



AMR'S ECONOMIC IMPLICATIONS FOR AUSTRALIA AND GLOBALLY: A REVIEW OF RECENT PIVOTAL INITIATIVES



This summary explores how antimicrobial resistance (AMR) is framed within **Health Technology Assessment (HTA)** frameworks worldwide and Australia's unique role in HTA reviews. It examines the pressing **market failures hindering AMR investment** and emphasises the pivotal economic **role of vaccines** in combatting AMR.

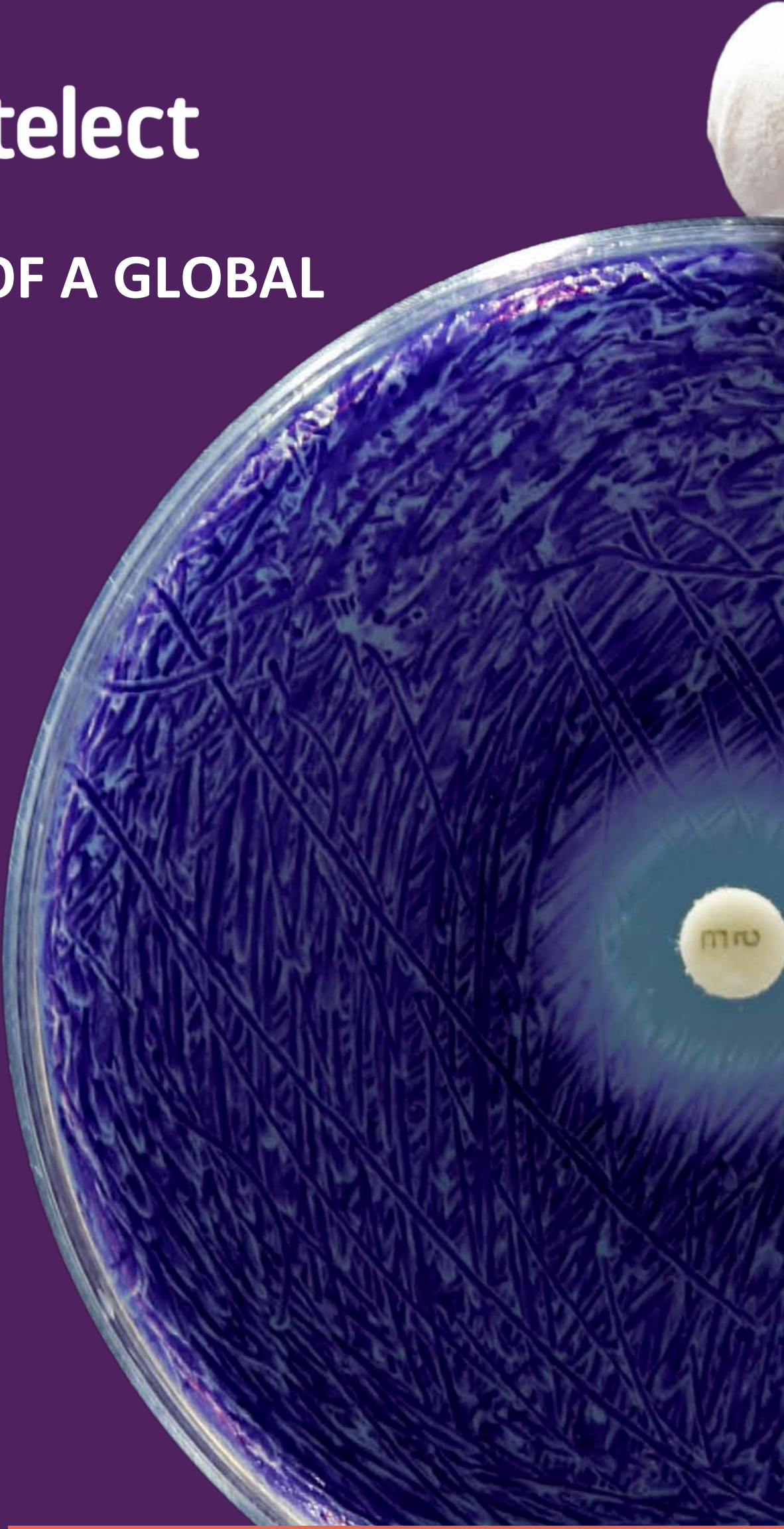
Key points from the **Political Declaration on AMR**, endorsed at the **United Nations General Assembly (UNGA)** in September 2024, are discussed, alongside **country-specific initiatives** designed at mitigating AMR, including **Australia's recent Health Technology Assessment (HTA)** review. This paper also spotlights **Biointelligence's expertise in bringing innovative AMR solutions to the market** and the impact of efforts such as the inaugural **Australian Vaccine Value Chain Conference (AVVCC)** on reshaping vaccine and antimicrobial development, valuation, and accessibility.



