

Co-chairs' Summary

G7 Joint Finance – Health Ministerial Meeting

Hybrid (Ancona, VTC), 10 October 2024

The Health and Finance Ministers of the G7 met on October 10th, 2024, at the margins of the G7 Health Ministerial Meeting in Ancona. The Meeting was chaired by Italy's Health Minister Orazio Schillaci and Economy and Finance Minister Giancarlo Giorgetti.

The Presidency opened the meeting recalling the importance of collective efforts to build resilience to pandemics, and identified two areas of action where coordinated efforts between Finance and Health actors can increase preparation to future health emergencies and enhance global security, with positive spillovers in the economic sphere: (i) addressing the growing challenge of antimicrobial resistance (AMR), and (ii) promoting regional manufacturing of health products. Progresses in both workstreams are of critical importance for enhancing sustainability of health systems in Africa.

The first part of the meeting focused on **supporting and incentivizing antimicrobial research and development**.

Due to its relevance, the commitments to strengthen the global response to AMR and accelerate R&D towards innovative products to prevent, diagnose and treat resistant bacterial infections have been on the G7 agenda since 2015, and gained renewed attention in recent years. The G7 Presidencies of the United Kingdom in 2021, Germany in 2022 and Japan in 2023 have all discussed AMR among the main global health issues, recognizing the interconnections between human, animal and environmental health and therefore adopting the One Health approach. Commitments were reiterated on several occasions by G7 Leaders and Health and Finance Ministers to support antibiotic development and explore and implement push and pull incentives to accelerate R&D.

Building on the work of previous G7 Presidencies, AMR has been one of the key priorities of the Health track of the Italian Presidency this year, while being addressed also in the Finance track, as Ministers emphasized their intent to discuss instruments to tackle it and promote research (G7 Finance Ministers and Central Bank Governors' Communiqué, Stresa, 23 – 25 May). G7 Leaders, in the Apulia G7 Leaders' Communiqué, committed to take action by supporting public-private partnerships and exploring innovative instruments to accelerate R&D of new antimicrobials, their alternatives, and diagnostics, including by implementing push and pull incentives.

The Presidency reminded that the topic of AMR is today at the center of the global agenda and was discussed in a High-Level Meeting at the UN General Assembly on September 26th, which marked a crucial occasion to renew global commitments and accelerate progress. Minister Schillaci then gave the floor to the two keynote speakers of the session, Prof. Guido Rasi, currently Full Professor of Microbiology at the University of Rome Tor Vergata and Advisor to the Minister of Health; and Prof. Kevin Outterson, founding Executive Director of CARB-X and recognized leader in the global efforts to contain antibiotic resistance.

Prof. Rasi introduced the topic of AMR stressing that more than 100,000 lives could be saved every year in G7 and EU countries if new antibiotics are developed and made available to treat those bacterial infections that no longer respond to existing drugs. He also illustrated the two main strategies for G7 governments to address this urgent issue, known as push and pull incentives, consisting respectively in deploying financial resources to reduce the costs of R&D and expanding the reward at the end of the R&D process. In particular, push incentives encourage private investors to allocate funding to antibacterial R&D projects by lowering the costs and risks of product development, which is primarily achieved through financial, technical, and business support during the R&D process itself. Conversely, pull incentives encourage private investors to allocate funding to antibacterial R&D projects by enlarging the potential future revenues, which is primarily achieved through mechanisms that enhance financial returns after market approval.

Prof. Outterson summarized the latest evidence on the insufficiency of the global antibacterial pipeline and the growing burden of drug-resistant bacterial infections at current levels of financing. He also presented a simulation exercise showing the forecasted impact that different investment scenarios would have on future antibiotic approvals and on key health and economic indicators. The simulation exercise represented the first comprehensive attempt to connect the most recent data about current public and private investments in AMR R&D, the status and direction of travel of the antibacterial pipeline, potential approvals of much-needed antibiotics in the coming years, and related impacts on lives saved and economic value of improved health outcomes. The presentation clearly showed that the global antibacterial R&D ecosystem is at risk of collapsing within 4 to 8 years without the swift implementation of sufficient push and pull incentives, and highlighted the value of stronger coordination across G7 Members. A methodological note and the outlines of the scenarios presented at the meeting are summarized in **Annex 1**.

