
Incentivising the development of new antibacterial treatments 2024

Progress Report by the Global AMR R&D
Hub & WHO

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World Health
Organization

Challenges & Opportunities

Since 2021, G7 Finance and Health Ministers have reinforced their commitment to accelerating antimicrobial resistance (AMR) strategies, addressing the antibiotic pipeline and market failure, preserving access to essential antibiotics, and enhancing research and development (R&D) to bring new antibacterials to market, particularly for the vulnerable populations most impacted by AMR [1-6]. The Global AMR R&D Hub and the World Health Organisation (WHO) presented a progress report to G7 Health and Finance Ministers in May 2022 [7], with an update in 2023 [8]. The current report provides an annual update on the financial landscape for antibacterial innovation, tracks country-by-country progress, and outlines key actions for the coming year to support G7 policy and activities.

AMR is a global health threat. AMR remains one of the top 10 global health threats, linked to 4.95 million deaths in 2019—surpassing those from HIV or malaria [9]. Recent global estimates suggest that resistant bacterial infections will cause 39 million deaths by 2050 [10]. The Global Leaders Group on AMR estimates that without a stronger response, global life expectancy will be 1.8 years lower than otherwise due to AMR by 2035 [11].

It also threatens the global economy, affecting international trade, healthcare costs, and productivity [11-14]. Without strengthened action, treating resistant bacterial infections alone would exert a global economic burden of USD 412 billion in healthcare costs and USD 443 billion in lost productivity each year up to 2035 [11].

Antimicrobials, particularly antibiotics, are essential to modern healthcare, but the clinical pipeline for new antibacterials remains inadequate for current and future needs. The newest data from WHO show that only 32 new antibiotics are in clinical development, but most of them derivatives of existing classes [15,16]. Overall the traditional antibacterial pipeline lacks sufficient innovation; only 12 innovative compounds are in development, with just four targeting pathogens designated as critical by WHO [17]. In contrast, the preclinical pipeline is dynamic and innovative, but also fragile because product developers have small teams and both products and companies are subject to high turnover [15]. The Global Leaders Group have highlighted that the world faces a severe antibiotic pipeline and access crisis, providing recommendations for action [18].

Markets for novel antibiotics show limited viability, as returns on investment for new 'reserve' antibiotics do not cover research, development, registration, manufacturing, and distribution costs. Major pharmaceutical companies have largely abandoned antibiotic R&D, leaving small or micro biotech firms struggling to survive [19] - many facing bankruptcy or liquidation.

Experts are exiting AMR R&D. Due to the unfavourable and uncertain financial situation, many scientific experts continue to leave the field across all stages of development, intensifying the fragility of the R&D pipeline [20].

Availability and equitable access to essential antibiotics remain unreliable across many G7 countries and globally [21]. In low and middle income countries (LMICs), in particular, limited access not only further drives resistance through inappropriate use but also fuels the market for substandard and falsified drugs, deepening health inequities and compounding the socio-economic impacts of AMR. Notably, deaths associated with lack of access to antibiotics surpasses those caused by AMR itself [9,10]. Ensuring a sustainable and equitable supply of both existing and novel antibacterials to meet global public health needs is crucial for securing a resilient, safe, and economically productive future.

Current incentives for AMR R&D are insufficient. ‘Push’ incentives - government or regulatory interventions which support R&D by directly lowering the costs of development - provide a crucial lifeline to some of the most promising R&D projects but are insufficient on their own to meet R&D goals and bring new products to market [22,23]. Pull incentives - policies rewarding R&D programs that successfully bring products to market and ensure access - have been slow to be implemented. Furthermore, mechanisms for equitable access and stewardship globally are limited, discouraging further investment in AMR R&D.

There is a need for innovative financing policies. More widespread adoption of policies rewarding successful R&D programs through pull incentives or other innovative financing mechanisms are particularly necessary. Such mechanisms would contribute to restoring market health, sustaining the development of novel antibacterials, and stimulating innovation, resulting in benefits to health, productivity, and economic growth [24-28]. Consultations with key stakeholders, including policy makers, funders, researchers, industry and civil society [29], indicate that pull incentives should be:

- Based on public health needs
- Delinked from volumes sold to ensure appropriate use
- Easy to implement in different health systems
- Aligned to pull in the same direction
- Include global stewardship and access obligations
- Paid over time, to ensure compliance and ability to respond to up-to-date information
- Of sufficient and predictable size to stimulate R&D (estimates from 2021 suggest between USD ~220 - 480 million [21], per year per antimicrobial over 10 years), with ‘fair share’ contributions from the G7 and the European Union (EU)

The G7 and the EU would gain significant economic and social benefits by investing early in a multifaceted antibiotic incentive program targeting urgent public health needs. Recent studies have highlighted the potential scale and return on investment from such initiatives [24,25,27].

In February 2024, the Global Leaders Group on AMR issued recommendations for mutually reinforcing financial and nonfinancial solutions for addressing the antibiotic pipeline and access crisis in human health [18].

Incentivizing New Antibacterial Development - Progress since 2023

According to data from the Global AMR R&D Hub's Dynamic Dashboard¹, investments in AMR R&D across all One Health sectors from public and philanthropic sources globally equate to USD ~1.5 – 2 billion per year. Since 2017, investments in AMR R&D have reached USD 13.75 billion – an increase of funding represented within Dynamic Dashboard of over USD 3.08 billion since April 2023.

G7 countries and the EU remain leading financial contributors to AMR R&D across the One Health spectrum. Public G7 + EU funding represents 68% (USD 9.4 billion) of the total global investment since 2017. In addition, philanthropic funders based in G7 countries, such as the Wellcome Trust and the Bill & Melinda Gates Foundation have invested a further USD 1.95 billion since 2017 (14% of overall funding in Dynamic Dashboard). Financial support extends to a range of initiatives to accelerate the development and market entry of needed new antimicrobials (e.g., CARB-X, GARDP, InnovFin Infectious Diseases). The leading financial contributors to CARB-X and GARDP include the Biomedical Advanced Research and Development Authority (BARDA – United States), the Wellcome Trust, the Federal Ministry of Education and Research (BMBF-Germany), the Global AMR Innovation Fund (GAMRIF – United Kingdom), the European Commission's (EC) Health Emergency Preparedness and Response Authority (HERA) and the Ministry of Health, Labour and Welfare (MHLW - Japan)².

