



Key messages from ReAct for: The High-Level One Health Ministerial Conference on Antimicrobial Resistance/French Presidency of the Council of the EU

Created in 2005 [ReAct – Action on antibiotic resistance](#) is one of the first international independent networks catalyzing, advocating, and stimulating for global engagement on antibiotic resistance. Since its inception, ReAct has been engaged in multiple EU and international processes related to antibiotic resistance. ReAct initiated the first EU study on the [burden of antibiotic resistance and antibiotics pipeline](#), which was conducted by ECDC and EMA, in collaboration with ReAct. This report was an important input to [the Council Conclusions](#) following the Swedish EU presidency in 2009, which led to the first EU Action Plan. Hereunder ReAct has identified some areas and gaps where the European Union should improve and deliver a solid response in the health sector.

Antibiotic resistance is a cross-border threat

Antibiotic resistance, although not a disease as such, is an obvious example of a global cross-border health threat with pandemic proportions. Currently, according to recent published figures, antibiotic resistance causes 1.27 million annual deaths globally and it is severely affecting the function of both basic and specialized health care.

Antibiotic misuse and overuse are major drivers of antibiotic resistance. In the EU, the use of antibiotics for humans shows a wide variation between countries which could not be explained by differences in morbidity. Furthermore, over-the-counter sales of antibiotics without a prescription still takes place in some EU member states. Sustainable access to effective antibiotics must be seen as a global public good. EU needs to take greater leadership and responsibility to preserve antibiotic effectiveness. The proposal for a regulation on serious cross-border threats to health should address the need of preserving antibiotic effectiveness by setting targets for antibiotic use in the health sector and avoiding over-the-counter sales. Importantly, it should also address preventive measures such as Immunization and Infection Prevention and Control (IPC), for which continued research is needed for effectively achieving health security, while also reducing the need of antibiotics.

Reforming the innovation system with a needs-driven end-to-end approach

Following the first action plan on antimicrobial resistance, the EU Commission showed strong leadership by implementing several important projects for antibiotic research and development within the Innovative Medicine Initiative (IMI) New Drugs for Bad Bugs (ND4BB) programme. Unfortunately, the EU-funding for these projects have been discontinued. One such project was ENABLE, an initiative for the early stages of antibiotic development led by Uppsala University which resulted in several potential antibiotic molecules being developed and with one candidate drug that has undergone a Phase I clinical study.

Major scientific challenges continue in early stages of drug discovery, and financing for preclinical and clinical development are neither sufficient nor targeted enough. While the antibiotic pipeline remains unresponsive to global needs, global and national discussions need to move away from focusing on “market fixing”, which often limits discussions to only focusing on how to re-enlist the big multinational pharmaceutical companies within the constraints of their traditional business model.



Considering that 81% of the [preclinical pipeline](#) continues to be dominated by micro-size (<10 employees) and small-size (<50 employees) institutions, EU member states and EU-institutions have to start seriously considering the alternatives, and start exercising far stronger public leadership in testing new ways to overcome the actual challenges.

Revitalizing antibiotic development requires an [end-to-end approach](#) on how antibiotics are developed, produced and distributed. The EU should introduce new incentives and approaches to R&D to separate the financing and costs of R&D from volume-based sales revenues while ensuring affordable access and rational use. [The Political Declaration](#) of the High-Level Meeting of the General Assembly on Antimicrobial Resistance 2016, acknowledged the importance of “*delinking the cost of investment in research and development on antimicrobial resistance from the price and volume of sales*”. 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. We expect that HERA, within its remit to “*promote advanced research and development of medical countermeasures and related technologies*”, will build up a sustainable needs-driven end-to-end approach.

Antibiotic shortages

Shortages of antibiotics are a chronic problem for many countries. This causes patients to lose access to important treatments and contributes to increases in antibiotic resistance when treatment providers are forced to prescribe alternative antibiotics. Over the years, ReAct has discussed this increasing problem with the European Commission and the World Health Organization leading to an [international meeting](#) on the magnitude, causes and possible solutions of antibiotic shortages.

Already in [the Council Conclusions from 2009](#) member states and the Commission were called upon to “*examine how to keep effective antibiotics on the market*”. The issue has since been brought up at several following EU presidencies and some member states have initiated projects, but a coordinated EU strategy is lacking. The EU should consider establishing pooled procurement and/or regional production to guard against disruptions of the supply chain of older existing antibiotics and work at global level to diversity global supply of API and production. Challenges with the antibiotic market, including shortages, would benefit from being addressed globally through a system of global rules-based governance under the leadership of the WHO alone or with other relevant multilateral UN agencies.

A “Pandemic Treaty”

At 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, and that relies on preventive measures for effectively achieving safe care delivery and health security. Furthermore, given the cross-border nature of antibiotic resistance, and its burden disproportionately affecting low- and middle-income countries (LMICs), the EU has an important role to play to support LMICs in their strategic work with antibiotic resistance and assuring that solutions can be accessible and adaptable in resource-limited settings.