Acknowledging that it has become increasingly urgent to take concrete and impactful measures to promote innovation, equitable access, and effective stewardship of new antibiotics and other life-saving products to combat drug-resistant infections, the Presidency announced its complementary initiatives to implement push and pull incentives to lower the costs of antimicrobial R&D and act on the market to improve revenue generation for innovative drugs. In particular, Minister Schillaci illustrated the new initiative of Ministry of Health, in collaboration with key partners such as the Ministry of Finance and the Italian Medicines Agency, to incentivize the development of new antibiotics through a pull incentive mechanism. The Italian Budget Law for 2025 contains a legislative proposal for new and recently-approved antibiotics meeting pre-defined criteria which are specific to the AMR challenge to gain direct access to the national Fund for innovative oncological and non-oncological medicines. This Fund offers several benefits to new products reaching the Italian market, including

immediate access to regional markets and exemption from the payback mechanism if the national pharmaceutical expense cap is exceeded.

In addition, Italy is joining the efforts of other G7 Members in financing global pooled efforts to support antibacterial R&D by allocating USD 21 million to CARB-X over the next three years. This funding will enhance CARB-X's efforts to replenish, coordinate and accelerate the world's most scientifically diverse portfolio of new antibiotics, vaccines, rapid diagnostics, and non-traditional products in the early-development pipeline.

Following the announcement, the other G7 Members praised the Italian Presidency for the concrete steps taken and highlighted their own contributions to CARB-X and other global, regional and national initiatives in the fight of antimicrobial resistance. The Membership also agreed on the importance of coordinating G7 efforts and maintaining the dialogue between Health and Finance Ministers to accelerate the development of antimicrobial drugs, vaccines and diagnostics, in line with the commitments of the Political Declaration of the High-level Meeting on Antimicrobial Resistance.

The second part of the meeting focused on **enhancing pharmaceutical manufacturing capacity in Africa**, including vaccine production, which represents another key component of the Italian Presidency's Health – Finance agenda. Minister Giorgetti highlighted that the growth of a pharmaceutical sector in Africa is strategic from different angles, including public health, economic development and global security, and achieving long-term sustainability of the industry is crucial for fostering growth and innovation. Supporting the development of a sustainable regional industry has the potential of significantly contributing to increase medicine supply and security and enable the scale-up of production during pandemics and other health emergencies, leading to better health outcomes. Ultimately, the development of a pharmaceutical industry in the continent will also allow to boost production of essential antibiotics, contributing to mitigate the acute lack of access in developing countries.

As the agenda is advancing at a fast pace and G7 engagement is growing, the Presidency conducted a first comprehensive exercise to map G7-supported initiatives aimed at enhancing pharmaceutical manufacturing capacity in Africa, summarizing the results in the Report: "Enhancing pharmaceutical manufacturing capacity in Africa: current scenario and future perspectives for G7 Members". The Report underscores a G7 financial commitments of more than 2,9 billion dollars between 2020 and 2024 and provides a better understanding of current initiatives, representing an important step to improve coordination and set priorities for action.

The Membership commended the Presidency for the initiative and welcomed the Report as a first comprehensive mapping exercise that will enhance G7 collaboration and guide future work. G7 Members also highlighted the opportunity to increase awareness of partners on the significant G7 work on this agenda, and welcomed the next step of discussing the Report at a Roundtable between G7 Finance Ministers and Finance Ministers from several African countries on October 26th in Washington, DC. The Roundtable will be an occasion to gather insights from African partners and encourage further engagement and domestic resource mobilization, while giving visibility to the G7 efforts.

Building on the discussion held during the roundtable session, the G7 intends to further strengthen the opportunities for collaboration among Members and between Health

and Finance Ministers on the two areas of work covered during the Meeting. The Membership also agreed on working more closely with LMICs and other partners to expand the discussions on addressing AMR in low-resource settings and enhancing regional pharmaceutical manufacturing capacity, including by taking these workstreams forward for further work in the G20, and specifically under the G20 Joint Finance-Health Task Force.



