

AMR & JAPAN'S G7 PRESIDENCY:

A Call for Pull Incentives to Drive Innovation

ROUNDTABLE REPORT



Introduction

On September 28, 2022, the Global Coalition on Aging (GCOA) convened a small, private roundtable of leaders from the United Kingdom (UK), the United States (US), and Sweden, alongside Japanese decision-makers and experts. The US and the UK are among the countries who have taken the most visionary, innovative, and impactful action to address the rising crisis in antimicrobial resistance (AMR).

Experts* shared examples of the most promising policy initiatives to date—novel pull incentives—that collectively provide a model for Japanese leaders for implementation in Japan and as they prepare to host the G7 in 2023. The roundtable offered both strategic insights and a tactical roadmap for Japan's global leadership on AMR.

"We need to act now and partner across the political spectrum to help us act fast and make a difference."

-Santiago Gonzalez, Senior Policy Advisor, Senator Michael F. Bennet (D-CO) US Senate

Experts at the roundtable identified four **critical actions** that Japan must take now to urgently address and lead on AMR as Japan assumes the 2023 G7 Presidency:

- Implement a pilot pull incentive to stimulate antibiotic innovation based on best-fit model for Japan, building on the experiences provided by the UK subscription pilot and the US PASTEUR Act.
- 2. Build policy guidance on AMR into the Health and Finance Ministers' meetings and communiques.
- Communicate the urgency for AMR policy action through Japan's G7 Presidency at the Summit level, which will underscore the Health and Finance support for G7 AMR actions and will become central for realization of healthy aging for all under the UN Decade of Healthy Ageing.
- Invite collaboration and partnership with other countries, both those already leading on AMR action and those seeking inspiration and guidance.

Background

Antimicrobial resistance and the lack of new antibiotics available to treat infections pose a growing threat to Japan and the world. If no significant action is taken to address AMR, drug-resistant diseases could cause 10 million deaths globally each year by 2050 and damage to the Japanese economy as catastrophic as the 2008-2009 global financial crisis. While AMR is a crisis for all of society, older adults are most at risk, making AMR a critical priority for super-aging Japan, where close to 40% of the population is over 60.2

"AMR poses multiple threats: It threatens current advanced medicine—such as hip transplants and chemotherapy—and puts development in global health at risk."

-Malin Grape, AMR Ambassador, Ministry of Social Affairs, Sweden

For years, Japan drove innovation in the development of antimicrobials. However, today, Japan's antimicrobial innovation pipeline is nearly bare, and Japan has no active pull incentives qualified by the Global AMR R&D Hub as contributing to innovation. The bare pipeline of novel antibiotics will deteriorate even further without the implementation of substantial pull incentives to stimulate innovation.

Sadly, though Japan had previously been a leader in antimicrobial innovation, it is now at the leading edge of the AMR crisis, which is profoundly challenging for all society and holds explicit challenges for super-aging societies like Japan. The AMR crisis has impact across all our lives, but its burden on newborns and early childhood as well as older adults is dramatic in today's 21st century.

In 2021, GCOA's AMR Preparedness Index systematically evaluated and ranked the top 11 global economies on how well they are addressing AMR. The UK outscored its peers, due in part to the introduction of its novel subscription model to spur antimicrobial innovation. The United States and Germany ranked second and third, respectively, with Japan coming in fifth. AMR and pull incentives have been on the G7 agenda for several years. Japan's 2023 G7 Presidency offers an important and invaluable opportunity to demonstrate the country's AMR leadership on the global stage.

What follows is a brief overview of key insights from experts at the roundtable. The insights aim to provide both context and guidance for Japanese leadership on urgent next steps to address AMR as Japan prepares to lead the G7.

^{1.} https://www.who.int/news/item/29-04-2019-new-report-calls-for-urgent-action-to-avert-antimicrobial-resistance-crisis

^{2.} https://asia.nikkei.com/Opinion/Japan-should-follow-US-efforts-to-develop-new-antibiotics

Japan

Since the introduction of the WHO's Global Action Plan on Antimicrobial Resistance in 2015, Japan has participated in several high-level meetings to prioritize policy action against AMR: the G7 Elmau Summit Leaders Declaration (June 2015), the Asia AMR Tokyo Ministerial Conference (April 2016), and the G7 Ise-Shima Summit (May 2016). Japan's 2016 National Action Plan on AMR laid out a 5-year plan to address AMR across six areas of concern, including research and development of new antibiotics.

"In late-stage R&D, we are setting up for the launch of pull incentives. Let us think about what we need to put in place to launch these pull incentives."

-Dr. Norio Ohmagari, Director, Disease Control and Prevention Center, National Center for Global Health and Medicine, Japan Japan has already begun to set up push incentives, and the Ministry of Health, Labour and Welfare included 1.8 billion yen in its 2023 budget to trial a pull incentive. Experts at the roundtable clearly identified implementing a trial pull incentive as the critical next step for Japan. Experts strongly agreed that Japanese pull incentives are essential for helping to solve the global AMR crisis and addressing immediate Japanese needs themselves, both at the health and fiscal/economic levels.

