

## Consultation response

# Proposals for the Council's Recommendation on AMR



AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3 trillion in 2020, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

The American Chamber of Commerce to the EU (AmCham EU) welcomes the proposal for the Council's Recommendation on Antimicrobial Resistance (AMR). Our member companies are actively engaged in the fight against AMR from a One Health perspective, by researching and developing innovative biopharmaceuticals, vaccines, diagnostics and other technologies to improve the health of humans and animals. Given the environmental impact of AMR, several of our companies have already committed to ambitious plans to minimise environmental impact from our manufacturing operations.

The 2021 AMR Preparedness Index highlighted the limited progress made by governments around the world to implement reforms that incentivise Research & Development (R&D) in much-needed novel antimicrobials. The EU and Member States should strengthen their commitment to act on the following priority areas:

- Promote antimicrobial **stewardship**: This is key to preserving the effectiveness of existing treatments. Patients must receive the right antibiotic, by the right route of administration, the right dosage and for the right duration. There should be consistent implementation of existing EU guidelines on prudent use of antimicrobials in human and veterinary medicine.
- Expand and better coordinate **surveillance** tools and increase our knowledge of the mechanisms of resistance, including by leveraging the expanded mandate of The European Centre for Disease Prevention and Control European (ECDC) and the newly-established European Health Emergency Preparedness and Response Authority (HERA). There should also be increased collaboration with industry on this field.
- Implement ambitious and comprehensive **prevention** measures in the context of One Health, notably broader and more effective use of vaccines, alternatives to antimicrobials and new technologies such as medical devices and diagnostics.
- Develop and implement **new economic models and incentives** to promote R&D on antimicrobials, vaccines and medical devices (including diagnostics) and to facilitate access to them. The European Commission should propose a robust EU-level pull incentive, in the form of transferable exclusivity extensions, as part of the Revision of the General Pharmaceutical Legislation. This would have a concrete positive impact on R&D investments. In parallel, it is also critical that Member States reform national-level Health Technology Assessment (HTA) and reimbursement systems to recognise the broader societal value of AMR-related technologies. This could help improve access and availability for novel and existing antimicrobials.

To tackle AMR from a holistic perspective, it is essential to **foster partnerships** between the human health, veterinary medicine and environment sectors. This is a core element of the One Health approach and is crucial to ensure that all actors work together to address AMR in an effective manner.

The EU and its Member States must collaborate with other like-minded governments and organisations, notably the USA. Given that AMR is a major health and economic issue that does not respect borders, international cooperation is essential. Alongside the Transatlantic Taskforce on Antimicrobial Resistance's (TATFAR) ongoing work, we look forward to HERA's engagement with the Biomedical Advanced Research and Development Authority (BARDA) and to better understand what role companies can play in supporting a common agenda. Finally, regional/global initiatives such as Preventing Zoonotic Disease Emergence are key to consistently adopt the One Health concept and to tackle major human and animal health challenges.