THE WICKED PROBLEM OF A GLOBAL HEALTH EMERGENCY

AMR is one of the most critical but underfunded global health threats of our time. Despite its urgency, AMR continues to struggle for attention and investment. This situation creates a paradox: overuse of antibiotics drives resistance, while countless people die from inadequate access to these life-saving medicines. Recent efforts, such as, the United Nations General Assembly (UNGA) High-Level Meeting on AMR and Australia's Health Technology Assessment (HTA) review, and the first Australia Vaccine Value Chain Conference (AVVCC) and others are advancing discussions on new initiatives, incentives and sustainable access solutions to combat AMR effectively.

Antibiotics may be the biggest success story in the history of medicine. Since Alexander Fleming's discovery of penicillin, many other drugs like it have been developed, making once-deadly infections curable. There are many situations that can expose you to an infection by opportunistic bacteria. From a minor paper cut to a surgical procedure, we rely on antibiotics to manage the infection risk. But every new antibiotic brings an expiration date, as bacteria inevitably mutate and start to develop resistance to these medicines.



"On average resistance is reported to most new antibiotic agents within 2 to 3 years post-market entry."

WHO 2022 [1]



THE CRITICAL ROLE OF VACCINES IN THE FIGHT AGAINST AMR

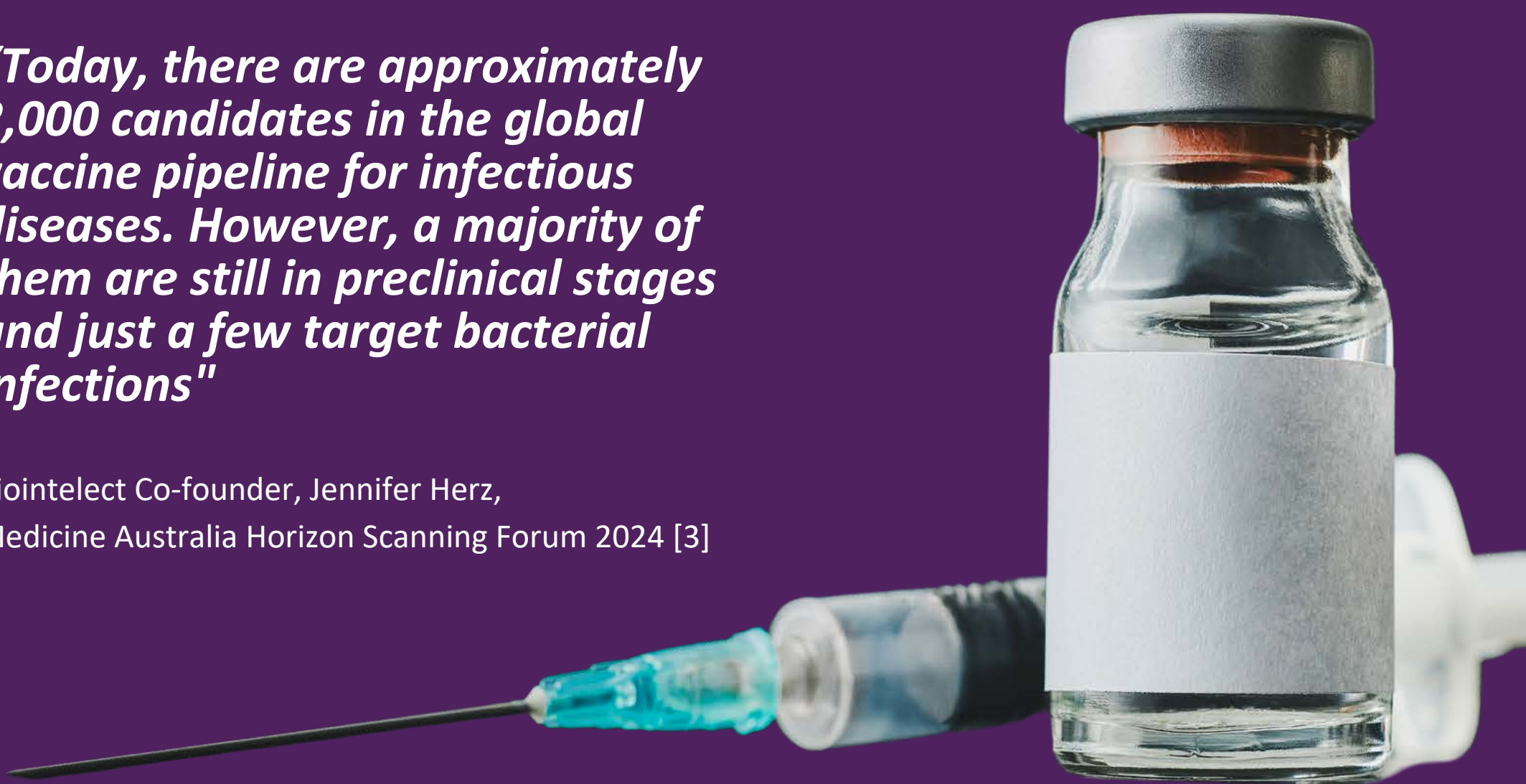
In addition, the important role of vaccines in reducing AMR has gained traction due to their preventive capabilities. By stopping infections before they occur, vaccines substantially reduce the need for antibiotics and antifungals, thereby slowing the emergence of resistant pathogens and preserving the efficacy of existing treatments. This dual impact—preventing infections and reducing antibiotic dependency—establishes vaccines as one of the cornerstones in the fight against AMR.

