FIGHTING SUPERBUGS

Ensuring Australia is ready to combat the rise of drug-resistant infections.

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MTP Connect

AAMRNet
Australian Antimicrobial Resistance Network

CONTENTS

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Report by evohealth

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FOREWORD

Stuart Dignam

Antimicrobial resistance (AMR) is one of the greatest threats to human life we face. It has been referred to as a silent pandemic and has gone largely unnoticed. It is no longer silent.

This superbug pandemic is set to dwarf COVID-19. In 2019 AMR directly killed 1.27 million people and was linked to almost 5 million deaths. That's roughly equivalent to one jumbo jet crashing every two and a half hours for an entire year. These deaths are preventable. Left unchecked, AMR could take 10 million lives per year and put at risk US$100 trillion of economic output if no action is taken by 2050. The impact on the Australian economy alone in the same timeframe would be AU$142-AU$283 billion.

AMR disproportionately impacts our most vulnerable, with the burden far higher in low- and middle-income countries, women, children, and people with underlying medical conditions such as diabetes.

Effective antibiotics underpin modern medicine, making AMR a critical and urgent threat to our entire health system. Yet we are sleepwalking our way in this pandemic. Very little has been done to stimulate research and development (R&D) and support access to new lifesaving, and health system enabling antibiotics. It is time to move on from simply acknowledging the threat. Significant action is urgently needed to protect us from AMR.

In November 2021 the bipartisan Parliamentary Standing Committee on Health Aged Care and Sport delivered its report, *The New Frontier – Delivering better health for all Australians (The New Frontier Report).* The report speaks extensively of the threat posed by AMR and the unique challenges in developing much needed new antibiotics. It also outlined key recommendations for the Australian Government to take to support the R&D, translation, commercialisation and most importantly, access to new antimicrobials and related technologies. These recommendations align closely with global calls, in particular those from the G7.

MTPConnect, through its multi-stakeholder expert group for AMR, the Australian Antimicrobial Resistance Network (AAMRNet), commissioned Evohealth to develop this report to explore how Australia can deliver on key recommendations of *The New Frontier Report.*

Our report suggests sensible steps to help protect our future health security by ensuring we are ready to combat the rise of drug-resistant infections. It also explores how Australia can support our Pacific Family by ensuring they have equitable access to new antimicrobials.

Australia has a significant opportunity to be a regional, and indeed global leader in the fight against this real and urgent threat to our way of life. We need to act. Now. We can no longer afford to wait.

Stuart Dignam

MTPConnect Chief Executive Officer and
co chair Australian Antimicrobial Resistance Network

EXECUTIVE SUMMARY

Antimicrobial resistance (AMR) is a global health emergency, recognised by the World Health Organization (WHO) as one of the top ten public health threats facing humanity[1]. Occurring when microbes such as bacteria, viruses, fungi or parasites become unresponsive to medicines that once killed them, AMR is a significant threat to human, animal and environmental health[1]. On our current trajectory, an estimated **10 million people globally** will die each year by 2050 from infections that can be readily treated today[2,3]. Without significant reform, devastating health and economic impacts will be seen within a generation.

Antimicrobial infections are becoming harder to treat...

Antibiotics are a cornerstone of modern medicine. They have made life-threatening infections treatable, chemotherapy and organ transplants possible, surgical procedures safer and significantly reduced the burden of infectious diseases. Yet, after decades of inappropriate use, the world is now facing a health emergency. Poor antimicrobial stewardship (AMS) (that is, efforts to conserve the use of antibiotics for those instances in which they are clearly indicated) has accelerated the development of drug resistance – it now takes just **two to three years** for new antimicrobial medicines to become ineffective against drug-resistant pathogens[4]. Over **5,200 Australians die from AMR-associated causes each year** and this number is only set to increase as the threat of AMR grows over the coming years[5].

