

Our position on Antimicrobial Resistance



What is the issue?

The World Health Organization recognises antimicrobial resistance (AMR) as one of the top ten threats to global public health. AMR threatens the effective prevention and treatment of an ever-increasing range of infections caused by bacteria, parasites, viruses and fungi. Resistance is compounded by misuse and overuse of antibiotics in both humans and animals. Continuing disruption of the natural environment due to extreme weather patterns contributes to the emergence and spread of AMR.

A recent study by The Lancet demonstrated the impact of AMR on patients worldwide. Analysis of data from over 200 countries in 2019 showed that 1.27 million deaths were directly attributable to bacterial AMR, ahead of both HIV and malaria. AMR is particularly prevalent in low-resource settings which deepens existing health inequities.

Rising bacterial resistance poses an immediate and profound threat to public health, modern medicine and patients. It threatens cancer diagnosis and treatment; undermines treatments for other life-threatening illnesses such as pneumonia and neonatal sepsis^{vi}; and adds serious and unnecessary risks to surgery, which rely on effective infection control.

Although the threat of AMR is serious and urgent, there are very few new antibiotics in development. This is due to three main factors:

- 1. The unique scientific challenges associated with discovering new antibiotics
- 2. The complexity of antibiotic development and running antibiotic clinical trials
- 3. The limited economic attractiveness of investing in antibiotic R&D and need for new commercial models

Similar challenges can also affect development of other interventions, such as anti-malarials, TB medicines and vaccines, further hampering efforts to get ahead of resistance.

What is GSK's view?

- The global community is at a critical point in the fight against AMR. COVID-19 showed that widespread infectious disease threatens lives and livelihoods. But the pandemic also demonstrated that collective effort generates a rapid, innovative response. There is a need for global solutions. While there is no single answer, in the aftermath of the COVID-19 pandemic, there is an opportunity to harness learnings e.g. the value of proactive investment in R&D and cross-sector partnerships and take decisive policy actions to mitigate the looming pandemic of AMR.
- Getting ahead of AMR and infectious disease will strengthen both health and economic resilience. Failing to tackle rising resistance will put lives at risk; place health systems under stress; and depress economies. The OECD has estimated that the related cost to the health care systems of EU/EEA countries is already around EUR 1.1 billion each year. Industry, governments and other stakeholders have an opportunity to stave off this threat by investing in measures to prevent and mitigate AMR and bolster health systems' resilience to infectious disease risks.
- A suite of complementary tools is needed to counter AMR. Antibiotics are a crucial part of our collective approach to tackle AMR as they help to treat and mitigate infections. Innovative economic tools are needed to stimulate development of new antibiotics; and ensure appropriate access. At the same time, we have an opportunity to get ahead of AMR through earlier intervention and prevention.



This includes improved sanitation and rapid diagnostics; addressing the climate and nature crises that can contribute to resistance; and importantly, using vaccines and other alternative approaches such as monoclonal antibodies and phages. Data surveillance will also aid in education of AMR and better equip us to act preventatively.

Vaccines are an important pathway towards preventing resistance as vaccines can help prevent
infections occurring in the first place, as well as transmission of bacteria that are already resistant (or
becoming resistant) to current therapies. Existing vaccines have already been shown to help combat
AMR and future innovation in vaccinology could pave the way to targeting other priority AMR threats
with vaccines. Viii Despite their potential, vaccines are still underused and undervalued as a tool
against AMR.

How can we get ahead of AMR together?

Industry, governments, and other stakeholders have a collective opportunity to get ahead of AMR together. Key areas where GSK is taking action to counter AMR include:

- Building on our long history in antibiotic development, we have a number of projects targeting priority
 pathogens deemed "critical" and "urgent" by WHO and the US Centers for Disease Control and
 Prevention. This includes a first-in-class antibiotic; and over the past two years, we have expanded
 our vaccines research programmes that could help counter AMR. The AMR Benchmark 2021
 recognised GSK as having the largest R&D pipeline among the big R&D-based companies.
- As advocates for new commercial models that incentivise investment in antibiotic R&D, while
 enabling global access, we helped found the AMR Industry Alliance and are partners in the AMR
 Action Fund.
- We have advocated for progressing antibacterial innovation through partnerships including Biomedical Advanced Research and Development Authority (BARDA), the EU Innovative Medicines Initiative Accelerator, and CARB-X.
- We have created educational programmes to raise awareness of AMR and detail the appropriate use
 of antibiotics to help healthcare professionals understand the challenges of AMR.
- To support surveillance efforts to understand the impact of resistant bacteria, we run the
 multinational Survey of Antibiotic Resistance (SOAR) programme, focused on community-acquired
 respiratory-tract infections.
- We have committed to minimise antibiotic discharge in our supply chain. At the same time, we will
 seek to ensure that factory discharges from our third-party antibiotic manufacturers and our own sites
 conform to the AMR Industry Alliance Common Antibiotic Manufacturing Framework and wastewater
 discharge limits.

What policy actions should governments take?

Governments have an opportunity to put concrete commitments behind long-discussed reforms by setting out a roadmap with clear timelines and accountabilities to:

 Establish market-based solutions that appropriately incentivise a full spectrum of interventions to combat infectious disease, including vaccines. This should include flexible



economic incentives and reimbursement approaches, as well as tailored valuations for assessing the full value of antibiotics and vaccines.

- Promote effective stewardship of existing and new antibiotics in humans, animals and
 agriculture, to protect the environment and public health, through responsible and
 appropriate manufacturing and use. Strengthened global manufacturing standards in AMR are key
 because high-quality antibiotics can reduce the likelihood of resistance^{ix}, as are coherent methods for
 collecting and sharing data.
- Enable appropriate access to a suite of interventions to combat infectious disease. Stronger
 infrastructures are needed to support routine immunisation programmes, along with reduced regulatory
 barriers for antibiotics and vaccines that address unmet needs.

¹ Antimicrobial resistance (who.int)

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WHO. No time to wait: securing the future from drug-resistant infections. 2019. Available from: https://www.who.int/docs/default-source/documents/no-time-to-wait-securing-the-future-from drug-resistant-infections-en.pdf?sfvrsn=5b424d7_6

iv https://wedocs.unep.org/bitstream/handle/20.500.11822/38373/antimicrobial R.pdf

^v Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis - The Lancet

vi http://www.healthdata.org/acting-data/antimicrobial-awareness-week-increasing-global-antibiotic-consumption-poses-major-health

vii Antimicrobial Resistance in the EU/EEA - A One Health response (europa.eu)

Fighting antimicrobial resistance with vaccines (nature.com)

ix falsified-and-substandard-healthcare-products.pdf (gsk.com)