A recent report by WHO outlined that the better use of current vaccines against the 23 pathogens (except gonorrhoea) by countries could reduce antibiotic use by 2.5 billion doses annually [2]. However, it is worth noting that fewer than 20% of industry-sponsored vaccines currently in clinical trials target bacterial infections [3].

Collaborative initiatives, such as the AVVCC led by Biointelect, further amplify this effort by gathering global expertise to drive innovation and accessibility in vaccine development for AMR prevention.

“Today, there are approximately 2,000 candidates in the global vaccine pipeline for infectious diseases. However, a majority of them are still in preclinical stages and just a few target bacterial infections”

Biointelect Co-founder, Jennifer Herz,
Medicine Australia Horizon Scanning Forum 2024 [3]





WHY AREN'T WE SEEING PROGRESS?

Worldwide drug-resistant infections claimed over 1.3 million lives in 2019 alone [4], the economic toll is projected to reach between USD \$1 trillion and USD \$3.4 trillion in gross domestic product (GDP) losses annually by 2030 [5]. Yet, in response to this growing crisis, only 12 new antimicrobial drugs were released globally between 2017 and 2021, and a further 27 drugs are in development to target the WHO's list of "critical" pathogens. Of those approved, only six have innovative potential to tackle antibiotic resistance, and just two target the most highly drug-resistant strains [6]. None of these new drugs are available or have been marketed in Australia today.

This highlights a misalignment between public health needs and the economic realities of drug development. The antibiotic business model of short-term and emergency use clashes with traditional pharmaceutical revenue structures that are based on high-volume sales. For AMR, however, preserving antibiotic effectiveness requires reduced use, careful stewardship, and targeted application, creating a low-demand environment that undermines revenue potential. This leaves pharmaceutical companies with limited financial incentives to recoup R&D costs through standard pricing and reimbursement methods. Additionally, novel antimicrobials in Australia are often perceived as undervalued due to the availability of low-cost generics and the use of the lowest-cost comparator reference pricing policy, further hindering a company's ability to achieve a viable commercial return.