...and the pipeline of novel antimicrobials is drying up

Worryingly, the innovation pipeline for the development of new antibiotics (and other novel antimicrobial medicines) is stagnating. There is an inherent market failure that is actively disincentivising research and development (R&D) of new antimicrobial medicines. This is one of the most prominent and significant factors underlying this escalating threat.

By their nature, antimicrobial medicines are designed for short-term and occasional use in response to acute infection, in contrast to chronic disease medications that can require lifetime use[6]. In addition, novel antibiotics are generally held in reserve so they can be used when drug-resistant infections occur[7]. This results in low sales volumes for antimicrobial medicines and poor commercial returns for pharmaceutical companies and drug developers. Consequently, there has been a steady decline in the number of companies developing novel antimicrobials in the last three decades. In fact, 15 of the 18 largest pharmaceutical companies have discontinued antibiotic R&D in the last 30 years[6, 8].

> *15 of the 18 largest pharmaceutical companies have discontinued antibiotic R&D in the last 30 years[6, 8].*

A two-pronged approach to funding reform is urgently needed

The market failure inhibiting the development of novel antimicrobials will not be solved overnight, nor will it be addressed with a single solution. There is growing recognition around the globe that a complementary and coordinated suite of actions is needed to transform the way we fund antimicrobial medicines. **Push incentives** (e.g. grants, subsidies and tax incentives) that fund R&D to enable the discovery and commercialisation of new medicines and technologies are necessary, but alone will not be sufficient to address the market failure for novel antimicrobials[9, 10]. **Pull incentives** that create and sustain an attractive antimicrobials market will also be needed to create a genuine value proposition for companies to re-invest in the development of antimicrobial medicines[9, 10].

Pull incentives can include the 'delinking' of commercial returns from sales volumes. Delinked models including subscription models are rapidly gaining global momentum. Subscription models have been piloted in the United Kingdom and Sweden[6, 11] and are being considered for legislative reform in the United States[12]. These models pay a fixed annual fee to drug developers for a guaranteed supply of novel antimicrobials, irrespective of utilisation in clinical practice. Alongside other pull incentives, these are showing great promise as a tangible solution to reform the market for novel antimicrobials. However, their success for combating AMR will require global alignment and coordination: with the possible exception of the United States, no country alone has the buying power to sufficiently transform the investment landscape for novel antimicrobials[4].

The need to reform funding

The Australian Parliament's Standing Committee on Health, Aged Care and Sport published a comprehensive report, *The New Frontier Report*, in 2021 that challenges current approval processes for new drugs and novel medical technologies. It includes a recommended targeted action to address the growing threat of AMR. The report calls for funding and regulatory change to support early stage and pre-commercial development of antimicrobial drugs and medical technologies, the implementation of a pilot scheme for value-based payments for new antimicrobial drugs and promotion of existing R&D initiatives to support the innovation pipeline[3].

Addressing the threat of AMR will require the development of **15 new antibiotics in the next 10 years**, with at least four targeting priority pathogens identified by the WHO[4]. With an average 10-to-15-year lead time for novel antimicrobials to make it from the laboratory bench to a patient, timeliness is critical. Government and key stakeholders must demonstrate leadership and a commitment to global public health in reforming the regulatory and funding landscape for novel antimicrobial medicines.

The time to act is now

The threat of AMR looms large. Urgent and affirmative action is needed. Without transformational system changes to enhance the availability of new antibiotics and other novel antimicrobial medicines, Australia faces a swathe of devastating impacts to human, animal and environmental health within a generation.

Recommendations

This independent report presents nine evidence-based recommendations that will equip the Australian healthcare system to prepare to fight the silent pandemic of drug-resistant infections, in line with the developments being seen at a global level.

These recommendations are informed by a comprehensive review of the academic and grey literature; interviews with Australian and global subject matter experts across industry, government and healthcare; and the contributions of an expert project steering committee. The recommendations closely align with seminal reports and expert voices in the AMR landscape both domestically and globally.

