

# Revitalizing the antibiotic pipeline by implementing new R&D pull incentives

With the 2024 UN High-Level Meeting on antimicrobial resistance (AMR) and its political declaration, together with the biennial AMR Ministerial Meeting, the world has set an ambitious agenda to tackle AMR.

The next four years offer renewed political momentum to deliver progress ahead of the next UN High-Level Meeting on AMR in 2029. A central priority is creating the necessary policy frameworks that stimulate R&D investment, reversing the long-standing antibiotic innovation drought. This is an issue that has received sustained attention at the G7 over the past decade, led most recently by the UK, Germany, Japan, Italy, and, in 2025, Canada.

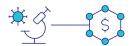
Alongside this political leadership, the global pharmaceutical industry is committed to playing a central role in addressing this challenge. As part of this, IFPMA launched the industry-led AMR Action Fund - a groundbreaking USD 1 billion initiative that aims to bring two to four new antibiotics to patients by 2030.

But such initiatives alone will not be enough. This paper describes the core challenges undermining antibiotic R&D and the solutions required to overcome them. Crucially, the urgency and importance of implementing sustainable, impactful R&D pull incentive models to support the pipeline of new antibiotics that patients and health systems need should not be underestimated. The industry stands ready to work with governments in advancing appropriate solutions and if we are successful, we can expect to see increased pharmaceutical R&D investment into all stages of antibiotic development, a stronger antibiotic pipeline, and new antibiotics that are available to patients that need them.

### **Executive summary**

Antimicrobial resistance represents one of the most pressing threats to global health, jeopardizing many of the advances in medical treatment that depend on the availability of effective and safe antibiotics.

Despite scientific advances, the antibiotic development pipeline remains alarmingly thin and is insufficient to keep up with the rising rates of resistance. Between 2017 and 2023, only 10 new antibiotics or combinations were approved globally, with just two classified as innovative by WHO. Most concerningly, the clinical pipeline is projected to decline further without urgent action. At its core, this issue is economic due to the necessity of restricting antibiotic use to preserve effectiveness, which creates a disconnect between the high costs of development and limited sales revenue, discouraging investment.



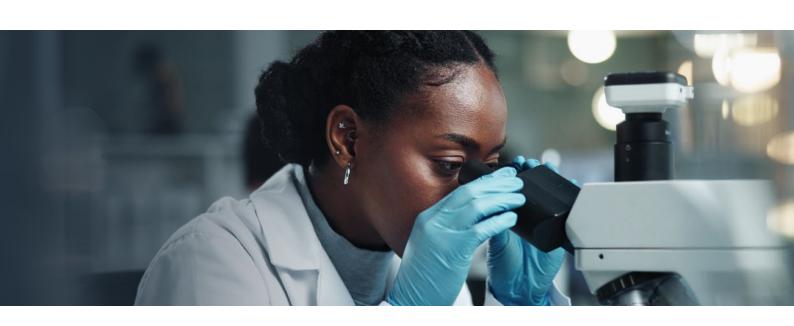
With existing market dynamics insufficient to drive antibiotic innovation, additional economic incentives are needed. There is general agreement among different stakeholders that this necessitates so-called "pull" incentives, designed to reward the successful development of new antibiotics.

To be sufficiently impactful, pull incentives must be globally aligned, with G7 countries and the EU contributing to the global total in proportion to their relative GDPs, and must be predictable and practicable. Pull incentives should be calibrated to an antibiotic's value in addressing unmet medical needs, encouraging innovation while supporting stewardship and preserving antibiotic effectiveness.



Urgent and coordinated action is needed to fully implement pull incentive models by 2029, when the 3rd UN High-Level Meeting on AMR is due to take place.

Leadership from the G7 and the EU will be critical in setting roadmaps and scaling solutions, while the G20 and other countries should join this collective effort by supporting global and regional action towards a healthy R&D ecosystem for antibiotics, and improved sustainable and appropriate utilization of all antibiotics.



