



## Antimicrobial resistance – recommendations for greater action

### Antibiotic resistance is a cross-border threat

Antibiotic misuse and overuse are major drivers of antibiotic resistance (ABR). In the EU, there is a wide variation between countries regarding the use of antibiotics for humans, and over-the-counter sales of antibiotics still takes place in some member states. The EU needs to take greater leadership and responsibility to preserve antibiotic effectiveness. **The proposal for a regulation on serious cross-border threats as well as the revised pharmaceutical legislation should aim to address this by calling for evidence-based and transparent targets for antibiotic use in the health sector and avoiding over-the-counter sales. It should also address preventive measures such as by setting standards for Immunization and Infection Prevention and Control (IPC), including by strengthening IPC within the curriculum for education and training of healthcare professionals.**

### Reforming the innovation system

**Revitalizing antibiotic development requires an end-to-end approach** from discovery to distribution. Major scientific challenges continue in early stages of drug discovery. Considering that 81% of the preclinical pipeline is dominated by micro-and small-size institutions, **the EU should start exercising far stronger public leadership in supporting the further development of promising compounds from these institutions through sufficient and targeted funding for the preclinical development.** The previously EU-funded project ENABLE promoted research in the early stages of antibiotic development, resulting in several potential antibiotic molecules being developed and with one candidate drug that has undergone a Phase I clinical study. Support to such projects must be strengthened, not discontinued. Approaches to incentivising antibiotic R&D need to move away from focusing on “market fixing”, which tends to limit discussions to how to re-enlist the big multinational pharmaceutical companies within the constraints of their traditional business model. **The EU should introduce new incentives and approaches to R&D that fully “delink” the financing and costs of R&D from volume-based sales revenues, while ensuring affordable access and rational use.** This, coupled with incentives throughout clinical development, would trigger low-cost production and public health driven distribution models from the day an antibiotic receives market authorization. **Within its remit to “promote advanced R&D of medical countermeasures and related technologies”, HERA should build up a sustainable needs-driven end-to-end approach for development of novel antibiotics.**

With regard to distribution and patient access, it is important that medicines are made available to all who need them, not least in low-resource settings (LMICs), while ensuring stewardship. **Challenges with the antibiotic market, including shortages, would benefit from being addressed globally through a system of rules-based governance.** The EU should consider supporting pooled procurement and/or regional production to guard against disruptions of the supply chain of older antibiotics and work at global level to diversify global supply of API and production of new and old products.

### EU's strategy for the global AMR agenda

At a global level, a forthcoming new legal instrument, or “**Pandemic Treaty**”, is an unprecedented opportunity to address the need for resilient health systems that are highly dependent on sustainable and equitable access to effective antibiotics. **The EU should invest in building robust health systems in LMIC and ensure that ABR solutions are accessible and adaptable in these settings, while working actively for including AMR in the Pandemic treaty, starting with significant new investments in medical countermeasures.** Furthermore, **the EU should promote a revision of the WHO Global Action Plan (GAP) based on the gaps identified by the WHO Comprehensive Review, and intensify efforts towards addressing urgent global governance and funding challenges.**