RECOMMENDATIONS

1. Pilot a subscription model in Australia for two novel antimicrobials.
2. Strengthen existing, and introduce additional, flexible data exclusivity extension options for novel antimicrobials in Australia.
3. Increase the quantum of AMR research funding in Australia.
4. Establish and appropriately fund an Australian AMR accelerator, as well as contribute to and leverage global initiatives such as CARB-X.
5. Continue to promote R&D investment in Australia, including through raising awareness of the Clinical Trial Notification (CTN) scheme and R&D Tax Incentive.
6. Provide accelerated pathways and reduce barriers for the regulatory approval of novel antimicrobials in Australia.
7. Develop fit-for-purpose HTA pathways for antimicrobial medicines as part of the HTA Review currently underway.
8. Identify AMR as Australia's 11th National Health Priority Area.
9. Encourage uptake of timely point-of-care testing for antimicrobial infections.

THE ISSUES AT A GLANCE

2-3 years
for drug-resistance to develop against new antimicrobials[13]

5,200
deaths in Australia are associated with AMR each year[5]

By 2050,
10,000 Australians
will die each year from drug-resistant infections[2, 3]

AU$1.5-3b
and **10-15 years**
to develop a new antimicrobial[13, 7]

Only **12 new antibiotics**
have been introduced globally since 2017[13]

15 of the 18
largest pharmaceutical companies have withdrawn from antibiotic R&D[6, 8]

Of 77 antibiotics in development,
only 27
target priority pathogens[14]

To combat antimicrobial resistance,
15 new antibiotics
need to be developed over the next 10 years[4]

A **50%**
increase in resistance to first-line antimicrobials could see an increase of cost to the Australian Government of
AU$1.6b[15]

THE ESCALATING THREAT OF ANTIMICROBIAL RESISTANCE

Antimicrobials are a cornerstone of modern medicine

Antimicrobial medicines that kill or weaken disease-causing bacteria, viruses, fungi and parasites are a cornerstone of modern medicine. The advent of antimicrobial medicines has enabled surgical procedures to be performed safely, common infections such as pneumonia and urinary tract infections to be easily treated and rampant diseases such as typhoid and cholera to be eradicated. Antimicrobials have revolutionised the treatment of infections, saving countless lives and contributing to an increase in life expectancy by almost 23 years in many countries[16].

With the escalating threat of AMR many of these gains could be lost within a generation. The widespread uptake and overuse of antibiotics in both humans and animals over several decades has enabled bacteria to develop resistance to drugs that once killed them. When resistant strains circulate, patients and clinicians are faced with the grim reality of infections that are extremely difficult or impossible to treat[2].

LIFE BEFORE ANTIBIOTICS....

In the pre-antibiotics era, infectious diseases were responsible for high rates of morbidity and mortality around the world. The average life expectancy was 47 years old and infectious diseases such as smallpox, pneumonia and syphilis to name a few, were widespread[17]. Some examples include:

- Tuberculosis was considered a death sentence[18].
- *Streptococcus pneumonia* resulted in fatality rates of **40 per cent**[18, 19].
- Approximately **70 per cent** of wound infections resulted in amputations[19].
- **90 per cent** of children who were infected with bacterial meningitis died[20].

Antibiotics have revolutionised the treatment of infectious disease globally – more so in developed countries[17]. The ability to treat and cure infections with antibiotics has been at the cornerstone of modern medicine – enabling procedures such as bone marrow transplants, chemotherapy and joint replacements[19].

Drug-resistant infections present a serious threat to global health

The WHO recognises AMR as one of the top ten threats to public health. Without action, we are on a global trajectory for catastrophic consequences to humans, animals and the natural environment within decades[1]. Millions of lives are already being lost to drug-resistant infections. It is estimated that almost five million deaths were associated with bacterial AMR in 2019 alone[21]. By 2050, it is forecast that 10 million people globally will die from infections that were once treatable[22].

