

# EXECUTIVE SUMMARY



## Incentivising the development of new antibacterial treatments: Progress report by the Global AMR R&D Hub and WHO 2023

In 2021 and 2022, G7 Finance and Health Ministers committed to expedite implementation of existing antimicrobial resistance (AMR) strategies, to take additional steps to address antibiotic market failure, create economic conditions to preserve the effectiveness of essential existing antibiotics and ensure their access, strengthen AMR research and development (R&D), and bring novel antibacterials to market that address public health needs<sup>1,2,3</sup>. An [initial progress report](#) was prepared by the Global AMR R&D Hub and WHO for the G7 Finance and Health Ministers in May 2022, with a [progress update](#) requested for 2023. The present report is a response to this request.

### Challenges & Opportunities

- **AMR remains one of the top 10 global public health threats facing humanity**, associated with the deaths of 4.95 million people in 2019, more than HIV or malaria<sup>4</sup>. Across the G7, almost half a million lives could have been saved in 2019, if all drug-resistant infections were prevented<sup>5</sup>.
- **AMR is a threat to the global economy, with impacts on international trade, health care costs and productivity**. If no action is taken, AMR could cost the world's economy USD 100 trillion by 2050<sup>6</sup>. The [World Bank](#) predicts global losses of up to 3.8% of annual gross domestic product (GDP) by 2050 and increased annual health care costs of up to USD 1 trillion by 2030. The Quadripartite organizations are currently assessing the broader short term economic impact of AMR across sectors.
- **Antimicrobials - and antibiotics in particular - are key infrastructure for health systems**, but the R&D [pipeline for new antibacterials is "insufficient"](#)<sup>7</sup> to tackle the challenge of increasing emergence and spread of antibiotic resistance. The [GLG on AMR](#) recently reiterated that the world faces a serious antibiotic pipeline and access crisis that requires innovative financing measures.
- **There is no viable market for novel antibiotics**. The return on investment for new 'reserve' antibiotics fails to cover the costs of their development, manufacturing and distribution. Most large pharmaceutical companies have exited antibiotic R&D, with the enterprises remaining, often small/micro biotech, struggling to sustain operations.
- **Availability and access to new and existing antibiotics, including generics, across many G7 countries can be unreliable**<sup>8</sup>, increasing the socio-economic impacts of AMR.
- **Push incentives, in isolation and at the current scale, are insufficient to meet R&D objectives and bring sufficient products to market**. In addition, mechanisms for equitable and appropriate access to these products are lacking. Industry representatives have signaled investment in AMR R&D will continue to decrease, without a viable market<sup>9</sup>.
- **Policies rewarding R&D programs that successfully bring products to market and ensure access - such as pull incentives or other innovative financing mechanisms** – will help support the development of a sustainable pipeline of novel antibacterials and reinvigorate innovation across the life sciences ecosystem, with positive impacts on health, productivity and economic growth.
- **The G7 could potentially benefit both economically and socially from investing in an antibiotic incentive program addressing the most urgent public health needs**<sup>10</sup>.

### Progress since 2022

<i>Investment in AMR R&amp;D</i>	G7 countries remain leading financial contributors to AMR R&D across the One Health spectrum (~USD 1.4 billion, per year - incl. EU, 84% of total annual investment according to the <a href="#">Global AMR R&amp;D Hub's Dynamic Dashboard</a> ). Financial support extends to a range of initiatives to accelerate the development and market entry of needed new antimicrobials (e.g., <a href="#">CARB-X</a> , <a href="#">GARDP</a> , <a href="#">Innovative Medicines Initiative</a> , <a href="#">InnovFin Infectious Diseases</a> ). The US, UK and Germany, are still the leading financial contributors to CARB-X and GARDP. Since 2022, the <a href="#">AMR Action Fund</a> has extended its portfolio with investments in companies developing traditional antibiotic therapies, non-traditional phage-based therapies and a diagnostics platform for rapid pathogen testing.
<i>G7 activities</i>	G7 countries continue to engage and explore a range of pull incentive options, the latter underpinned by the <a href="#">2021 G7 Shared Principles for the Valuation of Antimicrobial Therapeutics</a> . The UK is considering scaling up its existing subscription model for new antibiotics, Japan has announced a revenue guarantee program for 2023, and Canada, EU and US are in various stages of proposing, testing and implementing incentives to stimulate antibiotic innovation.

<sup>1</sup> G7 Finance Ministers' Statement on Actions to Support Antibiotic Development [accessed 9th March 2023]

<sup>2</sup> G7 Health Ministers' Communiqué 20 May 2022, Berlin [accessed 9th March 2023]

<sup>3</sup> G7 Finance Ministers and Central Bank Governors' Petersberg Communiqué [accessed 9th March 2023]

<sup>4</sup> Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis - The Lancet [accessed 1st March 2023]

<sup>5</sup> The burden of antimicrobial resistance in G7 countries and globally: AN URGENT CALL FOR ACTION [accessed 1st March 2023]

<sup>6</sup> Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations. The Review on Antimicrobial Resistance Chaired by Jim O'Neill December 2014 [accessed 10th April 2023]

<sup>7</sup> <https://www.who.int/news/item/22-06-2022-22-06-2022-lack-of-innovation-set-to-undermine-antibiotic-performance-and-health-gains>

<sup>8</sup> Outterson et al Clin Infect Dis. 2022 Apr 9;74(7):1183-1190. doi: 10.1093/cid/ciab612.