A recent analysis of investment in human therapeutics across the pipeline by public and philanthropic funders (using Global AMR R&D Hub Dynamic Dashboard data), again highlights the key role the G7 and EU play in antibacterial R&D, and emphasises that on the push side, antibiotic R&D will require an additional global investment ranging between USD 250 million - 400 million per year [28].

The AMR Action Fund also continues to accelerate the development of traditional and non-traditional antibacterials as well as diagnostics, with an annual investment estimated at USD 100 million per year, and nine companies now in its portfolio.

Since 2023, countries restated and bolstered prior commitments in the area and announced new activities towards these goals. Notably, on 14th June 2024, all G7 countries and the EU, reiterated commitments to 'implementing push and pull incentives, supporting public-private partnerships and exploration of innovative instruments to

¹ dashboard.globalamrhub.org

² See <https://dashboard.globalamrhub.org/reports/investments/funding-distributors> for further information on investments to CARB-X and GARDP

accelerate R&D on new antimicrobials, their alternatives, and diagnostics’ in the Apulia G7 Leaders’ Communiqué [30].

Notable developments June 2023 - Oct 2024:

- **Canada** - Committed to designing and implementing a pilot project to secure access to new antimicrobials for people living in Canada, pledged financial support for CARB-X over next two years and has launched the Pan-Canadian Action Plan on AMR (PCAP).
- **France** - The second joint action on AMR and healthcare associated infections EU-JAMRAI 2 was launched, coordinated by France. Publication of the 2024–2034 One Health Interministerial roadmap.
- **Italy** - Kept AMR high on the agenda during its presidency of the G7 in 2024. Pledged financial support for CARB-X over the next three years.
- **Germany** - Published DART30 and pledged further financial support for CARB-X and GARDP. Published an updated version of the Pathogen List and Criteria for Reserve Antibiotics.
- **Japan** - Selected Shionogi’s Cefiderocol for the Antimicrobial Securement Support Program (ASSP) and provided further financial support for CARB-X and GARDP.
- **UK** - UK-wide Subscription model for antibiotics become operational. Published an updated National Action Plan on AMR (2024–2029) and pledged significant financial support to tackle AMR, including activities to improve access to essential antimicrobial drugs in Africa as well as funds to help establish a global independent scientific panel for AMR. Further financial support for AMR research, including support for CARB-X and GARDP and for the establishment of the Fleming Initiative, was announced.
- **US** - Resubmitted the PASTEUR Act to Congress, ARPA-H announced a USD 104 million award under the DARTS program to combat AMR, and PACCARB published ‘A United Front: Collaborative Global Leadership To Combat AMR’, highlighting the need for advancement of market-based incentives for R&D of new AMR products based on public health needs.
- **EU** - The Council of the EU adopted the Recommendation on stepping up EU actions to combat AMR in a One Health approach, including a recommendation that the EC contributes to the design and governance of a EU-wide multi-country pull incentive scheme to stimulate antimicrobial innovation and access. DG HERA published its workplan for 2024 strengthening action on pull incentives and announced financial support for GARDP. At the United Nations High-Level Meeting on AMR, the EC announced funding to support the establishment of a global independent scientific panel for AMR.

See detailed overview of country-by-country progress across the push and pull continuum in [profiles](#) below. See [Box 2](#) for data sources used for the profiles. [Annex 1](#) provides a summary of the key features of existing and proposed pull incentives.

Next Steps & Key Action Areas

There has been progress across the G7 and EU over the last year and commitments have been made to strengthen AMR R&D, access and equity within the United Nations Political Declaration of the High-Level Meeting on AMR approved on the 26th September [31]. However, the translation of commitments into action should be accelerated and coordinated to ensure impact. Once again we urge Finance and Health Ministers to embed the following key action areas into their activities against AMR in the next 12 months:

1. Accelerate action and accountability

Addressing AMR and its socio-economic impacts is a priority for G7 countries, requiring accelerated action, shared priorities, targets and timelines for action.

- Elevate and embed AMR within global political discussions on climate change and pandemic preparedness.
- Implement concrete and measurable G7 commitments on developing and ensuring access to new antibacterials.
- Maintain AMR as a priority during G7 Finance and Health Ministers' meetings

2. Align and Enhance Financing Mechanisms for AMR R&D to reward innovation

Push incentives for AMR R&D are necessary but insufficient on their own; globally coordinated actions are needed to sustain public-private partners and implement pull incentives or other innovative financing mechanisms.

- Ensure that R&D is driven by public health needs.
- Strengthen the AMR R&D ecosystem with sustainable, adequate and predictable financing, including through supporting public-private partnerships such as CARB-X and GARDP.
- Leverage country-level experiences with pull incentive pilots to encourage more widespread adoption and inform and explore international collaborative mechanisms for antibacterial R&D.
- Request that the Global AMR R&D Hub supports necessary peer exchange and learning on pull incentives and their implementation and share recommendations with the G7 in 2025.
- Ensure pull mechanisms stimulate R&D, reward innovation, and provide equitable access, especially in LMICs.

3. Prioritize Equity and Global Access

Together with prioritizing the development of new antibacterials broadening equitable access to all antibacterials is also essential.

- Strengthen G7 commitments to initiatives like SECURE that improve global access to new and existing antibiotics.
- Enhance equitable access to priority antibiotics and other essential health products for AMR, including diagnostics and vaccines, by embedding AMR into international development and ensuring stewardship and access provisions are written into push funding agreements.

As we approach the end of this pivotal year for AMR, building on the commitments outlined in the Political Declaration from the United Nations General Assembly High-Level Meeting on AMR, and looking ahead to the 4th Global High-Level Ministerial Meeting on AMR in November, the G7 is poised to play a crucial role in translating commitments into concrete action.

Box 1: SECURE - Expanding Sustainable Access to Antibiotics

SECURE, developed by the WHO and GARDP, aims to improve access to essential antibiotics, support stewardship, and generate data on local AMR conditions and the effective use of new antibiotics. It has the potential to introduce new procurement and supply financing models, creating a pull by ensuring there is more widespread access and therefore a more viable and attractive market. SECURE's antibiotic portfolio will be tailored to individual countries' needs, including both scarce generics and newly approved reserve antibiotics for resistant infections.