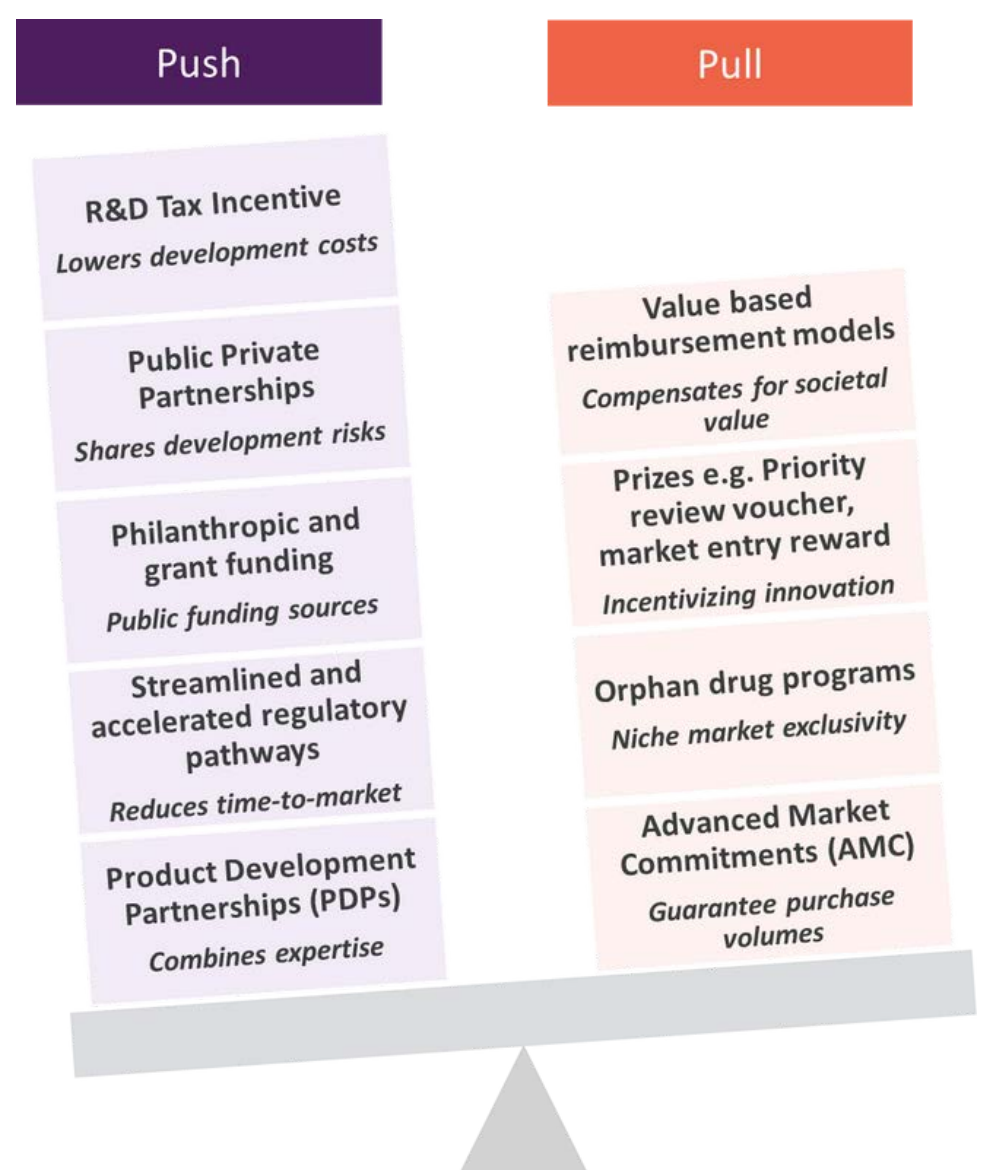
A CHALLENGE COMPOUNDED BY HTA FRAMEWORKS

Medicines Australia’s second Horizon Scanning Forum (March 2024) underscored the need for HTA reform to address not only future therapies but also those currently emerging, ensuring patients have faster access to the best available treatments [2].

HTA frameworks are central to how treatments are evaluated, priced, and reimbursed. Traditional HTA models primarily assess a drug’s direct impact on individual patient outcomes, overlooking broader public health benefits, like infection prevention and health system resilience. This narrow view can undervalue antibiotics, which not only treat infections but also protect patients undergoing surgery, cancer treatments and organ transplants, and help prevent disease outbreaks. Without a complete assessment of their societal value, antibiotics face inadequate investment, leading major pharmaceutical companies to abandon development.