<sup>9</sup> [https://www.amrindustryalliance.org/wp-content/uploads/2022/01/AMRIA\\_progress-report\\_FINAL.pdf](https://www.amrindustryalliance.org/wp-content/uploads/2022/01/AMRIA_progress-report_FINAL.pdf) [accessed 10th April 2023]

<sup>10</sup> <https://www.cgdev.org/blog/g7-investments-new-antibiotics-would-pay-big-everyone> [accessed March 9th 2023]

<i>Canada</i>	The Pan Canadian Action Plan on AMR is to be finalised in 2023. An expert external advisory group was established to develop a priority setting framework for pull incentives – a report from the <a href="#">Council of Canadian Academies</a> is expected in June 2023. In October 2022, Canada <a href="#">pledged support of CAD 300,000 for SECURE</a> . The <a href="#">Budget Plan 2023</a> commits to securing new antimicrobials for Canadians (funding level not provided).
<i>France</i>	<a href="#">2022-2025 National Strategy for Preventing Infections and Antibiotic Resistance</a> was published. Priorities include promoting innovative research, developing and maintaining products that contribute to preventing infections and controlling antibiotic resistance. French HTA authority (HAS) issued its new <a href="#">principles of evaluation of the Transparency Commission relating to drugs with respect to their access to reimbursement</a> .
<i>Germany</i>	Expansion of exemption from internal price reference groups for antimicrobials addressing certain resistance patterns (as added therapeutic value) - for reimbursement purposes (5x antibiotics). New legislation proposed in March 2023 ( <a href="#">ALBVVG</a> ) to further free reserve antibiotics from pricing restrictions. German Federal Ministry for Education and Research (BMBF) announced an additional <a href="#">EUR 50 million in funding for GARDP (2023-2027)</a> .
<i>Italy</i>	Publication of the report <a href="#">Antibiotic use in Italy - 2021</a> , which provides data and analysis on the trend in consumption and expenditure on antibiotics for human use in Italy. Publication of the second <a href="#">National Action Plan on AMR 2022-2025</a> in February 2023.
<i>Japan</i>	Commitment of YEN 1.1 billion in 2023 budget for a <a href="#">support program to secure antibiotics</a> targeting antimicrobial agents for drug resistant bacteria that pose a public health threat, starting in 2023. Also announced plan to ensure stable domestic supplies of priority antibiotics.
<i>United Kingdom</i>	Evaluating scale up of <a href="#">existing subscription model</a> currently valued at GBP 10 million per year for two antibiotics. The expansion phase could see two to three drugs per year being added to the subscription scheme. Currently updating <a href="#">National Action Plan on AMR</a> .
<i>United States</i>	<a href="#">President's Budget Request (PBR) for fiscal year 2024</a> includes USD 9 billion in mandatory funding to establish a <i>novel payment mechanism</i> to delink volume of sales from revenue for newly approved antimicrobial drugs and biological products that address a critical unmet need. Committed up to USD 300 million to CARB-X for supporting early stage R&D for new antimicrobials. The <a href="#">PASTEUR ACT</a> was reintroduced to Congress in April 2023.
<i>European Union</i>	The EC published final results from <a href="#">Bringing AMR Medical countermeasures to the market</a> (March 2023). Includes a simulation of four pull incentive mechanisms and some considerations on the legal and practical implementation at the EU level. Follow-up and implementation of chosen option(s) is supported by <a href="#">EU4Health Action 2023 CP-p-23-16</a> with a budget of EUR 22 million. Revision of the <a href="#">EU Pharmaceutical Legislation</a> was adopted in April 2023, including addressing AMR.

## Next Steps & Key Action Areas for G7 countries

Building on progress across the G7 over the last year, the following next steps for priority actions for Finance and Health Ministers are recommended with an outlook to deliver concrete action over the next two years:

### Renew Priorities and Timelines

- Further recognize and commit to tackle AMR within international political discussions and accords on pandemic preparedness and response.
- Work towards tangible and specific commitments and targets for G7 action on incentivizing the development of and equitable access to new antibacterials for agreement in the next two years, including contributing towards specific commitments and targets at the high-level meeting on AMR at the United Nations General Assembly in 2024.

### Encourage Alignment and Targeted Action on Financing Mechanisms, including Push and Pull Incentives

- Strengthen the AMR R&D ecosystem across the development pipeline through sustainable and predictable financing and resources to address the antibiotic R&D and access crisis, including commitment to further financing of public-private partnerships such as CARB-X and GARDP.
- Build on country-level experience gained through implementation and evaluation of pull incentive pilot approaches and explore the possibility of formulating international collaborative mechanisms on pull incentives for antibacterial R&D, as appropriate.
- Call on the Global AMR R&D Hub to establish a clear process for sharing information and evaluation of pull incentive models across countries, and to share recommendations with the G7 on coordination opportunities in 2024.
- Ensure pull mechanisms are designed to stimulate R&D and reward innovation, and provide appropriate global and equitable access, including for low- and middle-income countries that experience the highest burden of resistance.

### Prioritise Equity and Global Access to Priority Antibacterials

- Strengthen and build on commitments from G7 countries to support initiatives to ensure and improve global and equitable access to new and existing antibiotics, such as [SECURE](#).
- Bolster equitable and global access to antibiotics addressing the most urgent public health needs, and other essential health products for AMR, including diagnostics and vaccines, e.g., through better integration of AMR into international development co-operation initiatives and inclusion of access provisions in relevant push funding agreements.

**The Global AMR R&D Hub and WHO could – if considered useful – provide a further progress update under Italy's G7 Presidency in 2024**

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