SECURE has identified high-impact interventions to address the root causes of antibiotic access issues, categorized into four areas: optimizing antibiotic portfolios, enhancing information transparency, improving supply security, and ensuring responsible antibiotic access. The impact of procurement and economic interventions—such as pooled procurement, stockpiling, revenue/volume guarantees, and co-payments—has been validated through modelling, with ongoing refinements in consultation with countries and regions.

A methodology has been developed to select a small number of antibiotics for a proof-of-concept starting in 2025, alongside a partnership and governance model. Supportive interventions are already underway, including a review of regulatory measures to address shortages, development of a forecasting model, and cost-of-goods analyses. WHO is also preparing operational guidance to support countries in introducing new antibiotics, which can be tested during the proof-of-concept.

Box 2: Country Profile Data Sources

- **Gross Domestic Product and Population data:** World Bank <https://data.worldbank.org/>
- **Disability Adjusted Life Years (DALYs) and Deaths (total and per 100,000 population):**
 - Institute for Health Metrics and Evaluation (IHME), University of Oxford. MICROBE. Seattle, WA: IHME, University of Washington, 2022. Available from <https://vizhub.healthdata.org/microbe/>. (Accessed [11/10/2024])
 - European Centre for Disease Prevention and Control (ECDC) (2022), *Assessing the health burden of infections with antibiotic-resistant bacteria in the EU/EEA, 2016-2020*. Stockholm: ECDC, 2022
 - Used for EU profile only
 - Estimations of the burden of infections associated with antibiotic-resistant bacteria presented as total number of deaths and per 100 000 population by country
 - Estimations of the burden of infections associated with antibiotic-resistant bacteria presented as disability-adjusted life years (DALYs) total and per 100 000 population by country
- **Resistant Infections & Costs:**
 - European Centre for Disease Prevention and Control (ECDC) (2022), *Assessing the health burden of infections with antibiotic-resistant bacteria in the EU/EEA, 2016-2020*. Stockholm: ECDC, 2022
 - Used for EU profile only
 - OECD (2023), *Embracing a One Health Framework to Fight Antimicrobial Resistance*, OECD Health Policy Studies, OECD Publishing, Paris, <https://doi.org/10.1787/ce44c755-en>.
 - Resistant infections: share of resistant infections as percentage of total infections in 2019
 - Costs indicate health and labour cost of resistant infections per year up to 2050. Per capita in USD, purchasing power parity.
 - CCA (2019), *When Antibiotics Fail: The Expert Panel on the Potential Socio-Economic Impacts of Antimicrobial Resistance in Canada*, Council of Canadian Academies, <https://cca-reports.ca/wp-content/uploads/2018/10/When-Antibiotics-Fail-1.pdf>.
 - For Canada only: Data used to calculate comparable health and labour cost of resistant infections per year up to 2050, per capita.
- **Investments in AMR R&D (Public and Philanthropic sources):**
 - Global AMR R&D Hub Dynamic Dashboard
 - <https://dashboard.globalamrhub.org/reports/investments/countries>
 - <https://dashboard.globalamrhub.org/reports/investments/funding-distributor>
 - Data is subject to caveats and limitations
- **Number of new antibacterials approved and launched in each country:**
 - Outterson K, Orubu ESF, Rex J, Årdal C, Zaman MH. *Patient Access in 14 High-Income Countries to New Antibacterials Approved by the US Food and Drug Administration, European Medicines Agency, Japanese Pharmaceuticals and Medical Devices Agency, or Health Canada, 2010-2020*. Clin Infect Dis. 2022;74(7):1183-1190. doi:10.1093/cid/ciab612
 - Updates direct from country correspondence



CANADA

Population = 40,097,761 (2023)
GDP per capita = 53,371 USD (2023)

National Action
Plan on AMR



AMR BURDEN 2019

(Associated with resistant bacterial infections)

DALYS = **300k** (822/100k)

DEATHS = **14K** (38/100k)

RESIST INFECT = **17.7%** (average)

COSTS = **33 USD** per capita

Health and labour cost of resistant infections per year up to 2050, Per capita (USD)



Total AMR R&D spend
158 million USD
(Jan 17 to Oct 24)



Contribution to AMR R&D funding distributors
4.8 million USD
(Jan 17 to Sep 24)



Progressing with implementing commitments to design and trial an antibiotic access model



3 Number of new antibacterials approved & launched in Canada since 2010

2021

- **12-13 Oct:** Best Brains Exchange (BBE). A virtual meeting to bring together senior policy makers, subject matter experts and industry stakeholders to discuss AMR, pull incentives and their implementation in Canada
- **18 Oct:** Public Health Agency Canada (PHAC) officially launches the AMR Task Force, to enhance ability to work across federal departments and with stakeholders
- **Nov-Dec:** G7 Health and Finance Ministers publish the 'G7 Shared Principles for the Valuation of Antimicrobial Therapeutics' and 'Statement on Actions to Support Antibiotic Development'
- **16 Dec:** The Minister of Health was issued an AMR-specific call to action in the 2021 Prime Ministerial mandate letter which outlines the pressing challenges they will address in their role

2022

- **22 Mar:** BBE Summary report is published, 'Challenges in the Antimicrobial Business Model and Potential Incentives to Increase Access and Promote Innovation'
- **1 Jun:** PHAC commissions the Council of Canadian Academies (CCA) to conduct an examination of economic pull incentives for encouraging market entry and sustained market availability of high-value antimicrobials in Canada
- **17 Oct:** Canada pledges support of CAD 300,000 for further developing SECURE, a new antibiotic access initiative by GARDP and WHO

2023

- **28 March:** Canada's Budget Plan 2023 is published containing a commitment to 'secure new antimicrobials for Canadians'
- **11 May:** PHAC announces financial support for CARB-X of CAD 6.3 million over next two years
- **22 Jun:** Launch of the Pan-Canadian Action Plan on AMR 2023-2027 (PCAP). Economic and regulatory incentives are one of the priority action areas. Building momentum: Activities underway to address AMR in Canada published as a compendium to the PCAP
- **07 Sep:** CCA publishes 'Overcoming Resistance'. The report was commissioned by PHAC in 2022 to help develop a priority setting framework for pull incentives