Experts called on Japan to test a revenue-guarantee market incentive model that introduces the markets to the "fair share" concept and promises access to novel antibiotics. This model should be informed by the expertise and experiences from the UK and the US.

Alongside the G7, the UN Decade of Healthy Ageing, and superaging Japan, the policy environment is ripe for urgent action on AMR. Japan can look to commitments and efforts around Universal Health Coverage (UHC) and the Stop TB Japan Action Plan for models and levers for how to drive forward action and political leadership on AMR.

United States

US Congressional leaders calling for action on AMR understand that the US government is going to pay for AMR now or pay later.

AMR is recognized by US leaders as a national security issue because of the associated market instability. Research shows the market is unstable without a pull incentive. The PASTEUR Act will address this gap.

The US does not want to be in another circumstance relying on other countries during an emergency, as with personal protective equipment (PPE) during COVID-19.

When Senator Bennet and Representative Ferguson were designing PASTEUR, their teams recognized the need to lead with a meaningful investment. The US could not do a pull incentive at a small number, and leaders agreed on a US\$6 billion investment.

"We must change how we pay for antibiotics. Most new antibiotics are classified as 'reserve' by the WHO, which is not wrong, but companies are going bankrupt without anyone using their drug. We should pay them anyways because we are paying for protection. To compare it to a fire extinguisher, we pay when the extinguisher is installed behind glass, not when we break the glass to put out a fire."

-Kevin Outterson, Executive Director and Principal Investigator, CARB-X

United Kingdom

The UK government is committed to having AMR controlled by 2040, with a full antimicrobial pipeline and proper stewardship of new and old antimicrobials.

"Our Department of Social Care (and others) published the GRAM Report on the global burden of AMR...we have country-level data we can share...goes hand in hand with our ageing policy."

-Clare MacIver, Head of Global Strategy on AMR, Department of Health and Social Care, UK During the UK's 2021 G7 Presidency, leaders secured commitments in four areas: health, climate, environmental, and finance. Significantly, the Health and Finance Ministers introduced a plan to strengthen reimbursement for antibiotics.

The UK now has a pilot project in England that delinks payment from sales volume and usage. To come up with appropriate payments, the UK looked at the global amount of revenue needed to bring a product to market and asked what the country's share of that looks like. The UK has completed the subscription pilot and is now adapting the program for use at scale.

The UK further recognized the need for global collaboration to succeed against AMR: More countries must commit to a list of specific products to add to the subscription model, otherwise companies only get national revenues sporadically rather than the true global revenue of their product.

The UK is collaborating with Canada to adapt the subscription model for the Canadian healthcare system.

Conclusion

The year 2023 is a critical opportunity for Japan's leadership on the global stage. Global and Japanese experts agree that surveillance, appropriate use, and pull incentives in particular, must be on the table for discussion on the G7 agenda, coupled with collaboration among G7 countries to accomplish goals to combat AMR. Following Japan's G7 leadership, the next High-level Meeting on AMR at the UN General Assembly will take place in September 2024, making Japan uniquely well-positioned to both dictate policy priorities and direct political attention ahead of this meeting.

"We see [the AMR crisis] as: government is going to pay now or pay later. This could be the next pandemic, so let's get ahead of it."

-David Sours, Chief of Staff, Representative Drew Ferguson (R-GA) US Congress

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Appendix

About the PASTEUR Act

The Pioneering Antimicrobial Subscriptions To End Upsurging Resistance Act (PASTEUR Act) would:

- Establish a subscription model to encourage innovative antimicrobial drug development aimed at treating drug-resistant infections. This model will be fully delinked, meaning that participating developers would not receive income, as a part of their subscription payments, based on volume or quantity of sales.
- Subscription contracts would contain terms and conditions including product availability to individuals on a government health insurance plan, supporting appropriate use, and completion of postmarketing studies. These contracts could be valuated between \$750 million and \$3 billion.
- Build on existing frameworks to improve usage of the CDC National Healthcare Safety Network, the Emerging Infections Program, and other programs to collect and report on antibiotic use and resistance data.
- Include transition measures such as smaller subscription contracts to support novel antimicrobial drug developers that need a financial lifeline.

SOURCE:

https://www.bennet.senate.gov/public/index.cfm/2021/6/bennet-young-doyle-ferguson-introduce-pasteur-act-to-fight-antimicrobial-resistance

About the UK Subscription Model

The UK subscription model aims to incentivize companies to invest in researching and developing new antibiotics, helping secure much-needed alternative treatment options for NHS patients.

The model, which was launched in July 2019 and put into place in June 2020, will pay a fixed annual fee to companies that develop high-need antibiotics, based on a product's value to the NHS rather than how many prescriptions are issued. The first two drugs to be financed by the new UK subscription model were announced in April 2022.

SOURCES:

https://www.pewtrusts.org/en/research-and-analysis/articles/2022/04/27/pilot-project-in-uk-helps-to-spur-development-of-new-antibiotics-to-thwart-superbugs

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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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