To address the economic challenges, a combination of push and pull incentives is essential (Figure 1). Push incentives, like R&D tax credits, public-private partnerships, philanthropic funding, and streamlined development pathways, help reduce upfront R&D costs, allowing companies to innovate without bearing the full financial burden. On the other side, pull incentives reward successful market entry and innovation through mechanisms like value-based reimbursement models, priority review vouchers, orphan drug programs, and advanced market commitments (AMCs). Together, these incentives aim to sustain a pipeline that supports early-stage development and rewards products that reach the market.

Figure 1
Summary of key push and pull factors influencing the economic challenges for the development of AMR targets





GLOBAL AMR MOMENTUM: AMBITIOUS GOALS AND INTERNATIONAL INCENTIVES

The COVID-19 pandemic has re-emphasised that infectious diseases do not respect national borders, and there is renewed debate on the urgency of AMR being recognised at the highest levels. At the 2024 UNGA High-Level Meeting on AMR, world leaders committed to reducing the estimated 4.95 million AMR-related deaths annually by 10% by 2030 [7]. This commitment reflects a growing international consensus on the need for decisive actions to address this public health threat.

Achieving this goal requires innovative financial and regulatory models to align economic incentives with public health needs while ensuring sustainable supply of effective antimicrobials while mitigating risks of resistance through responsible stewardship.

Building on the UNGA's Political Declaration, the World Innovation Summit for Health (WISH) made further recommendations to tackle AMR [8], including:

- By 2027, high-income countries should commit to only prescribing antibiotics (with a few defined exceptions) when need is confirmed by a diagnostic test. Low- and middle-income countries should achieve this by 2030. *[Recommendation 4]*
- By 2026, all high-income countries should have introduced pull incentives for the development of new antimicrobials, to deliver on global antibiotic priorities. *[Recommendation 5]*



In the United States, the PASTEUR Act represents a significant step forward in addressing the economic misalignment in antibiotic R&D. Through a subscription-style model, the Act guarantees pharmaceutical companies an upfront payment for access to new antibiotics, reducing the need for high sales volumes that can encourage overuse. This approach provides a predictable income stream while maintaining stewardship, as companies are incentivized to innovate without being driven by volume-based revenue [9].



Germany has taken a different approach by focusing on reimbursement incentives through its statutory health insurance system. German regulations allow antibiotics that treat WHO-designated priority pathogens to receive a “reserve antibiotic” status, qualifying them for accelerated reimbursement processes and removing the requirement to prove additional benefits over existing therapies through the Act on Fair Competition among Statutory Health Insurance Funds (GKV-FKG). This streamlines the path to market, ensuring essential antibiotics are available without additional regulatory burdens [9].



The United Kingdom has implemented a similar approach with its “Netflix-style” subscription model, which delinks antibiotic payments from usage volume. The UK’s pilot project guarantees annual payments for selected antibiotics, creating stable revenue for manufacturers regardless of sales [9]. This model is paired with an antimicrobial-specific HTA process and the STEDI framework (Spectrum, Transmission, Enablement, Diversity, and Insurance Value), which evaluates antibiotics based on their broader societal value, including infection prevention and health system resilience [10].



In Sweden, the partially delinked payment model piloted by the Public Health Agency of Sweden (PHAS) provides a hybrid approach, combining both national and regional funding. Four companies receive guaranteed revenue for antibiotics over a two-year period, with an optional two-year extension. If sales exceed a specified threshold, the companies receive an additional 10% of guaranteed compensation, which balances incentives for availability and responsible usage [9].



THE PATH FORWARD FOR AUSTRALIA

The current HTA system is not fully equipped to capture the societal and public health value of antibiotics, which play a critical role in safeguarding health infrastructure and preventing infections in various medical contexts. To close this gap, Australia's recent HTA review has proposed several specific changes that aim to realign economic incentives and improve antibiotic access.

1

Exempt HTA Fees for Priority Antibiotics

The review recommends waiving HTA fees for antibiotics that target WHO-listed priority pathogens or address critical public health risks in Australia. This exemption would lower entry costs for essential antibiotics, helping companies introduce these drugs to the Australian market without the burden of high upfront fees.

2

Specialised HTA Framework for Antibiotics

A tailored HTA pathway for antibiotics is proposed, recognizing their unique public health value. This framework would account for broader societal benefits, ensuring antibiotics are assessed based on their role in infection prevention and health system resilience, making antibiotic development more attractive for companies.