2024

- **10 Jan:** Through the Canadian Institutes of Health Research (CIHR), Canada is a funder country in the 2024 Joint Programming Initiative on AMR (JPIAMR) transnational funding call, with a focus on bacterial and fungal resistance
- **15 Jun:** Apulia G7 Leaders' Communiqué commits to implementing push and pull incentives, supporting public-private partnerships and exploration of innovative instruments to accelerate R&D on new antimicrobials, their alternatives, and diagnostics
- **20 Aug:** PHAC commits to designing and implementing a pilot project to secure access to new antimicrobials for people living in Canada. See also departmental plan for 2024-2025
- **30 Sep:** PHAC publishes website to keep stakeholders updated with progress on its incentive pilot

Next Steps

- **2024-2027:** Implementation of a 3-year pilot to secure access to new antimicrobials



FRANCE

Population = 68,170,228 (2023)
GDP per capita = 44,461 USD (2023)

National Action
Plan on AMR



AMR BURDEN 2019

(Associated with resistant bacterial infections)

DALYS = **660k** (1k/100k)

DEATHS = **36k** (54/100k)

RESIST INFECT = **13.8%** (average)

COSTS = **22.8 USD** per capita

Health and labour cost of resistant infections per year up to 2050, Per capita (USD, Purchasing Power Parity)



Total AMR R&D spend

167 million USD

(Jan 17 to Sep 24)



High Unit pricing model for antibiotics that meet minimum clinical standards



Number of new antibacterials approved & launched in France during 2010-2020

2021

- **Mar:** Renewal of the framework agreement between the French Government and Industry Group as part of the extended 'Strategic Contract' (2023-2026) which is the forum where antibiotic innovation models are being developed as part of whole life-cycle and industrial ecosystem approach
- **Nov-Dec:** G7 Health and Finance Ministers publish the '[G7 Shared Principles for the Valuation of Antimicrobial Therapeutics](#)' and '[Statement on Actions to Support Antibiotic Development](#)'

2022

- **07 Mar:** Publication of the latest AMR Plan for the human sector in France "[2022-2025 National Strategy for Preventing Infections and Antibiotic Resistance](#)," which operationalises the Interministerial Roadmap. It emphasises infection prevention, antibiotic stewardship, and the promotion of innovative research. The strategy also aims to protect the existing therapeutic arsenal by incentivising the availability of off-patent antibiotics and supporting the market entry of new products. The "[One Health](#)" [French National Action Plan on AMR Overview](#) is published and a [High-Level One Health Ministerial Conference on AMR held in Paris](#) as part of the French Presidency of the Council of the European Union
- **22 Nov:** Publication of the [Interministerial Roadmap to control AMR](#) (first edition in 2016), aims to set the strategic One Health direction for 10 years from which the three sectors operationalise their own plans.

2023

- **15 Feb:** French Health Technology Assessment authority (HAS) introduces new evaluation principles for drug reimbursement, focusing on antibiotics targeting multi-resistant bacteria with an adapted framework. HAS also releases a [working document](#) that influenced these updates
- **12 Oct:** [Global Health Strategy 2023-2027](#) is published, with strengthened efforts to combat AMR as a focus area
- **Nov:** Beginning of the public consultation that led to the New Roadmap being published in Sept. 2024

2024

- **10 Jan:** Through Agence Nationale de la Recherche (ANR), [France is a funder country in the 2024 JPIAMR transnational funding call](#), with a focus on bacterial and fungal resistance
- **13 Feb:** Launch of the second joint action on AMR and healthcare associated infections [EU-JAMRAI 2](#), coordinated by France, with the objective of promoting interdisciplinary collaboration among countries, institutions, and sectors, and implementing concrete One Health actions to safeguard the effectiveness of antimicrobials and protect public health
- **15 Jun:** [Apulia G7 Leaders' Communiqué](#) commits to implementing push and pull incentives, supporting public-private partnerships and exploration of innovative instruments to accelerate R&D on new antimicrobials, their alternatives, and diagnostics
- **11 Sep:** Publication of the [2024-2034 One Health Interministerial roadmap](#) titled "Prevention and Reduction of Antibiotic Resistance, Fight Against Antimicrobial Resistance"

Next Steps

- **2025:** France will participate in the [Horizon Europe Candidate Partnership: One Health AMR](#)
- **2020-2030:** [French National Priority Research Programme on antibiotic resistance](#) continues, with EUR 40 million investment over 10 years



AMR BURDEN 2019

(Associated with resistant bacterial infections)

DALYS = **640k** (1.1k/100k)

DEATHS = **35k** (57/100k)

RESIST INFECT = **35.7%** (average)

COSTS = **63.4 USD** per capita

Health and labour cost of resistant infections per year up to 2050, Per capita (USD, Purchasing Power Parity)



Total AMR R&D spend
10 million USD

(Jan 17 to Sep 24)



Existing national pathways to higher antibiotic valuation are being explored



Number of new antibacterials approved & launched in Italy during 2010-2020

2021

- **18 Nov:** Italian Medicines Agency (AIFA) establishes a working group - [AIFA-OPERA](#), Ottimizzazione della PrEscRizione Antibiotica- Optimization of Antibiotic Prescription - to support the Agency in promoting optimal use of antibiotics and reducing the onset of resistance
- **Nov-Dec:** G7 Health and Finance Ministers publish the '[G7 Shared Principles for the Valuation of Antimicrobial Therapeutics](#)' and '[Statement on Actions to Support Antibiotic Development](#)'

2022

- **10 Mar:** AIFA publishes the report "[Antibiotic use in Italy - 2020](#)" - data and analysis on the trend in consumption and expenditure of antibiotics for human use in Italy
- **11 Jun:** Publication of [Italian guidelines on diagnosis and management of infections caused by multidrug-resistant bacteria](#) by scientific societies, commissioned by the Ministry of Health
- **18 Oct:** Italy contributed to the country profile published in "[Addressing the burden of infections and antimicrobial resistance associated with health care](#)" by OECD
- **18 Nov:** AIFA publishes [recommendations on targeted therapy of resistant infections](#)
- **29 Dec:** An annual budget of EUR 40 million (2023-2025) for financing National Action Plan (NAP) roll-out is secured ([Article 1, paragraph 529, of Law no. 197](#)), to implement the measures and interventions envisaged in the NAP on AMR 2022-2025