Resistance to antibiotics is emerging at a faster rate than ever. It now takes just two to three years for pathogens to develop resistance to new medicines[13].

The impacts of AMR are wide-ranging. Infections that are difficult or impossible to treat pose great threats to human health, including more frequent and longer-lasting infections, and more hospitalisations and deaths from infection[15]. There are also threats to animal health, with livestock and wildlife susceptible to more frequent and severe infections. When infections occur in food-producing animals, it can accelerate the spread of AMR in humans[23]. There is also strong evidence for the impact of AMR on the natural environment, including through the release of antimicrobial compounds into water and soil[24].

> *If we do not slow the rise of antimicrobial resistance, we will return to the dark ages of medicine where surgery becomes inherently risky and currently treatable infections and injuries kill once again.*
>
> – CSIRO[22]

Numerous families of drug-resistant bacteria are fuelling the rise of AMR around the world. Of note, the WHO has identified 12 'priority pathogens' that are resistant to existing medicines and pose the greatest threat to public health[25, 26].

WHO Priority Pathogens:

Critical priority

- *Acinetobacter baumannii,* carbapenem-resistant
- *Pseudomonas aeruginosa,* carbapenem-resistant
- *Enterobacteriaceae,* carbapenem-resistant, ESBL-producing

High priority

- *Enterococcus faecium,* vancomycin-resistant
- *Staphylococcus aureus,* methicillin-resistant, vancomycin-intermediate and resistant
- *Helicobacter pylori,* clarithromycin-resistant
- *Campylobacter spp.,* fluoroquinolone-resistant
- *Salmonellae,* fluoroquinolone-resistant
- *Neisseria gonorrhoeae,* cephalosporin-resistant, fluoroquinolone-resistant

Medium priority

- *Streptococcus pneumoniae,* penicillin-non-susceptible
- *Haemophilus influenzae,* ampicillin-resistant
- *Shigella spp.,* fluoroquinolone-resistant

Many of these priority pathogens circulate in Australian hospitals and the community, although levels of drug resistance vary. For example, while Australia has relatively low rates of resistance to fluoroquinolones, our rates of drug resistance to methicillin (*S. aureus*) and vancomycin (*E. faecium*) are high to very high compared to other countries[27] (Figure 1 p. 10).

The appropriate use of the right antibiotic for the right patient at the right time is critical to mitigating the threat of AMR. The causal role of antibiotic overuse in the development of drug-resistant infections is well documented. It has led to a plethora of critical AMS practices that have been implemented around the world to curb inappropriate use of antibiotics. For example, through the *Preventing and Controlling Infections Standard*, the Australian Commission on Safety and Quality in Health Care requires all health service organisations to have an AMS policy to support appropriate prescribing[28]. While AMS is necessary to slow the spread of drug resistance and preserve our current suite of antibiotics, it is not sufficient to curtail the significant loss of life or economic impacts forecast by 2050.

Even with the best stewardship practices, drug-resistant pathogens will continue to circulate, leaving patients susceptible to life-threatening infections.

Figure 1.

Resistance to vancomycin among Enterococcus faecium in Australia and Europe, 2014 (adapted from AURA, 2016)*

* *Enterococcus faecium* can be responsible for a number of infections including common infections such as endocarditis, urinary tract infections and cellulitis[27,29].