Annex 1: Push and pull incentives to support antimicrobial research and development: results from a pipeline simulation

Background and methodological note

With the objective of illustrating the impact of different levels of antibacterial push and pull incentives¹ on future antibiotic approvals and related health and economic indicators, the Italian G7 Presidency, with the technical support of CARB-X, presented a simulation exercise on antimicrobial resistance (AMR) during the Joint Finance – Health Ministerial meeting on October 10th, 2024, in Ancona.

The model behind the simulation collated and integrated – for the first time ever – the most recent data on the status of the global antibacterial pipeline, current public and private investments in AMR R&D, probabilities of technical and regulatory success (PTRS) for antibacterial R&D projects, estimations of the effects of different amounts for push and pull incentives, and health and economic impacts associated with the potential approval of innovative antibiotics. The model also incorporated economic attrition, where lower levels of investment in push and pull incentives increased the likelihood of R&D projects failing to progress due to financial constraints rather than scientific challenges.

The following data inputs served as the foundation of the model:

- **Status of the global antibacterial pipeline:** Data from World Health Organization (WHO), “2023 Antibacterial agents in clinical and preclinical development: an overview and analysis”, 14 June 2024. As a proxy for high-impact antibiotics, the simulation focused on R&D projects targeting bacteria in the Critical group of the 2024 WHO Bacterial Priority Pathogens List and fulfilling at least one of the WHO innovation criteria.
- **Target of six to ten approvals of innovative, high-impact antibiotics per decade:** Data from The Review on AMR, “Tackling Drug-Resistant Infections Globally: Final Report and Recommendations,” May 2016; German GUARD Initiative, “Breaking through the Wall: A Call for Concerted Action on Antibiotics Research and Development,” February 2027; DRIVE-AB, “Revitalizing the antibiotic pipeline: Stimulating innovation while driving sustainable use and global access,” March 2018.
- **Current funding for antibacterial R&D from public and philanthropic sources (push incentives):** Data from the Dynamic Dashboard of the Global AMR R&D Hub (data retrieved on 17 September 2024).
- **Current funding for antibacterial R&D from private investors:** Data from David Thomas and Chad Wessel, “The State of Innovation in Antibacterial Therapeutics”, BIO INDUSTRY ANALYSIS, February 2022.
- **Probabilities of Technical and Regulatory Success (PTRS) and estimations of effective push and pull incentives:** Data from Kevin Outterson, “Estimating the Appropriate Size of Global Pull Incentives for Antibacterial Medicines.” *Health Affairs*, Vol. 40, no. 11, 1 November 2021.

¹ **Push incentives** encourage private investors to allocate funding to antibacterial R&D projects by lowering costs and risks of product development. This is achieved through financial, technical, and business support during the R&D process itself. **Pull incentives** encourage private investors to allocate funding to antibacterial R&D projects by enlarging potential future revenues. This is achieved by enhancing financial returns after market approval.

- **Health and Economic Indicators:** Data from the Dynamic Dashboard of the Alliance for Reducing Microbial Resistance (ARMoR), based on Rachel Bonnifield and Adrian Towse, “G7 Investments in New Antibiotics Would Pay Off Big – For Everyone”, Center for Global Development, 8 December 2022.

The different scenarios analyzed are based on potential decisions by G7 Health and Finance Ministers over the next 18 – 24 months and the related impact over a time horizon of 30 years. These scenarios included varying levels of investments in push and pull incentives and their impact not only on the pipeline (R&D projects in clinical development and new antibiotics approved per year) but also on lives saved and the economic value of better health in G7 countries plus the European Union. The economic value of better health is calculated by assigning a monetary value for every disability adjusted life year (DALY) averted. DALYs averted are converted from lives saved, using the GRAM study’s AMR DALYs/deaths ratio for each individual country.²

The data and scenarios presented at the G7 Joint Finance and Health Ministers’ Meeting are consistent with recent projections from other research groups, and in particular with the latest estimates published by the Global Research on Antimicrobial Resistance (GRAM) Project in September 2024 and the projections produced by the Center for Global Development, building on the GRAM results, on the impact of future drug development that targets Gram-negative pathogens on reduction of health care costs and improved health outcomes.³

All figures in the simulation are in nominal USD (without inflation adjustments). The estimates do not account for the costs and benefits associated with facilitating access and stewardship in LMICs, which remain priorities as important as innovation. With increased investments to strengthen access and stewardship in LMICs, much larger gains will be seen globally.