2023

- **26 Jan:** Regional funding allocation criteria for AMR actions approved by the Permanent Conference for relations between the State, Regions, and Autonomous Provinces
- **02 Feb:** Publication of the second [NAP on AMR 2022-2025](#). One of the six main objectives states 'fostering innovation and research on the prevention, diagnosis and treatment of antibiotic-resistant infections' and covers concrete scientific areas for research
- **03 Apr:** Publication of [Antibiotic use in Italy - 2021](#), providing data and analysis on the trend in consumption and expenditure of antibiotics for human use in Italy

2024

- **10 Jan:** Through the Fondazione Regionale per la Ricerca Biomedica (FRRB) and the Ministry of Health, [Italy is a funder country in the 2024 JPIAMR transnational funding call](#)
- **23 Apr:** Ministry of Health approved funding for regional AMR actions, following the outcomes of evaluations performed by a Technical Committee formed in Dec. 2023
- **15 Jun:** [Apulia G7 Leaders' Communiqué](#) commits to implementing push and pull incentives, supporting public-private partnerships and exploration of innovative instruments to accelerate R&D on new antimicrobials, their alternatives, and diagnostics
- **10 Oct:** Ministry of Finance pledges EUR 21 million for CARB-X

Next Steps

- **2025:** Italy will participate in the [Horizon Europe Candidate Partnership: One Health AMR](#)



GERMANY

Population = 84,482,267 (2023)
GDP per capita = 52,745.8 USD (2023)

National Action
Plan on AMR



AMR BURDEN 2019

(Associated with resistant bacterial infections)

DALYS = **840k** (987/100k)

DEATHS = **43k** (50/100k)

RESIST INFECT = **15.5%** (average)

COSTS = **36.3 USD** per capita

Health and labour cost of resistant infections per year up to 2050, Per capita (USD, Purchasing Power Parity)



Total AMR R&D spend

344 million USD

(Jan 17 to Sep 24)



Contribution to AMR R&D funding distributors

231 million USD

(Jan 17 to Sep 24)



High Unit pricing model for

antibiotics that meet minimum clinical standards



Number of new antibacterials approved & launched in Germany during 2010-2020

2021

- **Jan:** Initial list of multidrug resistant pathogens and criteria for 'reserve' designation published by the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) following the designations' creation in April 2020 (§35a of the German Social Code Book V) as part of the Fair Competition among Health Insurers Act
- **15 Jul:** Federal Ministry for Research and Education (BMBF) commits EUR 25 million over seven years to support [UNITE4TB](#), a public private partnership that aims to enhance treatments for drug-resistant and drug-sensitive tuberculosis
- **Nov-Dec:** G7 Health and Finance Ministers publish the '[G7 Shared Principles for the Valuation of Antimicrobial Therapeutics](#)' and '[Statement on Actions to Support Antibiotic Development](#)'
- EUR 5.1 million investment into GARDP for the 2016-2021 period expires

2022

- **Apr:** Final report of Germany's AMR strategy - [DART2020](#) - is published
- **17 Oct:** German Federal Ministry for Education and Research (BMBF) [announces EUR 50 million](#) for GARDP over the next five years (2023-2027).

2023

- **14 Feb:** Ministry of Health (BMG) introduces the "[Act to Combat Supply Shortages of Off-Patent Medicines and to Improve the Supply of Pediatric Medicines](#)" (ALBVVG). This law provides greater oversight powers for monitoring and ameliorating shortages of antibiotics and other off-patent essential medicines
- **30 Apr:** The follow-up AMR strategy, [DART2030](#) is published, with R&D of new diagnostics, antibiotics, alternatives to antibiotic treatments and vaccines a key priority area
- **10 May:** BMBF [announces EUR 39 million](#) in funding for CARB-X and EUR 2 million for CARB-X's global accelerator network

2024

- **10 Jan:** Through the BMBF, [Germany is a funder country in the 2024 JPIAMR transnational funding call](#), with a focus on bacterial and fungal resistance
- **Feb-Apr:** Updated version of "[Pathogen List and Criteria for Reserve Antibiotics](#)" published which determines the antibiotics that could be eligible for favourable pricing terms (§35a paragraph 1 SGB V). Criteria and procedures subsequently updated
- **May:** [Action Plan for DART30 \(2024-2026\)](#) is published, outlining measures envisaged to achieve the goals laid out in DART30
- **15 Jun:** [Apulia G7 Leaders' Communiqué](#) commits to implementing push and pull incentives, supporting public-private partnerships and exploration of innovative instruments to accelerate R&D on new antimicrobials, their alternatives, and diagnostics
- **July:** Pricing rules that apply to antibiotics which successfully achieve the reserve designation are adopted

Next Steps

- **2025:** Germany will participate in the [Horizon Europe Candidate Partnership: One Health AMR](#)
- **2025-2028:** The [Federal Ministry of Economic Cooperation and Development \(BMZ\)](#) will invest [EUR 11 million](#) in GARDP



JAPAN

Population = 124,516,650 (2023)
GDP per capita = 33,834 USD (2023)

National Action
Plan on AMR



AMR BURDEN 2019

(Associated with resistant bacterial infections)

DALYS = **1.4M** (1.1k/100k)

DEATHS = **87k** (68/100k)

RESIST INFECT = **14.7%** (average)

COSTS = **55.9 USD** per capita

Health and labour cost of resistant infections per year up to 2050, Per capita (USD, Purchasing Power Parity)



Total AMR R&D spend
110 million USD

(Jan 17 to Sep 24)



Contribution to AMR R&D funding distributors
9 million USD

(Jan 17 to Sep 24)



Implemented 'revenue guarantee assurance' in 2024 for access to 1 antibiotic



Number of new antibacterials approved & launched in Japan since 2010

2021

- **07 Jun:** Japan provides [USD 1.8 million to GARDP](#) (April 2021 to March 2022)
- **17 Nov:** G7 Health Ministers publish the '[G7 Shared Principles for the Valuation of Antimicrobial Therapeutics](#)' & G7 Finance Ministers release a joint '[Statement on Actions to Support Antibiotic Development](#)'