#### Introduction



Antibiotic-resistant bacteria pose a major risk to global health security, patient outcomes, and modern healthcare in general. Close to 5 million deaths are associated with resistant bacterial infections each year, which includes 1.1 million directly attributable deaths. Between now and 2050, resistant infections could be directly responsible for more than 39 million deaths and contribute to 169 million deaths overall1, with annual healthcare costs potentially rising from USD 66 billion today to USD 159 billion<sup>2</sup>. Conversely, ensuring the availability of newly developed antibiotics to treat resistant infections could avert approximately one third of projected AMRattributable deaths1 and reduce annual healthcare costs by USD 83 billion by 2050, with the global economy almost USD 750 billion larger as a result2.

But the current antibiotic innovation landscape is unlikely to meet global patient needs. IFPMA research published in 2024 demonstrated that between 2017 and 2023, only 10 new antibiotics or combinations were approved by any stringent regulatory authority3, only two of which were classified as innovative by the WHO. And, despite their scientific and regulatory success, smaller companies behind seven of these antibiotics faced financial struggles leading to bankruptcy or distressed sales, with USD billions of losses to investors<sup>4,5</sup>. Ongoing supply chain costs, postapproval requirements, and the public health need to restrict use further strain an already fragile business model, leaving many new antibiotics only partially available in global markets, even among G7 and other high-income countries6.

Without immediate action to meaningfully incentivize R&D investment, the clinical pipeline is projected to decline further over the next decade. In our 2024 analysis, we presented modelling data and scenarios for how the pipeline could evolve over the next decade depending on whether effective new incentives are introduced. In the absence of these, new antibiotic approvals could become highly sparse after 2030, with only six antibiotics in development across phase II and phase III clinical trials combined in 2033<sup>3</sup>.

### What is the challenge?



New antibiotics are needed to address the rising burden of resistant infections worldwide. Beyond treating individual infections, antibiotics provide considerable value as insurance against the spread of drug-resistant infections and future resistance, can reduce opportunities for the emergence of multidrug resistance, and support the delivery of a wide range of medical procedures and care. For example, hospitalized cancer patients are up to twice as likely as other hospitalized patients to develop a resistant infection<sup>7</sup>.

However, the antimicrobial innovation ecosystem is considered broken by most international organizations, stakeholder groups, and experts. This is directly evidenced by an insufficient clinical pipeline – there are currently only eight antibiotics in phase III clinical trials that target WHO priority pathogens, of which only two are considered innovative<sup>8</sup>. This is not due to bad science or lack of innovative development ideas, as evidenced by the relatively healthier and more diverse preclinical pipeline for both traditional and non-traditional technologies aiming to address resistant infections<sup>9</sup>.

Most new antibiotics, once approved and incorporated into treatment guidelines, are classified by WHO as "Reserve" antibiotics, meaning they are intended for last-line use. This is for a good reason – their use is deliberately limited to preserve effectiveness. While "Reserve" antibiotics are a crucial foundation for safe and effective healthcare delivery, there is a significant disconnect between the investment required to develop and bring these to market, and the potential returns developers can achieve based on sales alone.

# Effective economic incentives are needed to spur antibiotic development

Stakeholders largely agree that both push and pull economic incentives are needed for a healthy antibiotic R&D ecosystem.

Push incentives help to de-risk early-stage investment into antibiotic research, provide companies with the necessary funding to begin development of their products, and play an important role in supporting continued, broad research activity. This is especially important as venture capital continues to dry up<sup>10</sup>.



Push incentives in the form of public-private partnerships and public funders like CARB-X, GARDP, BARDA, and others, have helped maintain a degree of preclinical research activity, and have also supported later stages of product development for a few molecules.

For example, CARB-X alone has funded more than 100 projects up to phase I clinical trials<sup>11</sup>. At the same time, the industry-led AMR Action Fund<sup>12</sup> has invested in 10 later-stage companies as of July 2025. The Fund has played a crucial role in supporting the continued development of promising assets, but it cannot address the fundamental market challenges.

While important, push incentives are collectively far below the scale needed to ensure a long-term, sustainable ecosystem that attracts increased at-risk investment throughout the development stages.

