

# The Role of G7 Governments in Global Efforts to Encourage Antimicrobial Development Through a Pull Incentive: Challenges and Collaboration

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# Introduction



Since the advent of penicillin in 1941, the world's inaugural antibiotic, antimicrobials have formed the cornerstone of modern healthcare infrastructure, saving millions of lives from infectious disease and secondary infections.<sup>1</sup> They are the critical foundation of so many routine procedures—ranging from simple outpatient surgeries to intensive procedures like hip replacements or caesarean sections—that they are often taken for granted. But antimicrobials as healthcare infrastructure, along with improved sanitation and widespread immunization, are fundamental for the increased longevity enjoyed today.<sup>2,3</sup>

However, this is threatened by antimicrobial resistance (AMR). AMR results when microbes are no longer susceptible to the antimicrobial products used against them. The loss of this critical piece of healthcare infrastructure has dire implications for health systems globally.

By 2050, more than 25% of the population in every Group of Seven (G7) member country will be over age 65.<sup>4</sup> Without effective antimicrobials, health systems will be hard-pressed to serve patients of any age, not least the large and growing population of older adults. Today, nearly 5 million people die each year due to AMR, and by 2050, it's estimated that 100 million people will die every year from AMR. The development and introduction of new antimicrobial treatments is therefore essential, while safeguarding the efficacy of existing drugs,



**By 2050, it's estimated that 100 million people will die every year from AMR.**

but innovation is not possible without support.<sup>5</sup> We are on the verge of returning to a pre-1950 world without antibiotics precisely at the time when the need is even greater, with a population more old than young.

On April 10, 2024, the Global Coalition on Aging convened experts and officials from across the United States, the United Kingdom, Italy, Canada, Japan, and the European Union to discuss progress on pull incentives—a policy option that could help solve the innovation challenge, complementary with existing push funding mechanisms.<sup>6</sup>

Participants discussed the value of antimicrobials to patients, the current state of the antimicrobial pipeline, and the progress that each government is making toward effective pull incentives, as well as the critical need to collaborate globally.



“We must introduce pull-type incentives to promote and secure research and development of antibacterial drugs as a countermeasure against the AMR crisis. This will improve the predictability of the antibacterial drug market, support sustainable research and development, and contribute to international fair share. To achieve this, cooperation between not only the G7 countries’ governments but also among industry and academia is essential. In particular, Japan has a significant role to play. At this meeting, we would like to share information, promote antimicrobial drug development, and make significant progress in countermeasures against AMR.”

**Hiroaki Tabata**, Member of the House of Representatives, Japan

## Definitions

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### AMR

Antimicrobial resistance (AMR) refers to the process by which the microbes that cause infectious diseases grow resistant to treatment with time and exposure to antimicrobials.

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### PUSH INCENTIVES

Push incentives refer to funding initiatives that support antimicrobial development from the stage of basic research through clinical trials. This includes funding for research from government agencies, product development and phase 1 support from CARB-X, or clinical development support from the Global Antibiotic Research & Development Partnership (GARDP) or the AMR Action Fund.

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### PULL INCENTIVES

Pull incentives refer to funding that helps support antimicrobials after they have been commercialized. Post-market funding for antimicrobials can help to delink revenue from sales volume, making it possible for manufacturers to support continued antimicrobial production and new research & development without needing to actively sell new antimicrobials. This helps to ensure that new antimicrobials are not over-used, which helps to maintain their effectiveness for the times they are needed as a last resort.

# Key Takeaways

The meeting discussion resulted in four defined takeaways:

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## 1. The lack of new antimicrobials and increasing resistance against existing antimicrobials have a severe impact on those most at risk of infection.

Older adults and the immunocompromised—such as people living with cystic fibrosis (CF), cancer, or HIV—especially rely on access to safe antimicrobials that ensure they can age in good health. Yet, older antibiotics are growing less effective due to increasing AMR, and new development is nearly at a halt, meaning that for millions, options are running out.

Because of the thick, sticky mucus in their lungs, people with CF face a heightened risk of infections. Routine use of antibiotics in CF care is medically necessary, which is threatened by increasing AMR. In 2022, 12.7% of people with CF reported having multi-drug resistant pseudomonas, and more than 15% of people with CF cultured positive for methicillin-resistant *Staphylococcus aureus*.<sup>7</sup> For them, AMR is not a distant threat—it is already impacting access to life-saving antimicrobials. People living with CF are a glimpse into the future of a life without antibiotics for us all, where common infections are life threatening.