2022

- **11 May:** 'Act on the promotion of national security through integrated economic measures' (Act No 43 of 2022) is approved – Economic Security Preparation Act. Antibiotics are designated as a critical product qualifying for support under economic security legislation
- **15 Jul:** Provides [USD 1.8 million to GARDP](#) for April 2022 to March 2023
- **27 Dec:** Commitment of YEN 1.1 billion (USD ~8 million) announced in Japan's 2023 fiscal year budget for a 'Antimicrobial Securement Support Program (ASSP)' targeting antimicrobial agents for antimicrobial resistant bacteria that pose a public health threat. ASSP will provide a revenue guarantee, a compensation payment for lost profits due to antimicrobial stewardship regulation – subsidizing the difference between actual sales and forecasted size of target antimicrobials (based on expert evaluation)

2023

- **19 Jan:** Japan announces a plan to ensure stable domestic supplies of priority antibiotics. Support will be provided to companies for establishing national Active Pharmaceutical Ingredient (API) manufacturing and storage facilities for four β -lactam antibiotics (cefazolin, cefmetazole, ampicillin/sulbactam, tazobactam/piperacillin)
- **7 Apr:** [2nd NAP on AMR 2023-2027](#) is published, with one of the aims to promote research on AMR and foster R&D to secure the means to prevent, diagnose and treat AMR infections
- **Jul:** The Ministry of Health, Labour and Welfare (MHLW) certifies the projects for ensuring stable supply of four β -lactam antibiotics and will start providing involved companies with subsidies for installing facilities for the production and stockpiling of APIs
- **12 Sep:** Japan supports CARB-X with [USD 1 million](#) (April 2023-March 2024)
- **19 Oct:** Japan support GARDP with [USD 1.8 million](#) (April 2023 to March 2024)
- **07 Nov:** MHLW selects Shionogi's Cefiderocol for ASSP (active against Carbapenem-resistant Enterobacteriaceae -CRE)

2024

- **20 Feb:** A public call for ASSP for FY2024 is held and Shionogi's Cefiderocol is selected (as 2023)
- **Apr:** Japan supports GARDP with USD 1.79 million to GARDP and CARB-X with USD 1 million (April 2024 to March 2025)
- **15 Jun:** [Apulia G7 Leaders' Communiqué](#) commits to implementing push and pull incentives, supporting public-private partnerships and exploration of innovative instruments to accelerate R&D on new antimicrobials, their alternatives, and diagnostics

Next Steps

- **2024-2025:** Japan will continue to consider antimicrobials for ASSP



AMR BURDEN 2019

(Associated with resistant bacterial infections)

DALYS = **580k** (861/100k)

DEATHS = **32k** (48/100k)

RESIST INFECT = **10.8%** (average)

COSTS = **19.1 USD** per capita

Health and labour cost of resistant infections per year up to 2050, Per capita (USD, Purchasing Power Parity)



Total AMR R&D spend
1.3 billion USD

(Jan 17 to Sep 24)



Contribution to AMR R&D funding distributors
103 million USD

(Jan 17 to Sep 24)



Active 'subscription model' pull incentive for antibiotics



11 Number of new antibacterials approved & launched in the UK since 2010

2021

- **Nov-Dec:** G7 Health and Finance Ministers publish the '[G7 Shared Principles for the Valuation of Antimicrobial Therapeutics](#)' and '[Statement on Actions to Support Antibiotic Development](#)'

2022

- **16 May:** [Addendum to the 5-year national action plan on AMR](#) is published with aims including prioritizing investment in the R&D of new therapeutics and diagnostics and global access to therapeutics
- **July:** The world's first subscription model for antibiotics moves from pilot phase (Jul 2020-Jul 2022) to an implemented model. It pays drug companies a fixed fee (GBP 10 million per year for 3-10 years) regardless of sales volume to ensure access to new antibiotics (GBP 11-19 million per year, per antibiotic, 2x antibiotics)

2023

- **22 May:** UK announces up to [GBP 39 million for AMR research](#), including [GBP 24 million for CARB-X](#) and GBP 5 million for GARDP, as part of the Global AMR Innovation Fund (GAMRIF)
- **16 Aug:** [UK commits GBP 210 million to support the Fleming Fund's activities to tackle AMR in countries across Asia and Africa over the next 3 years](#)
- **Dec:** Period of subscription model evaluation and [stakeholder consultation](#) (2022-2023) ends

2024

- **3 Jan:** House of Commons Science, Innovation and Technology Committee's report on [The antimicrobial potential of bacteriophages](#) is published. Government [publishes response to report](#) on 1st March.
- **10 Jan:** Through the 7 UK Research and Innovation Research Councils, the UK is a funder country in the [2024 JPIAMR transnational funding call](#), with a focus on bacterial and fungal resistance. GBP 16.5 million is made available to UK research organisations
- **8 May:** [UK's 2nd National Action Plan on AMR 2024-2029](#) is published, with aims, amongst others of supporting the development of new antimicrobials. [Seed funding for the Fleming Initiative](#) announced.
- **16 May:** [GBP 1.8 million allocated](#) to the Medicines and Healthcare products Regulatory Authority (MHRA) to provide regulatory and scientific support for innovators creating novel antimicrobials and diagnostics; [Funding of GBP 85 million to tackle AMR pledged](#); Includes GBP 50 million to partner with countries in Africa for improving access to essential antimicrobial drugs, and up to GBP 10 million over the next 5 years to help establish a global independent scientific panel for AMR.
- **15 Jun:** [Apulia G7 Leaders' Communiqué](#) commits to implementing push and pull incentives, supporting public-private partnerships and exploration of innovative instruments to accelerate R&D on new antimicrobials, their alternatives, and diagnostics
- **12 Aug:** [UK-wide Subscription model for antibiotics becomes operational](#). First round of procurement (outside of the pilot) launched with evaluation of eligible patented products occurring 2024-2026 with new contracts starting in 2026 (minimum 3 and maximum 16 years duration). New and pilot products will be evaluated according to the updated Clinical Technical Evaluation (CTE) and placed into one of 4x value bands to determine the contract value (max. GBP 23.7 million per product, per year available)

Next Steps

- **2024:** Subscription model for antibiotics expands across UK
- **2024-2027:** Announcement of an [additional GBP 7 million for GARDP](#)



