



## EXECUTIVE SUMMARY

### Incentivising the development of new antibacterial treatments: Progress report by the Global AMR R&D Hub and WHO

Under the UK's G7 Presidency in 2021, Finance Ministers committed to take additional steps to address antibiotic market failure and create economic conditions to preserve essential existing antibiotics and ensure their access, strengthen antimicrobial resistance (AMR) research and development (R&D), and bring new drugs to market if they meet identified public health needs. To support this work, the G7 Finance Ministers requested the Global AMR R&D Hub and WHO to prepare a progress update for G7 Finance and Health Ministers in 2022. This brief is in response to this request.

#### Challenge

- In 2019, an estimated [1.27 million deaths](#) were a direct result of antibiotic-resistant infections, making AMR a leading cause of global mortality at a magnitude comparable to HIV and malaria. The World Bank and the World Economic Forum have singled out AMR as one of the biggest global health risks, with predicted losses of up to 3.8% of gross domestic product (GDP) globally by 2050. The time to act is now.
- The antibiotic market is broken. The return on investment for new so-called [reserve antibiotics](#) fails to cover the costs of their development, manufacturing and distribution.
- The commercial outlook for these reserve antibiotics is dire as they compete with the generic antibiotics given to most patients. New reserve antibiotics are only used for patients with resistant infections, severely restricting potential sales.
- This dynamic has resulted in the vast majority of large pharmaceutical companies exiting the antibiotic R&D space.
- The lack of viable commercial market severely limits the ability of the remaining small-and-medium enterprises in the field to attract investors.
- This is a complex challenge that requires targeted and increased investment and long-term commitment.

#### Progress to date

Building on the commitments highlighted in the [G7 Finance Ministers' Statement](#) in December 2021, covering activities to support antibiotic development, from implementation of national AMR Action Plans to actions to address antibiotic market failure and strengthen sharing of best practices, progress includes the following:

- AMR continues to be a serious health threat to G7 countries. Over the last decade, G7 countries have increased their commitment to addressing AMR through concerted domestic and global action.
- G7 countries are leading financial contributors to AMR R&D, including supporting a range of initiatives to accelerate the development and market entry of needed new antimicrobials (e.g., [CARB-X](#), [GARDP](#)).
- G7 countries are in various stages of developing and implementing a range of pull incentives to encourage antibiotic development. Key updates include:
  - UK: In April 2022, the National Institute for Health and Care (NICE) published its draft guidance on the value of [ceftazidime with avibactam](#) and [cefiderocol](#) to the National Health System, as part of the UK's subscription model pilot. The UK is set to become the first country in the world to pay drug companies (Pfizer, US; Shionogi, Japan) a fixed fee (10 million GBP per year) for supplying antibiotics.

- US: The Pioneering Antimicrobial Subscriptions To End Up surging Resistance Act of 2021 (PASTEUR Act) - a bill authorising the Department of Health and Human Services (HHS) to enter into subscription contracts for critical-need antimicrobial drugs - is gaining more [bipartisan co-sponsors](#) (40 to date).
- Germany: Changes in §35 Sozialgesetzbuch (SGB) Fünftes Buch (V) and Act for Fair Competition Among Health Insurance Funds in the Statutory Health Insurance Sector (GKV-FKG). Reimbursement exemption from internal price reference groups for antimicrobials addressing certain resistance patterns (as added therapeutic value). Allows higher unit prices for selected antibiotics and backs development and production of generic antibiotics. Cefiderocol (Fetroja) is included in the assessment.
- In March 2022, the [AMR Action Fund](#) made its first two investments in Adaptive Phage Therapeutics and Venatorx Pharmaceuticals. The AMR Action Fund was set up by a coalition of pharmaceutical companies with the support of WHO, the European Investment Bank and Wellcome Trust to bring 2-4 new antibiotics to patients by 2030.

## Next steps & key action areas

Recognising the urgency of the AMR challenge, the following next steps are recommended for implementation in a timely manner:

- **Increase awareness and calls to action:** Broaden awareness of AMR R&D challenges and opportunities by issuing specific calls to action with relevant partners and stakeholders, including the Quadripartite (AMR Multi-Stakeholder Partnership Platform, One Health Global Leaders Group (GLG) on AMR; Multilateral health and development organizations (e.g., UNICEF, World Bank); Global and national industry and public health advocacy groups.
- **Maintain push funding for AMR R&D:** Establish global R&D targets based on patient needs for the investment in the R&D of new antibacterial treatments and encourage specific national commitments; Strengthen R&D targeting priority bacterial pathogens to ensure a steady supply of new antibacterials, and missing vaccines, that address urgent public health needs; Build on significant investment in early stage product development and further support later stage clinical development; Provide coverage across the R&D pipeline and increase the donor base for CARB-X and GARDP.
- **Increase and coordinate pull incentives:** Implement a coordinated and aligned global pull incentive focusing on urgent public health needs. Recognising the complexity of achieving consensus on a single concept across diverse domestic health systems within the G7, countries are urged to prioritise and accelerate efforts to develop and implement new innovative delinked pull incentive models that target priority bacterial pathogens and lead to the development of new and novel antimicrobials. The Global AMR R&D Hub can facilitate sharing of lessons learned and coordination to align global pull incentives.
- **Advance equity and access through AMR development cooperation:** Take up access to priority antibiotics as a key factor in mitigating the AMR response. Development cooperation agencies should expand their remits to AMR, including the development of needed new antibacterial treatments (e.g., through the [Global Fund](#)). G7 countries should consider financing the [SECURE](#)<sup>1</sup> pilot.
- **To maintain momentum, the Global AMR R&D Hub and WHO could – if considered useful – provide a further progress update under Japan’s Presidency in 2023.**

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<sup>1</sup> <https://gardp.org/what-we-do/secure/>