For example, an adult man living with CF has drug-resistant pseudomonas. His pseudomonas is resistant to every known antibiotic approved to treat the infection. In 2017, out of options, he was put on a new IV medication that ultimately shut down his body culminating with potential liver damage. He continues using this antibiotic today despite the damage it does to his body because without it, he wouldn't be able to address the pseudomonas which is ultimately riskier as once it colonizes in the airways it is incredibly difficult to eradicate.



“People with CF use antibiotics routinely, and reducing antibiotic use isn’t possible in the CF population because it is medically necessary. This leaves people with CF vulnerable because over time, fewer antibiotics remain effective for them. Novel antibiotics are critical for helping those with CF live long, healthy lives.”

**David Elin**, Senior Director, Advocacy & Government Affairs,  
Cystic Fibrosis Foundation

This need extends beyond those living with CF. People living with other chronic diseases often take medications that can lower their ability to fight infections, and the risk of chronic disease increases with age. Even today, there are 9.8 million people who receive chemotherapy for cancer per year, globally, and infection is the second leading cause of death for people with cancer. Immunosuppressed organ transplant recipients, who number 170,000 annually, are reliant on functional antimicrobials to account for their increased risk of infection. A further 4.35 million people receive kidney transplants or dialysis, which may also require antibiotics, as do surgeries in general—one in five births globally are by caesarean section. Antibiotic-resistant sepsis disproportionately affects neonates and young infants with vulnerable immune systems. Effective antimicrobials are needed to support all these people.

The AMR crisis is occurring at the same time as the market is failing to produce new drugs, accelerating the issue. While up to eight novel antimicrobials were developed per year through the 1980s, since then, most years have seen the release of just a single new drug. Patients in need are being left high and dry.

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## 2. The current state of the antimicrobial pipeline is inadequate against growing AMR and must be prioritized.

Currently, there are few antimicrobial candidates that meet the World Health Organization (WHO) innovation criteria targeting priority pathogens. It is important to build a more robust and diverse pipeline and that those projects with demonstrated efficacy in clinical studies will reach patients fairly and equitably.

We are losing the race against resistance. According to the latest data from the Global AMR R&D Hub, based on the annual WHO antibacterial pipeline analysis, the antimicrobial pipeline is weak, with fewer than 100 candidates. Most of these are in very early stages of clinical development—Phases I and II.<sup>8</sup> Only about 16% of products in Phase I will ultimately come to market.<sup>9</sup> Further, most of the products in the pipeline are derivatives of existing antibiotic classes with well-established mechanisms of drug resistance.



“The pipeline for antimicrobials is quite stagnant, and we have very few innovative products against critical priority pathogens. Innovation is crucial to keep up with the very fast, evolving challenge of drug resistance. Coordinated action is essential to win this race.”

**Valeria Gigante**, Team Lead, AMR Division, World Health Organization

“There are different mechanisms to promote innovation and accessibility, and we need to have a toolbox with different levers to make sure that we are fighting the market failure of antimicrobials.”

**Laurent Muschel**, Acting Head of HERA (Health Emergency Preparedness and Response Authority), European Commission

Considering candidates that target WHO priority pathogens, the situation is even more bleak: six fulfill at least one of the WHO innovation criteria; three are in Phase III, one in Phase II, and two in Phase I.

Scientific innovation is expensive and time-consuming. For antimicrobials, there is both a market failure and a public health failure: keeping new antimicrobial products “on reserve” to reduce the likelihood of resistance developing means there is a low return on investment. As a result, life-saving antimicrobials do not reach patients. Fifteen out of eighteen global pharmaceutical companies have exited the antimicrobial development field, leaving much of the research and development process to small biotechnology companies, further challenged by a steady “brain drain” of scientific and research professionals in the AMR sector.<sup>10</sup>



“Multi-stakeholder approaches are important to tackling AMR. Partnership is key to driving conversations about the need for new models to support long-term market sustainability for novel antimicrobials.”

**Jennifer Young**, Vice President, Global Policy and Public Affairs for Specialty Care, Policy Planning, and Strategy, Pfizer

“We are grateful that multiple G7 governments have responded to the antibacterial pipeline and access crisis by supporting global push incentives such as CARB-X. Together with allocating sustainable and predictable funding for push incentives, G7 governments must also implement adequate pull incentives to attract renewed investments into antibacterial R&D from private investors and companies. Push incentives alone cannot support much-needed innovation to stop superbugs.”

**Kevin Outtersen**, Executive Director, CARB-X



The outlook for current projects' success is shaky. Of the twelve biotechnology companies that have developed antimicrobials over the past 10 years, seven have ceased operation. The market cannot support new antimicrobials, an inherent challenge unlike any other therapy in today's medicine chest. Post-commercialization unviability is causing underinvestment throughout the pipeline. Half of the biotechnology companies in antimicrobial development do not have enough cash to operate for even a year, and one-third have such tight cashflow that they are effectively already dead. If ever there was a market that is inherently flawed, profoundly in need of externally created market incentives, it is the antimicrobials market.