THE URGENT NEED FOR NEW ANTIMICROBIAL MEDICINES

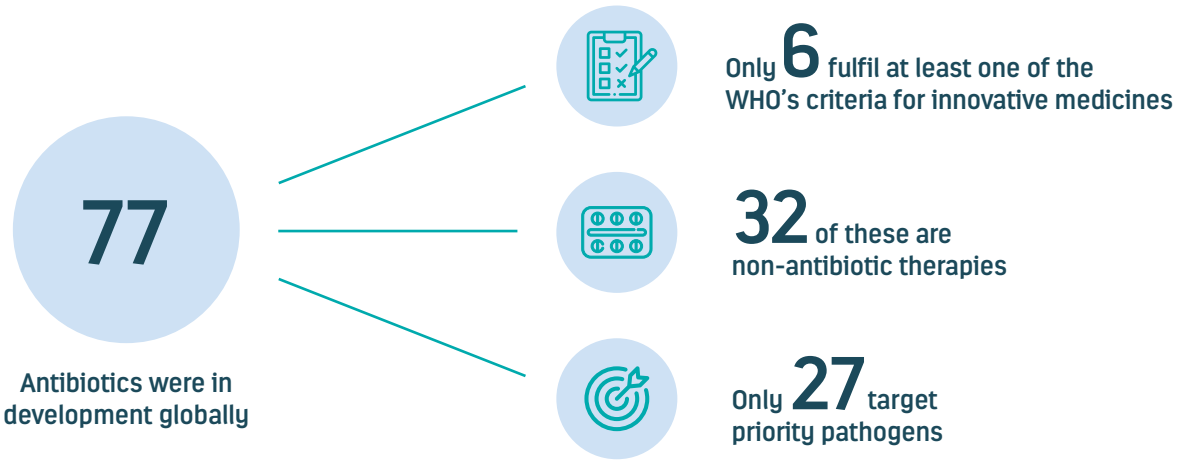
As the prevalence of drug-resistant infections rises, access to a steady supply of novel antimicrobial medicines that can effectively target and kill drug-resistant pathogens will be critical[8]. Although we historically have had a wide range of antibiotics available to Australian patients, the nature of AMR is such that many of these medicines are at risk of becoming ineffective or less effective should drug-resistant strains of common pathogens emerge[27]. Unless new antimicrobial therapies are developed and accessible, patient lives will be needlessly lost.

To mitigate the escalating threat of AMR, **15 novel antibiotics** will need to be developed and made available to patients within the next ten years[4]. Of these, at least **four antibiotics** will need to target the WHO priority pathogens[4]. And yet, there is a stagnating pipeline of novel antimicrobial medicines – signalled by the withdrawal of large pharmaceutical companies from antibiotic R&D, a dwindling pipeline of novel antimicrobial therapies in development and a limited focus on genuinely novel and innovative therapies[2, 6].

15 new antibiotics need to be developed within the next 10 years to combat AMR[4].

A market failure for antimicrobial innovation

According to the WHO, in 2019[13]:



One of the most important challenges in combating AMR is that the development of novel antimicrobial medicines is not keeping pace with public health needs. Over the last 30 years, few antibiotics have been developed that offer significant clinical benefits compared to existing medicines[8]. For example, no novel class of antibiotics has been brought to market since 1987[30]. This has coincided with declining industry activity: 15 of the 18 largest pharmaceutical companies having discontinued antibiotic R&D in the last 30 years[2, 8], and there has been a 35 per cent reduction in the number of antibiotic patents filed between 2007 and 2012 alone[14]. Unless this trend is reversed, thousands of Australians and millions of people globally remain at risk of dying from currently treatable infections.

No novel class of antibiotic has been brought to market in 35 years[30].

The commercial challenges of antimicrobial medicines

AU$1.5 to 3b
to develop a new antibiotic[7]

10-15 years
to identify, develop, test and market a new antibiotic[13]

Only 1 in 30 novel antimicrobial candidates in preclinical development are successfully commercialised[13]

Low sales volumes

Despite their immense public health importance, antimicrobials are not generally considered commercially attractive for investors. By their nature, antibiotics are designed for short-term and occasional use. In clinical practice, their use is constrained by AMS, with novel antibiotics held in reserve for drug-resistant infections[7]. The associated low sales volume, combined with the relatively low price paid, means pharmaceutical companies are often unable to recoup the costs of development[31]. For example in the US, after passing FDA approval, the antibiotic must earn US$300 million a year just to break even, however, industry records have shown that few antibiotics make even US$100 million per year[32]. The inadequate return on investment acts as a disincentive for pharmaceutical companies to invest in novel antimicrobials, particularly when compared with more profitable therapeutic areas such as oncology[2].

