on mental health and research on loneliness in the EU – part of it being a cross-sectoral approach including cooperation with non-governmental actors, and also recognising that culture and societal norms play a role in explaining perceptions of loneliness.

<u>The Presidency conference on Life Sciences – The Era of Personalised Medicine, Stockholm,</u> <u>26–27 June 2023</u>

During its last month, the Presidency will also host a conference on life sciences. The conference spotlights life sciences, with the aim of taking the next step in the development and organisation of personalised medicine, which is a key issue for Europe. It will provide an opportunity for international dialogue and collaboration between the key stakeholders. The conference will highlight the importance of research and innovation, point out opportunities and challenges, and set out the future course for Europe.⁴

Expert meeting on antibiotics

On 6 March 2023, an expert session was arranged under the auspices of the Swedish Presidency of the Council of the European Union. The purpose was to discuss challenges and possible solutions on sustainable access to existing and new antibiotics. Two background documents served as basis for the discussion; 1) an illustrative model of the antibiotic Research & Development and Access Chain and its challenges, developed by the Swedish presidency and 2) a policy brief developed by the European Health Observatory on Health Systems and Policies on how the EU can support sustainable innovation and access to effective antibiotics. The session, attended by 75 EU/EEA member state representatives and experts, was also a part of the preparations of the succeeding high-level meeting on AMR.

⁴ To access a preliminary version of the agenda, please see <u>Official Website of the Swedish Presidency</u> <u>of the Council of the European Union</u>

Dr. Malin Grape, Sweden's Ambassador on Antimicrobial Resistance, commenced the expert session by expressing the severity of antibiotic resistance and lack of access to effective antibiotics and also the devastating future effects if we refrain from accelerating action. Common infections and injuries, that were once treatable, are becoming more dangerous and are taking increasing numbers of lives once again. Antibiotic resistance is killing over 1 million people every year. Dr. Grape concluded her presentation with presenting the fragmented antibiotic Research & Development and Access Chain to illustrate the current challenges in the antibiotic life cycle.

The introduction by Dr. Grape was followed by a presentation from Dr. Michael Anderson, Dr. Dimitra Panteli and Prof. Elias Mossialos on the key outcomes of their work presented in the policy brief, focusing on feasible actions at EU-level to ensure innovation and development of new antibiotics and how the EU can promote sustainable and timely access to pre-existing and new antibiotics, once developed and approved.

Following this, group discussions were organized among member states representatives and experts, each group assigned a certain thematic area, related to the antibiotic Research & Development and Access Chain. The focus for discussions was on possible solutions to the identified challenges and their implementation, and the themes included: drug discovery, clinical stages, registration on markets, production and supply, as well as public procurement.

The results from the group discussions were reported in writing and then compiled and presented by the organising team. Accessible information, strategic prioritisation, and support through existing agencies, such as HERA and EMA, and to invest in young scientists were among the suggested solutions to stimulate antibiotic R&D. Furthermore, possible EU-level initiatives were highlighted, for instance expanding clinical trial networks, pipeline coordination and the need for pull incentives de-linking revenue from volume and price.

To improve availability to antibiotics, abolished registration fees, E-labelling, increased transparency in production and supply chains and differentiated sourcing as well as virtual stockpiling and increased EU production capacity were among the many proposed measures. Also, several procurement and contracting aspects were discussed, which may be implemented at EU-level or nationally according to common principles. These span from longer contract duration and rewarding delivery security to joint procurement and revenue guarantees contracting access. Experts unanimously agreed on the urgency of securing sustainable access to new and existing antibiotics and called for increased and more targeted funding, based on public health needs. New methods of funding and efforts to improve pipeline attrition rate were suggested by the experts, such as specific funding for Small and Medium size Enterprises (SMEs), milestone rewards in development of new antibiotics, market entry rewards and subscription payment models. The collective expert input was used to complete the fragmented antibiotic Research & Development and Access Chain with solutions, in order to present an end-to-end approach to sustainable access to antibiotics.⁵

⁵ To access this PPT, please see <u>Official Website of the Swedish Presidency of the Council of the European Union</u>