The paradox of not wanting to use new antimicrobials because of the limited supply of new antimicrobials hinders companies' ability to recoup costs. And yet—novel antimicrobials are critically needed. Help is needed just to support continuing research and manufacturing long-term—much the way that other infrastructure like roads or water pipes are regularly maintained. Just like these, antimicrobials are a global public good.

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### **3. Incentive structures to develop new antimicrobials must be supported, with consideration to globally equitable access to products once they reach the market.**

The UK is currently the only country with a fully functional pull incentive. Other countries must rise to the challenge and complement the UK system with their own incentives. While this expectation rests more heavily on the shoulders of G7 countries and the EU, governments must also consider regulatory mechanisms that will ensure access to novel antimicrobial products globally, including low-and-middle-income countries (LMICs).

Delinked pull incentive models have been consistently identified by leading experts in economics and AMR as a policy option that could fix antimicrobial market failures. Delinked pull incentives reward successful innovation by creating a viable market and known return on investment.<sup>11</sup>

Delinking revenue from volume is important, as AMR would not be helped by a policy that relies on increased use of antimicrobials for the recouping of revenue. Any antimicrobial use spreads resistance. There must be a system in which the drugs patients need are always available but used only when needed.

The UK is leading the way on pull incentives, and other countries, especially in the G7 and European Union, should accelerate efforts to join them.<sup>12</sup>



“Our pilot demonstrated the feasibility of delinking payments from volumes used. In England, hospitals purchased the products in a normal way through their wholesalers. Companies submit to us a record of their sales invoices that they provided to each hospital. We reconciled this with health service data, and then pay a top-up fee to make it equal to our agreement.”

**David Glover**, Deputy Head, Medicines Analysis Team, NHS England

“In 2023, a small-scale pull incentive began in Japan in the form of an annual revenue guarantee. The budget is modest, about \$8 million USD annually, but it was important for us to start.”

**Hajime Inoue**, Assistant Minister for Global Health and Welfare, Ministry of Health, Labor, and Welfare, Government of Japan

## Overview of Pull Incentives Already Implemented or Under Consideration



### UK

The UK launched a pilot subscription model in 2019, which saw annual payments for the provision of selected antibiotics that meet outstanding clinical criteria. The pilot incentive amounted to \$6.3 to \$25.5 million USD annually.<sup>13</sup> At present, the UK has recently completed its consultation on proposals for the full subscription model program. In April 2024, the thematic analysis of the consultation responses and guidance on commercial arrangements and how companies should engage with the NHS will be published. Following this, the prior information notice that will see the full suite of documents on the subscription model will be published for companies to view. An invitation to tender is expected to be published in Summer 2024.



### US

The Pioneering Antimicrobial Subscriptions To End Upsurging Resistance (PASTEUR) Act was reintroduced to Congress for the third time in 2023. This bipartisan bill would establish a system to implement 5-10-year subscription contracts for critical-need antimicrobial drugs with an annual incentive amount between \$75 to \$300 million USD. PASTEUR seeks to address the market failures seen in antimicrobial development.<sup>14</sup>



### Japan

In 2023, Japan introduced a revenue guarantee model with an annual incentive amount of around \$8 million USD following the release of their updated AMR National Action Plan. The potential market size for any selected antibiotic is estimated, and 20% is subtracted from that estimate as an antimicrobial stewardship measure. The resulting level of revenue is then guaranteed by the government. The organization that makes the antibiotic is reimbursed up to that guaranteed amount if sales produce a level of revenue that falls below it. If actual revenue is above that line, the company must invest any profits into research and development.



## Sweden

Sweden piloted a revenue guarantee program between July 2020 and December 2022. Reimbursements were partially decoupled from sales volume, and an incentive of at least \$0.4 million USD per product was guaranteed. In return, the four contracted pharmaceutical companies committed to keeping stock in Sweden and guaranteeing delivery to hospitals within 24 hours. Sweden saw new access to several antimicrobials during the pilot, and faster than other European countries.<sup>15</sup> Pilot projects with reimbursement models for new and medically important antibiotics are continuing.<sup>16</sup>



## Canada

Plans for an economic incentive pilot program are underway following an expert report commissioned by the Public Health Agency of Canada.<sup>17</sup>



## EU

There is a wide interest across EU member states in a voluntary revenue guarantee pilot, to improve access to newly developed antimicrobials, to be able to deliver them quickly to patients in need. The set-up of the mechanism is being prepared by HERA across the European Union following an expert assessment published in 2023.<sup>18</sup> Discussions for either a transferable exclusivity extension in the pharmaceutical legislation and/or additional financial incentive models are ongoing in the parliament and the council.

