

European Union Leadership Critical for Affordable & Responsible Antibiotic R&D

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Antimicrobial resistance (AMR) is a global threat, which refers to microbes becoming resistant to antimicrobial medicines developed to treat them. Every time an antibiotic medicine is used, it increases the possibility of the microbe becoming resistant. Currently, AMR causes an estimated 25,000 deaths per year in the European Union (EU) and 700,000 worldwide.

AMR is a pressing threat to the world's sustainability and development efforts. For some countries, the era of effective antibiotics will soon end. Much of the global overuse of antibiotics occurs in low- and middle-income countries (LMICs) where the drivers are magnified by a lack of access to effective antibiotics, unregulated antibiotics sales and availability, and limited regulatory enforcement of aggressive antibiotics marketing practices by pharmaceutical companies. AMR has far-reaching implications for many of the United Nation's (UN) Sustainable Development Goals; it could undermine global achievements in health, development, poverty reduction and economic growth sectors.

Tackling the rise of AMR is high on the political agenda. The World Health Organization (WHO) issued its *Global Action Plan on AMR*; the UN convened a high-level meeting in September 2016, which resulted in a *Political Declaration on AMR*; and AMR has been recognised as a crucial international public health threat by the G7 and the G20. In Europe, the EU will soon launch its second *EU Action Plan on AMR*, including support for research and innovation. Individual EU Member States, particularly the Netherlands, the United Kingdom (UK) and Germany, are leading the charge to tackle AMR.

Many factors contribute to AMR, including the lack of preventive measures to avoid infections, inappropriate and routine use of antibiotics to promote growth in food production and animals, and the lack of development of proper new antibiotics. Affordability of existing antibiotics is still a problem in many LMICs. While the 'One Health' approach must be implemented to effectively address the interrelated factors that contribute to AMR, this policy brief provides key recommendations for the EU and EU Member States to develop antibiotic research and development (R&D) initiatives that result in affordable and appropriately used novel antibiotics.

Many ongoing initiatives in antibiotic R&D exist at the global, EU and EU Member State levels; however, there is little alignment between them. Furthermore, most, if not all, of these R&D initiatives lack the necessary conditions to ensure appropriate use of newly developed antibiotics. Conditions that ensure affordable patient access despite an often substantive public contribution to R&D are also lacking. Most antibiotic R&D efforts will originate in the EU and the United States (US) because they are home to leading research

centres. It is therefore crucial to insert a 'social justice' perspective of equity when developing new innovation models for antibiotic R&D. This will ensure that valuable new antibiotics are also available, affordable and suitable for people in LMICs.

As a leader in antibiotics research, the EU and its Member States must lead the way in shaping truly innovative antibiotic R&D efforts to respond to this urgent global crisis.

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