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Seizing the opportunity for European leadership on antibiotic development and access

EVENT REPORT



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A Friends of Europe dinner debate, entitled 'Seizing the opportunity for European leadership on antibiotic development and access', took place on 8 November 2022, in partnership with the Global Antibiotic Research and Development Partnership (GARDP). The event brought together high-level policymakers, health experts, members of the pharmaceutical industry, scientists and patient advocates to explore Europe's role in antibiotic development and the global fight against antimicrobial resistance (AMR). Discussions focussed on challenges around antibiotic Research and Development as well as access at the national, EU and global levels.

Key conclusions and recommendations

- Antibiotics are an EU priority with strong political momentum.
- Europe is poised to take a leading role in antimicrobials.
- Push and pull incentives are needed in Europe to drive development. The complexities of the market for antibiotic development and use mean that a combination of measures are needed. The wider impacts of those incentives need to be carefully reviewed.
- Both infrastructure and investment are needed to support antibiotic development.
- Innovation, access, stewardship and solidarity should be guiding principles of Europe's role in antibiotic development and the global fight against AMR.
- Improved regulatory pathways for product development are needed, particularly to build trust and encourage alignment of stakeholders
- International partnerships are needed to fight AMR.

Introduction

Antimicrobial resistance (AMR) and a lack of new drugs entering the market represents a crucial threat to public health and modern healthcare. Years of antibiotic misuse coupled with failure to implement effective infection prevention and control (IPC) measures have driven bacterial resistance around the world. With the spectre of forecasts estimating 10mn AMR-related deaths per year by 2050, alarm bells are sounding louder than ever.

A cornerstone of modern medicine, antibiotics changed the landscape in treating bacterial infections. The loss of effective antibiotics could allow common infections to again become life-threatening and hinder basic surgical procedures. Despite the gravity of the situation and the high value of new, readily available and affordable

antibiotics to health systems, the development of new antibiotics has been stalled worldwide. Antibiotics do not fit well into the traditional drug development pathways, as profitability is limited by usage restrictions – stewardship. The combination of low prices for current antibiotics and usage restrictions limits the market potential of new antibiotics, creating a disconnect between long-term public health interests and for-profit short-term objectives. Since the development of novel antibiotics is not a commercially viable investment for pharmaceutical companies, significant public or not-for-profit structures and funding mechanisms are required to complement private sector efforts.

Progress has been made in recent years, but work remains to be done. With growing infrastructure, political will and the creation of the European Health Emergency Preparedness and Response Authority (HERA), there is a window of opportunity to stimulate innovation and develop solutions, allowing Europe to take a leading role in the global AMR crisis.

Peter Beyer, Deputy Executive Director of the Global Antibiotic Research and Development Partnership (GARDP), led the debate by evoking three recent publications that demonstrate the urgency of addressing the current AMR situation. The publications included one recent study from the Lancet that cited 133,000 AMR-linked deaths in 2019 in the World Health Organization's European region (53 countries). Beyer likened AMR to climate change – a situation that is rapidly changing from an abstract notion to a crisis with repercussions felt at the personal level.

Since GARDP was established by the WHO in 2016, with political and monetary support from several countries, including EU member states, progress has been made on new antibiotic development and access for global AMR priorities as defined by WHO. Additional global initiatives that are complementary to GARDP, such as CARB-X and ICARS, and industry-specific initiatives, such as the AMR Action Fund, have also been formed and are developing additional strong strategic responses to address the global health security threat of AMR. AMR is a regular topic on the agenda of the G7 and G20 Summits, although funding, while increasing, is not sufficient to the scale of the challenge. Europe needs to define clear priorities and develop efficient economic models for developing solutions for AMR.

It was suggested that AMR may remain a priority under the upcoming Swedish European Council Presidency beginning in January 2023. A ministerial meeting on AMR is planned for March 2023.

Revised pharmaceutical legislation and a new Council recommendation, both expected in 2023, must be leveraged to address issues across Europe and at the global level. Key actions will include tackling vulnerabilities in the supply chain revealed by the COVID-19 pandemic. More work is needed to identify the enablers and barriers to implementing mechanisms to improve production, procurement and sustain supply and access to antibiotics. This should include ways to optimise the use of existing antibiotics.

During the meeting it was confirmed that HERA, a newly created Commission service, will prioritise AMR. Elements at the EU level include efficient regulatory processes to bring products to market, reliable intelligence in terms of assessment and forecasting, support for research and development, establishing effective medical countermeasures around prevention and diagnosis, establishing methodologies for mapping supply chains, and monitoring stockpiling, stock-outs, procurement and distribution. AMR

presents a high disease burden with high costs to public health systems. International partnerships, such as the G7, G20, EU-EC, the WHO and other institutions, are critical to create a real global impact.