AMR BURDEN 2019

(Associated with resistant bacterial infections)

DALYS = **3.9M** (1.2k/100k)

DEATHS = **160k** (50/100k)

RESIST INFECT = **24.5%** (average)

COSTS = **105.8 USD** per capita

Health and labour cost of resistant infections per year up to 2050, Per capita (USD, Purchasing Power Parity)



Total AMR R&D spend
5.2 billion USD

(Jan 17 to Sep 24)



Contribution to AMR R&D funding distributors
462 million USD

(Jan 17 to Sep 24)



3 pieces of legislation have passed into law (**NTAP, GAIN, and IPPS**) and 2 remain (**DISARM, PASTEUR**) to improve developer returns



Number of new antibacterials approved & launched in the USA during 2010-2020

2021

- **17 Nov:** G7 Health Ministers publish the '[G7 Shared Principles for the Valuation of Antimicrobial Therapeutics](#)'
- **13 Dec:** G7 Finance Ministers release a joint '[Statement on Actions to Support Antibiotic Development](#)'
- **24 Jun:** Introduction of the [DISARM Act](#) to Congress. Removes the current incentive for hospitals to choose lower-cost antibiotics. The Act would increase payments for certain novel AMR products but also requires hospitals receiving increased payments to establish stewardship programs and report data to the Center for Disease Control (CDC)

2022

- **19 May:** The U.S. Department of Health and Human Services (HHS) funds CARB-X with [USD 20 million in 2022](#) and options to provide up to USD 300 million over the next 10 years
- **16 Aug:** [National Action Plan for Combating Antibiotic-Resistant Bacteria Progress Report for Fiscal Year 2022](#) is published

2023

- **24 Mar:** [The President's Budget Request for FY 2024](#) includes USD 9 billion to develop innovative antimicrobials through a payment mechanism that delinks sales volume from revenue for critical-need drugs. The [PACCARB report, "Preparing for the Next Pandemic in the Era of Antimicrobial Resistance,"](#) recommends developing novel antimicrobials, vaccines, diagnostics, and threat-agnostic platform technologies for resistant pathogens.
- **27 Apr:** Resubmission of the [PASTEUR Act to Congress](#). Submitted for the [first time on 20 Sept 2020](#), gaining increasing bi-partisan support. Authorizes HHS to enter into subscription contracts for critical-need antimicrobial drugs
- **27 Sep:** [ARPA-H announces a USD 104 million award](#) under the DARTS program to combat AMR
- **14-15 Nov:** [In-person meeting](#) of the Transatlantic Taskforce on AMR (TATFAR)

2024

- **22 Apr:** CDC publishes their 2023 stewardship update on [Antibiotic Use in the United States](#)
- **May:** PACCARB publishes '[A United Front: Collaborative Global Leadership To Combat AMR](#)', highlighting the need for advancement of market-based incentives for R&D of new AMR products based on public health needs
- **15 Jun:** [Apulia G7 Leaders' Communiqué](#) commits to implementing push and pull incentives, supporting public-private partnerships and exploration of innovative instruments to accelerate R&D on new antimicrobials, their alternatives, and diagnostics
- **16 Jul:** CDC publishes new data on [AMR Threats in the U.S. from 2021-2022](#) as well as a [COVID-19: U.S. Impact on AMR, Special Report 2022](#)

Next Steps

- **2024-2026:** Fourth implementation phase and [work plan of TATFAR](#) continues



AMR BURDEN 2019

(Associated with resistant bacterial infections)

DALYS = --- (5.2k/100k)

DEATHS = **35k** (180/100k)

RESIST INFECT = **21%** (average)

COSTS = **27.1 USD** per capita

Health and labour cost of resistant infections per year up to 2050, Per capita (USD, Purchasing Power Parity)



Total AMR R&D spend

2.2 billion USD

(Jan 17 to Sep 24)



Contribution to AMR R&D funding distributors

23 million USD

(Jan 17 to Sep 24)



Progressing with implementing commitments to design and trial an antibiotic access model



Number of new antibacterials centrally-approved in the EU since 2010

2021

- **Jan:** Horizon Europe (2021-2027), the key EU funding programme for research and innovation, initiated following political agreement in Dec 2020 with an indicative budget of EUR 93.5 billion
- **21 Mar:** EU4Health programme (regulation EU 2021/522) established also with a EUR 5.5 billion 7-year budget determining the EU's action in the field of health including some AMR actions
- **26 Oct:** European Parliament [Health Working Group Session on Incentives](#)

2022

- **21 Nov:** Budget secured for AMR actions (including incentives) through the finalisation of the [EU4Health Action 2023 "CP-p-23-16"](#) with a budget of EUR 22 million

2023

- **2 Feb:** The Directorate-General Health Emergency Preparedness and Response Authority (DG HERA) publishes a feasibility study on [stockpiling AMR countermeasures](#)
- **13 Mar:** DG HERA publishes the final results of its [study on bringing AMR medical countermeasures to the market](#)
- **26 Apr:** The European Commission (EC) adopts a [Council Recommendation on stepping up EU actions to combat AMR in a One Health approach](#), accompanied by a [Commission Staff Working Document](#), as part of the ongoing reform of the [EU pharmaceutical package](#). The EC has included [Transferable Data Exclusivity Vouchers](#) in its reform of the pharmaceutical package and received the mandate from the Council to contribute to the design and governance of a EU-wide multi-country pull incentive scheme to stimulate antimicrobial innovation and access
- **13 Jun:** Council of the EU adopts the 26 Apr Recommendation, including EC contribution to the EU-wide multi-country pull incentive scheme and establishment of and investment in a European One Health AMR partnership
- **23 Nov:** European Parliament's Panel for the Future of Science and Technology (STOA) provides a [range of options for revising pharmaceutical incentive structures](#)
- **21 Dec:** DG HERA publishes its [2024 Work plan](#), highlighting its activities for development and availability of and access to preventive, diagnostic and therapeutic medical countermeasures for AMR, notably through pull incentives

2024

- **10 Jan:** Call for proposals opens for the [European Partnership on One Health AMR](#)
- **13 Feb:** Kick off meeting of the [European Union Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections \(EU-JAMRAI 2\)](#). A key priority area is to improve [access to selected AMR-related products](#) both for human and veterinarian use
- **15 Jun:** [Apulia G7 Leaders' Communiqué](#) commits to implementing push and pull incentives, supporting public-private partnerships and exploration of innovative instruments to accelerate R&D on new antimicrobials, their alternatives, and diagnostics
- **26 Sept:** EC announces funding of EUR 2.5 million to support the establishment of a global independent scientific panel for AMR

Next Steps

- **2025:** DG HERA continues its roll out of a voluntary multi-country pull incentive
- **May 2025:** Start of the [Horizon Europe Partnership: One Health AMR for Research and Innovation](#)
- **2024-2027:** DG HERA pledges [EUR 20 million for GARDP](#)

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Annex 1: Summary of selected market adaptation and incentive models (G7 and EU). *A non-exhaustive summary of incentive models and pricing / reimbursement mechanisms for patented/non-patented antibacterials provided. Data based on Årdal et al [32] and updated Sep 2024. See also Annex 2.