Scenario 1: The cost of inaction



The “business as usual” scenario assumes current levels of financing per year of USD 150 million for push incentives and USD 700 million for pull incentives, including current market revenues.

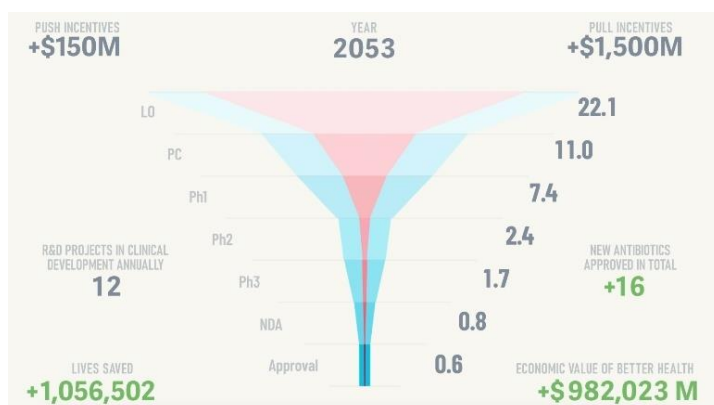
The simulation shows that the antibacterial R&D ecosystem faces an imminent risk of collapse, with the number of

projects in clinical development globally halving in 4 years and falling to less than five by 2034. In G7 countries alone, it is estimated that 1.75 million people will die because of AMR in the coming 30 years.

² <https://vizhub.healthdata.org/microbe/>

³ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(24\)01867-1/fulltext;](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)01867-1/fulltext;)
<https://www.cgdev.org/publication/forecasting-fallout-amr-economic-impacts-antimicrobial-resistance-humans>

Scenario 2: A minimally viable pipeline



with significant health and economic benefits.

The pipeline stabilizes with 12 R&D projects in clinical development globally each year, delivering at least 16 more high-priority antibiotics in the 30 years between 2024 and 2053. Almost one million lives will be saved, and the economic value of better health outcomes will be close to USD 1 trillion.

Scenario 3: Push without pull



Increased funding for push incentives (USD 150 million per year more than today) while maintaining current levels of market revenues and pull incentives will lead to a pipeline with only 8 R&D projects in clinical development globally in any given year, delivering 9 fewer antibiotics than Scenario 2 by 2053.

In comparison to business as usual, more than 400,000 lives will be saved and the economic value of better health outcomes would amount to about USD 450 million, but this would still be less than half of the impact of Scenario 2.

Scenario 4: Pull without push



Increased funding for pull incentives with revenue guarantees of USD 363 million per drug per year covering at least six antibiotics at any given moment while maintaining current levels of push incentives will lead to a pipeline stabilized with only 8 R&D projects in clinical development globally on an annual basis, delivering 6 fewer antibiotics than Scenario 2 by 2053.

In comparison to business as usual, more than 600,000 lives will be saved and the economic value of better health outcomes would amount to about USD 650 million, but this would still be less than 2/3 of the impact of Scenario 2.

Scenario 5: A healthy antibacterial R&D ecosystem



Higher amount of funding for both push and pull incentives (USD 350 million more for push incentives annually coupled with revenue guarantees of USD 363 million per drug per year covering at least ten antibiotics) will lead to a healthier pipeline delivering larger health and economic benefits.

The pipeline stabilizes with at least 20 R&D projects in clinical development globally on an annual basis, delivering an average of almost 10 high-priority antibiotics per decade. 1.25 million lives will be saved, and the economic value of better health outcomes reaches USD 1.3 trillion.

Main conclusions

With current investment levels, the antibacterial R&D ecosystem is on the brink of collapse, highlighting an urgent need for increased funding to fully implement push and pull incentives.

Push and pull incentives work synergistically, and the public return on public investment increases as more push and pull incentives are deployed to reverse the collapse of the pipeline.

Increased coordination and investment among G7 governments could lead to the approval of six to ten innovative, high-impact antibiotics per decade up to 2050, averting millions of deaths and generating substantial economic returns.

Acknowledgements

We thank Prof. Kevin Outterson, Dr. Damiano de Felice and the wider CARB-X team for dedicating valuable time and resources to produce the simulation and deliver an engaging presentation to the G7 Finance and Health Ministers in Ancona.