3

Flexible Reimbursement Models

The review suggests introducing reimbursement policies that delink revenue from sales volume, such as advanced market commitments and guaranteed supply agreements. These models would provide revenue stability for developers, reducing financial risk and ensuring that essential antibiotics remain accessible without relying on high sales volumes.

4

Pilot Subscription Fund for Novel Antibiotics

Inspired by the UK's subscription model, a pilot fund in Australia would offer fixed payments to companies developing novel antibiotics. This approach would create predictable income, making antibiotic R&D financially viable even with low usage, while ensuring critical drugs are available when needed.

5

National Coordination and Alignment with Global Strategies

Australia's HTA reforms aim to align with both national frameworks, like the PBS, and global AMR strategies. Coordinating efforts across various levels of government and with international initiatives would strengthen Australia's response to AMR and foster international collaboration.

6

Data Collection and Economic Modelling:

Data from pilot programs would inform economic models that reflect the true, long-term value of antibiotics. This evidence-based approach allows for continuous refinement of HTA and reimbursement structures, ensuring they adapt effectively to the evolving AMR landscape.

 **GLOBAL AMR MOMENTUM:
AMBITIOUS GOALS AND
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“A new reimbursement model which delinks the value of an antimicrobial from the volume used in the health system is essential to enable [pharmaceutical companies] to launch novel antimicrobials in Australia.”

Dr. Scott Preiss, Medical Affairs Director of Vaccines, GSK

The global rise of AMR highlights the urgent need to address the development and access crisis for new antimicrobials. The Australian Department of Health and Aged Care (DoHAC) has already begun work on identifying potential funding mechanisms and economic models to incentivise availability of antimicrobial products. However, the Review acknowledges that significant additional resources and work will be required to design and implement these recommendations effectively.

A key challenge lies in adapting international best practices to Australia's unique healthcare context. For example, while the UK's “Netflix-style” model offers insights, Australia’s different funding structure e.g., Pharmaceutical Benefits Scheme (PBS), and specific AMR patterns requiring a tailored approach. The Review emphasises that any new payment and reimbursement reforms must align with Commonwealth, and State and Territory funding structures while remaining consistent with global strategies.

The Review's recommendations set a clear path forward for Australia's approach to AMR. Success will require sustained commitment from government, industry, and healthcare providers. The proposed pilot subscription fund will provide valuable data to refine and improve funding mechanisms, while the new HTA framework will ensure more appropriate evaluation of antimicrobial value.

 CLOSING THOUGHTS

The fight against AMR represents one of the most pressing public health challenges of our time.

Achieving success requires a multi-pronged approach and a fundamental shift in how we value, assess, and fund not only antimicrobials but also the prevention of infectious diseases, ensuring timely access to both breakthrough medicines and vaccines.

Australia's HTA Review represents a significant step forward in addressing the global AMR crisis. The innovations in HTA frameworks and funding models being pioneered by countries like the UK offer promising insights, but their success will depend on sustained commitment and international cooperation.

However, success in addressing AMR requires sustained commitment, strategic investment, and international collaboration. The recent global and national reforms in HTA system and initiatives in driving vaccine-based solutions, show that progress is possible. The path forward involves a collective, coordinated effort to ensure that the tools needed to combat AMR—both antibiotics and vaccines—are accessible, effective, and valued appropriately within our healthcare systems. Only through such collaboration can we hope to turn the tide against AMR and secure a healthier future for all.





HOW CAN WE HELP?

At Biointellect, we ensure you navigate the right path to market for new health technologies, combining industry-leading commercialisation consulting with deep expertise at every stage of the development pathway.

Biointellect hands-on experience in infectious diseases, bringing vaccines and therapeutics to market. We understand the unique challenges and the critical importance of innovations that address pressing global health threats, like antimicrobial resistance (AMR). Our strong networks, along with a deep understanding of AMR, Health Technology Assessment (HTA), and policy perspectives, ensure that your product is positioned for success in the complex regulatory and commercial landscape.

Whether you're developing vaccines, therapeutics, or other innovative solutions, our comprehensive services cover all aspects of the value chain. From development to market access, we work with you every step of the way to ensure your innovation achieves its full potential.

Contact us to speak to our experts and how we can support your AMR solutions.

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