The greatest funding challenges lie in the later stages of clinical development. Moreover, only a handful of antibiotics that begin clinical trials will reach the market or patients, reflecting the risks of all pharmaceutical R&D. But in the case of antibiotics, even when these are approved and launched, ongoing post-approval costs13, coupled with the need to restrict their use to preserve effectiveness, make it difficult to achieve sustainable returns. Combined, these factors have resulted in significant investor reluctance to pursue antibiotic R&D investments as part of their portfolios. Between 2011 and 2020, only USD 100-200 million per year were invested, with only 12 antibacterial company IPOs compared to 109 for oncology companies in the US<sup>10</sup>. This lack of investment leads to limited R&D efforts, and thus an ongoing loss of active AMR R&D professionals14, resulting in a vicious circle. If this trend continues, it will hinder our capacity to deliver the new antibiotics the world needs.



There is consensus among G7 and other governments that pull incentives are needed to address this gap, yet progress in implementation has lagged behind push incentives significantly.

Considerable effort has already been invested in describing effective pull incentive models and they must be advanced urgently if we are to stimulate the necessary R&D investment and thereby establish an overall healthy antibiotic R&D ecosystem.

Pull incentives complement, but fundamentally differ from push incentives in that they:



are de-risked from the government's perspective as they only apply to products that are developed successfully, that is, upon achieving regulatory approval, as opposed to research grants and other push incentives, which will often result in failure,



provide a sustainable, predictable return on R&D investment outside the volume of sales, at a level that can incentivize re-investment in R&D and is based on an antibiotic's value in addressing unmet medical and societal need.



directly support antibiotic market sustainability and the availability of new antibiotics.

Years of research by experts building on one another and improving key assumptions that reflect the realities of the innovation ecosystem have established a value of USD 4.2 billion (2019 USD)\* for an effective pull incentive at the global level (for a fully decoupled, end-to-end 10-year subscription model). The most common assumption to achieve this global value is based on proportional contributions by G7 countries and the EU. This "fair sharing" principle<sup>17</sup> reflects those countries' leadership in biomedical innovation and efforts in combatting AMR.

Research shows government investment in pull incentives delivers significant returns that increase with longer time horizons – on average, a 5-fold return over 10 years for the G7 and EU, and a 20-fold return over 30 years<sup>18</sup>. Another study found that a combined set of AMR interventions which includes increasing innovation, could yield a 28-fold return across macroeconomic benefits, GDP-based health value, and reduction in health costs<sup>2</sup>.

To date, several different pull incentive models have been proposed. The industry is agnostic on which models or their combinations" are employed in different markets, provided that they can be implemented at sufficient scale and deliver the required impact. However, based on experience and discussions to date, the following models appear most likely to achieve that:



### Subscription models or revenue guarantees:

In the case of a subscription model, the payor commits to paying an annual fee to the company in exchange for the supply of the volume of antibiotic needed to meet the country's public health need. With a revenue guarantee, the company receives a top-up payment, which corresponds to the revenue gap between the agreed annual antibiotic public health value, and actual sales revenue.



### Transferable exclusivity vouchers (TEV):

Upon antibiotic regulatory approval, the developer receives a voucher that can be used to extend exclusivity of another product in their portfolio or that can be sold to another entity to do the same.



### Lump-sum market entry rewards (MER):

The payor provides a one-off payment to the developer upon antibiotic regulatory approval.

<sup>\*</sup> The 2019 aspect of the incentive value is an important consideration. For example, the article 15 also presents an alternative scenario with an average subscription pull incentive value of USD 3.1 billion for a developer that acquires a Phase II-ready asset (at USD 500 million), which was adjusted for inflation to USD 3.6 billion in a recent publication 18.

<sup>\*\*</sup> TEV and MER can be complemented by subscription models or revenue guarantees to support sustainable antibiotic launches and market availability, which would also count towards the total incentive size.

# How should pull incentives be designed to support antibiotic development?

Drawing on existing academic literature, policy reports, and discussions in various markets and in the multilateral fora, we believe pull incentives should be designed and implemented according to a set of core principles to deliver the necessary impact.