## 4. Global collaboration and attention to countries' "fair share" is an imperative to tackle AMR.

AMR is a global public health issue that does not recognize borders, and it will only be solved through global partnership and collaboration, including the critical collaboration with industry partners. The G7 and EU together can shoulder the burden to make a solution possible, and the more countries involved means that the collective whole will be greater than the sum of its parts.

As with any piece of shared infrastructure, the global community must share the burden of developing a common resource. Kevin Outterson of CARB-X has estimated various countries' "fair share" investment, according to GDP.

A pull incentive is a major global health contribution, as those who can pay are saving the lives of those who cannot, and in doing so, are protecting against the spread of more vicious infectious diseases down the line. LMICs have the highest burden of AMR, and failing to include countries that are less able to contribute to research and development efforts would eventually negate efforts to develop new products due to spreading resistance.

**TABLE 1** Annual Fair Share by Country<sup>19</sup>

	ANNUAL FAIR SHARE (US\$ MILLION)									
	US	CANADA	JAPAN	UK	FRANCE	ITALY	GERMANY	SWEDEN	EU27	G7+EU27
GDP SHARE	41.5%	3.6%	9.6%	6.0%	6.2%	5.0%	8.7%	1.1%	39.3%	100.0%
LOW-END SIZE	\$91	\$8	\$21	\$13	\$14	\$11	\$19	\$2	\$86	\$220
MID-RANGE SIZE	\$129	\$11	\$30	\$19	\$19	\$16	\$27	\$3	\$122	\$310
HIGH-END SIZE	\$199	\$17	\$46	\$29	\$30	\$24	\$42	\$5	\$189	\$480



“The success of pull incentives will depend on how many countries come together and invest to tackle this problem.”

**Lotte Steuten**, Deputy Chief Executive, OHE

“Pull incentives will be a critical component of development of and access to antimicrobials. More needs to be done: that’s the take home message. Alignment and targeted action on financing mechanisms across the push-pull spectrum will help us to see establishment of feasible targets for AMR research and development that are informed by public health needs and prioritization of global equity.”

**Lesley Ogilvie**, Director, Global AMR R&D Hub Secretariat

While there is an initial monetary cost, this investment will result in significant savings to healthcare systems as populations age. It is cheaper to cure and protect against infectious diseases than to allow development into intractable health outcomes. The current healthcare burden of AMR is estimated at about \$1 trillion USD globally. A fair share contribution of G7 members to a \$4.5 billion USD pull incentive to fund a single novel antibiotic would result in a very high return on investment: 5 to 1 for G7 countries.<sup>20</sup>

**TABLE 2** Pull Incentive Returns on Investment, Across the G7 Countries<sup>21</sup>

	10-YEAR LIVES SAVED	30-YEAR LIVES SAVED	10-YEAR ROI (BENEFITS PER USD)	30-YEAR ROI (BENEFITS PER USD)
CANADA	2,500	48,100	4.5	20.4
EU (DE, FR, IT)	20,000	384,900	3.9	18.2
JAPAN	14,100	269,700	6	27.7
UK	4,600	88,400	2.5	11.4
US	20,000	383,000	5.9	27.6
<b>G7 TOTAL</b>	<b>61,300</b>	<b>1,174,100</b>	<b>5</b>	<b>23.1</b>

# Conclusion

With the United Nations General Assembly High-Level Meeting focused on AMR this year, 2024 is a crucial opportunity for countries to demonstrate their commitment and show results. At the 2022 G7 Meeting, all member countries pledged to incentivize research and development for antimicrobials, with an emphasis on pull incentives. Two years later, that commitment has only been met by the UK.

This is not enough. Urgent action is needed now. There will never be more political momentum on AMR than this year. All countries must take this opportunity to address AMR through collaborative multi-stakeholder action and commitments to invest a fair share in our most vital healthcare infrastructure.

# Expert Participants

The Global Coalition on Aging (GCOA) would like to thank the JPMA for its partnership and the following experts for their participation in our workshop, and for their invaluable contributions that made the creation of this report possible. The content of this report was developed based on the discussion content at the April 10, 2024, workshop, and should not be taken to represent the exact views of any single workshop participant or be endorsed by them.

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GCOA represents a cross-section of global business including technology, pharmaceuticals, healthcare, home care, financial, transportation, and consumer sectors. We engage global institutions, policymakers, and the public to drive debate on, create, and promote innovative policies and actions to transform challenges associated with the aging of the global population into opportunities for social engagement, productivity and fiscal sustainability.

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