Developing new products: incentives and investments

What degree of profitability is acceptable for products that are a cornerstone of medical care? Discussions around development, pricing, registration and procurement must take into account the high value of antibiotics in global health and to public health systems.

The development of new antibiotics is stymied by limited marketing opportunities and ineffective economic models. A representative from investment finance, described the difficulties of making the case for investing in antibiotics. The market profile is similar to that of orphan products in high income countries, yet without the typical high orphan pricing. A participant noted that investors need to take a wider view than just one molecule. There is a need to recognise that therapeutic areas such as cancer that are seen as providing high returns will not continue if health systems and providers do not have new antibiotics. Furthermore, low-and-middle income countries (LMIC) also face major access issues. It was highlighted that the current economic model is not working for for-profit industry, since the market is not providing required returns on investments.

Another participant noted that investment needs to be encouraged. Small and medium enterprises (SMEs) with potentially effective solutions cannot get their products developed because there is not enough investment. Innovative incentive schemes are needed to foster development. To stimulate antibiotic development in Europe, mechanisms are needed to support SMEs developing appropriate treatments to address AMR. Currently, SMEs have a high attrition rate. A number of SMEs have gone bankrupt and need timely interventions that generate support at scale.

Both push and pull incentives are needed, but there was no consensus at the meeting on which pull mechanism should be adopted at the EU level. Participants noted several issues that should be considered when looking at pull incentives including: predictability, scale and ability to implement across the EU, transparency, the need to focus on the benefits and challenges of direct (e.g. subsidies) and indirect incentives (e.g. TEV) for stimulating AMR R&D, the value of antibiotics to health systems, the potential effect on prices and competition, the experience of other countries (for example the US), and the possibility to apply conditions to address concerns for example on stewardship and access.

Some participants concurred that Europe faces many challenges around bringing products to market – not only in terms of funding but also with associated regulatory processes.

The need for sustainable access worldwide was highlighted. Any incentive mechanisms created in high-income countries should consider impact on low-income countries as

well. An international approach is needed for globally sustained products and trials. “We need to think outside of each regional bubble”. Incentive schemes for antibiotic development must integrate access and affordability. Participants heard warnings that health systems are already strained. Besides the COVID-19 pandemic, the European social protection platform is struggling with competing priorities, including health, unemployment, pensions, inflation, energy, migration flows and the Russia-Ukraine War. Innovation must, therefore, be balanced with solidarity.

The development of new products aside, de-registration of existing antibiotics is a real threat. A national representative warned that a solution must be found to avoid de-registration in Europe. The potential of combining older generic antibiotics to strengthen efficiency and offer protection to existing treatments was discussed. A public health approach is needed to assess risks and benefits in order to delay risk of resistance. Registration is one area where novel solutions could be introduced to bring new products to market.

International partnerships

There was wide agreement that partnership and international cooperation are crucial if the world wants to retain antimicrobial agents in its medicine chest. It was confirmed that the European Commission counts on working with Member States, the G7 and G20, the pharmaceutical industry, the veterinary sector, economic institutions and international organisations, such as the WHO, to address the global dimension of AMR. “It is important to work globally and support LMICs”.

It was noted that while the EU had made welcome investments in clinical trial networks, this was an area where there was a need for greater collaboration and coordination to develop both pan EU and international networks.

HERA will work with partners to commit countermeasures to stockpiling and address supply chain disruptions. The audience was cautioned that low and middle income countries (LMIC’s) will be hardest hit by AMR. It is crucial to generate the evidence necessary to inform effective policies in HICs and LMICs.

Thoughts on prevention

Implementing strong IPC measures in Europe and globally is key to mitigating AMR. Calling for optimised use of antibiotics as last-resort products, one participant noted: “Prevention and responsible antibiotic use are key to a holistic response.”

Public awareness must also be increased. The common sanitary gestures adopted to prevent COVID-19 should be sustained. Raising public awareness must be part of the prevention and control strategy in Europe and beyond.

Conclusion

The solution to AMR requires enhanced prevention and control measures, combined with incentives for innovative antibiotic research and development, and access. As a critical global problem, AMR needs multi-faceted responses that take into account the challenges of each country and region.

Improving the regulatory pathway for product development, ensuring fair pricing, balancing stewardship and access inequalities, promoting Infection prevention and control, public awareness, monitoring supply chains, stocking and procurement are all areas where Europe can take firm action and a global leadership role. Incentives to create novel therapies and recombine existing molecules are among the strategies that Europe can take to ensure the world continues to have access to effective treatments.

By capitalising on emerging legislation, novel solutions and strong political momentum, Europe is poised to take a leading role in fighting AMR.