Countries should also learn from each other's experiences, in support of both timely implementation and cross-border alignment.

	centive ciple*	What is needed at the global level?
Effe	ctive	<ul> <li>Models in individual markets need to collectively add to sufficient value globally, with the understanding that incentive size will vary based on individual product characteristics</li> <li>This value needs to be significant enough to provide a return on investment at a level that can incentivize further investment into antibiotic R&amp;D across development stages</li> </ul>
Арр	ropriate	<ul> <li>Clear eligibility criteria that can apply to a diverse range of potential future products</li> <li>Robust antibiotic valuation frameworks with suitable evidence requirements across incentive tiers</li> <li>Decoupled from the volume of sales to help preserve antibiotic effectiveness</li> </ul>
Pred	dictable	<ul> <li>Incentive models and the accompanying valuation criteria need to be clear and predictable, and sustained during long research &amp; development cycles</li> <li>Assessment for incentive eligibility and value, and commitment to pay, should take place early enough in clinical development – contingent on successful regulatory approval – to support private investment throughout resource intensive stages</li> <li>Subscription model and revenue guarantee contracts should be designed so that they provide a predictable return on R&amp;D investment over a longer period</li> </ul>
Prac	cticable	<ul> <li>Due to the urgency of the challenge, countries or regions should prioritize models that can be implemented rapidly. This could include prioritizing models that can work within current health systems and other relevant structures, or that require the least structural change to implement</li> </ul>
Glod	bally ned	<ul> <li>While national priorities may vary, eligibility criteria should be aligned across individual country incentive programs in order to collectively reach globally effective incentive levels</li> <li>Initial prioritization criteria could draw on established global priorities such as the WHO Bacterial Priority Pathogen List, or regional priorities such as the US CDC Antibiotic Resistance Threats</li> </ul>
Fair shar	-	<ul> <li>The G7 and the EU should contribute to the pull incentive target proportionally, based on their relative GDPs</li> <li>Additionally, other countries should explore how they can contribute their own market-based solutions<sup>19,20</sup></li> </ul>

<sup>\*</sup> Depending on the region or country, these principles may need to be adapted to specifics, or additional considerations brought in.

Pull incentives can have built-in mechanisms to recognize differences in antibiotic values; for example, the UK model includes a 4-fold difference in size between the lowest and the highest incentive bands<sup>21</sup>. In general, less differentiated products that answer a less critical unmet need may receive an incentive below the average value, whereas highly differentiated products that lead to more significant improvement in overall treatment capabilities and patient outcomes should receive an above-average reward. A high ceiling will encourage investors and developers to aim for more ambitious product characteristics, while payments significantly below the average value will be insufficient to drive at-risk investment into new product development.

# How do we continue making progress from here?



We call for urgent action to ensure full, effective implementation of pull incentive models that will lead to a stronger antibiotic market globally by 2029, the year of the 3rd UN-High Level Meeting on AMR.

### We call on the G7 countries and the EU:

- To continue prioritizing antibiotic R&D pull incentives and by 2029, fully implement a package aligned with best practices exemplified and tested by several leading countries, and in accordance with the established global-level fair share. To achieve this, we recommend that:
  - Countries build an actionable roadmap towards full implementation by 2029, with annual reporting of progress, such as at an accompanying dedicated AMR session at the G7 Health and Finance Ministerial meetings.
  - Countries advance pilot programs to permanent and full-scale solutions.
  - Countries that have yet to initiate tangible action do so without further delay, engaging the support of industry and other governments in building on learnings from other markets.
  - Countries employ a cross-sector collaborative engagement strategy regarding pull incentive implementation including policymakers, AMR thought leaders, payors and industry.
- For G7 presidencies between now and 2029, to ensure strong positioning of AMR within health and finance ministerial agendas, with host countries committing to actionable steps domestically, starting with Canada in 2025.

## We call on the G20 and all other countries globally:

- To join the coalition of the willing and explore models based on their individual country situation that will both contribute to a healthier antibiotic R&D ecosystem and support incountry antibiotic availability and access.
   Where appropriate, countries should also work towards a common regional solution such as by EU Member States supporting a meaningful pull incentive at the EU level.
- To take supportive action nationally that will contribute towards a healthy antimicrobial market and facilitate product launches.
   This includes regulatory harmonization and reliance, appropriate procurement/ reimbursement systems, and surveillance
   demand forecasting, also in the context of progressing sustainable access models in lower income settings.

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From resistance to resilience: what could the future antibiotic pipeline look like?







Sustainable access to effective antibiotics







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