	Approach	Status & name	Financing	Will this incentive impact antibacterial (AB)...			Will this require adaptations to existing procedure for...			
				R&D	Access	Stewardship	Medicine pricing	Health technology assessment (HTA)	Medicine purchase	Medicine reimbursement
UNITED KINGDOM (UK)	SUBSCRIPTION MODEL	Active UK Antimicrobial Products Subscription Model	Portfolio max. GBP 100 mn. Product max. GBP 23.7 mn /yr. for up to 16 yrs. Value according to Bands 1-4	Expected	Novel ABs – YES Generic ABs – NO LMICs – NO	YES delinked and via existing national provisions	YES prices set to reinforce prescribing guidelines	YES HTA determines the band allocated	YES One tender covering the 4 nations	NO
UNITED STATES OF AMERICA (US)	SUBSCRIPTION MODEL	Inactive PASTEUR ACT	USD 0.4-3 bn (3-5 awards – total max. USD 11 bn over 10 yrs.)	Expected	Novel AB – YES Generic ABs – potentially LMICs – potentially	YES delinked and via new national provisions	YES as above	Potentially since the HTA will likely inform the subscription amount	NO	NO
SWEDEN (SE)[#]	REVENUE GUARANTEE MODEL*	Active (pilot ended)	Currently extended until end of 2025	Not planned	Novel ABs – YES Generic ABs – new model 2024; LMICs - NO	YES partially delinked	YES	NO	YES adapted contracts	YES
JAPAN (JN)	REVENUE GUARANTEE MODEL*	Active (pilot phase)	YEN 1.1 billion in budget 2023; YEN 1.2 billion in 2024	Potentially	Novel ABs – YES Generic ABs – NO LMICs - NO	Potentially via existing national provisions	NO	Potentially since the HTA will likely inform the guarantee amount	NO	NO top-up; between consumption and guarantee
GERMANY (DE)	HIGH UNIT PRICE MODEL	Active GKV-FKG - Act	Higher price realisation within existing system	Potentially	Novel ABs – YES Generic ABs – NO LMICs – NO	Potentially via existing national provisions	YES a new process must be implemented for new ABs	YES since HTA or other valuation processes will need to reflect different evidence standards	NO	NO
FRANCE (FR)	HIGH UNIT PRICE MODEL	Active MoH	as above	Potentially	Novel ABs – YES Generic ABs – NO LMICs - NO	Potentially as above	YES as above	YES as above	NO	NO
WHO/ GARDP[#]	ACCESS MODEL	Inactive SECURE	Grants received for design and piloting	Potentially	LMICs – YES	Potentially provisions likely	-	-	-	-

[#][Canada](#) and [Switzerland](#)[#] are expected to take a similar approach through their forthcoming pilots; [European Union \(EU\)](#) continues roll out of a multi country pull incentive pilot; [#]non-G7 countries.

Annex 2: Market incentives – overview of mechanisms

Pull incentives encompass a variety of mechanisms proposed including these examples [26, 29]:

- **Subscription Model:** Fixed annual payments or minimum revenues for a set period in return for sufficient antimicrobial product supply guarantee, delinked from the volumes sold
- **Market-Entry Reward and Monetary Prizes:** One-off or milestone-based payments to reward completed development stages (typically late-stage R&D) or market launch of new antimicrobials
- **Ongoing Revenue Incentives:** Minimum price guarantees or reimbursement system carve-outs to reflect public health effects and societal value of new antimicrobials
- **High Unit Price Model:** This incentive aims to ensure that antimicrobials can benefit from high sales revenues despite low volumes and/or weak data, similar to orphan medicines
- **Exclusivity Extension:** Further patent or data exclusivity extensions granted to a successful new antimicrobial. When this can be traded across products (or companies) this is known as a transferable exclusivity voucher
- **Accelerated Approval and Priority Review Vouchers:** Vouchers for accelerated assessment and approval of antibiotics or other products under development by the same company (typically tradable between firms)

Contacts:

www.globalamrhub.org

Dr. Lesley Ogilvie
Secretariat Director
Global AMR R&D Hub

lesley.ogilvie@dzif.de

www.who.int

Dr. Alexandra Cameron
Senior Expert, Unit Head A.I.
Impact Initiatives and Research
Coordination (IRC)
World Health Organization

camerona@who.int

This publication was prepared by (in alphabetical order): Dr. Alexandra Cameron (Unit Head, WHO Antimicrobial Resistance Division); Suzanne Edwards (Economist, Global AMR R&D Hub); Dr. Valeria Gigante (Scientist, WHO Antimicrobial Resistance Division); Dr. Lesley Ogilvie (Secretariat Director, Global AMR R&D Hub); with contributions from the Global AMR R&D Hub's Board Members and Observers, and the Secretariat Team.

Global AMR R&D Hub

The Global AMR R&D Hub is a partnership of countries, non-governmental donor organisations and intergovernmental organisations to address challenges and improve coordination and collaboration in global AMR R&D using a One Health approach. The Hub was launched in May 2018 at the request of G20 members and is steered by a Board of Members.



World Health Organization

The WHO is committed to shaping the public health R&D priority setting agenda to combat antimicrobial resistance and will continue to review the preclinical and clinical antibacterial pipeline annually. In addition, WHO has expanded its pipeline analyses to include the antifungal pipeline and has conducted a bacterial vaccine pipeline review.