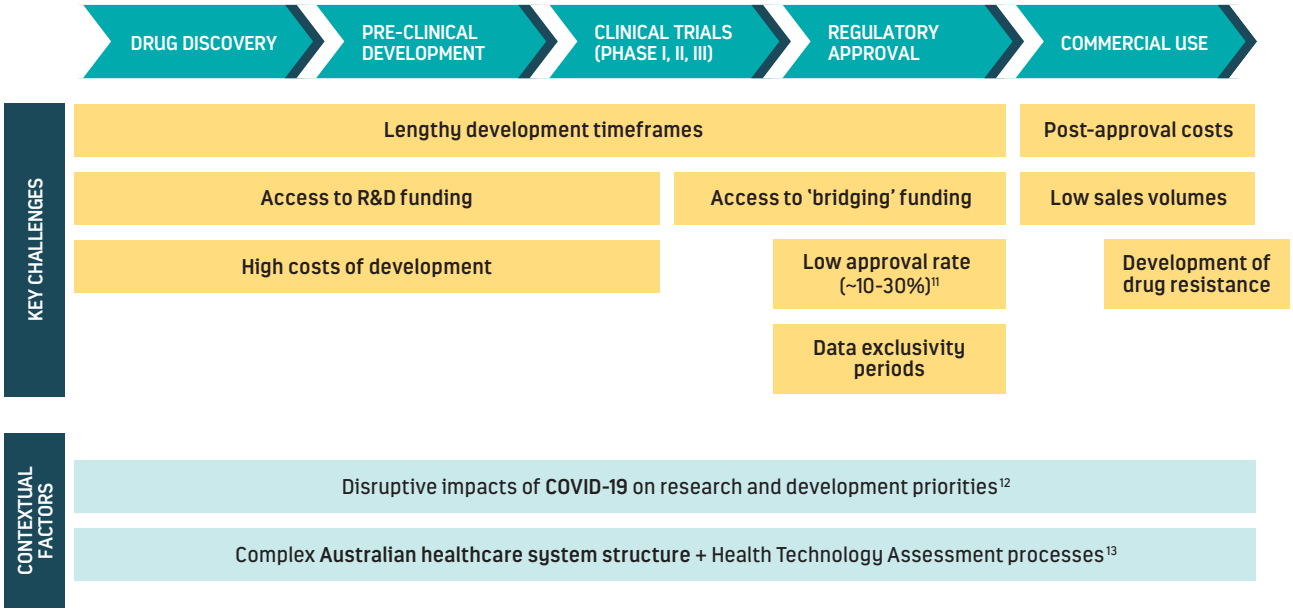
> *Market rewards for the development of new drugs for unmet medical needs such as new antimicrobials... can be insufficient to incentivise the needed R&D.*
>
> *– The New Frontier Report*[3].

High costs of R&D

Antibiotic R&D is a high cost endeavor, with AU$1.5 to AU$3 billion needed to bring a new product to market[7]. While this is similar to other pharmaceutical products the return on investment on antibiotics is much lower. The challenges of low sales volumes are compounded by the costs, failure rates, risk exposure and effort required at every stage of the R&D lifecycle (Figure 2).

Figure 2.

Challenges for novel antimicrobials across the R&D lifecycle



ADDRESSING THE MARKET FAILURE FOR NOVEL ANTIMICROBIALS

Novel medicines and technologies cannot be developed overnight. With a 10 to 15 year lead time to bring a new antibiotic to market and a stagnating innovation pipeline, it is essential to urgently invest in novel therapies to address the threat of growing AMR[7]. Addressing the market failure for the development of novel antimicrobials needs to be treated as a matter of national and global urgency.

TWO APPROACHES TO FUNDING REFORM

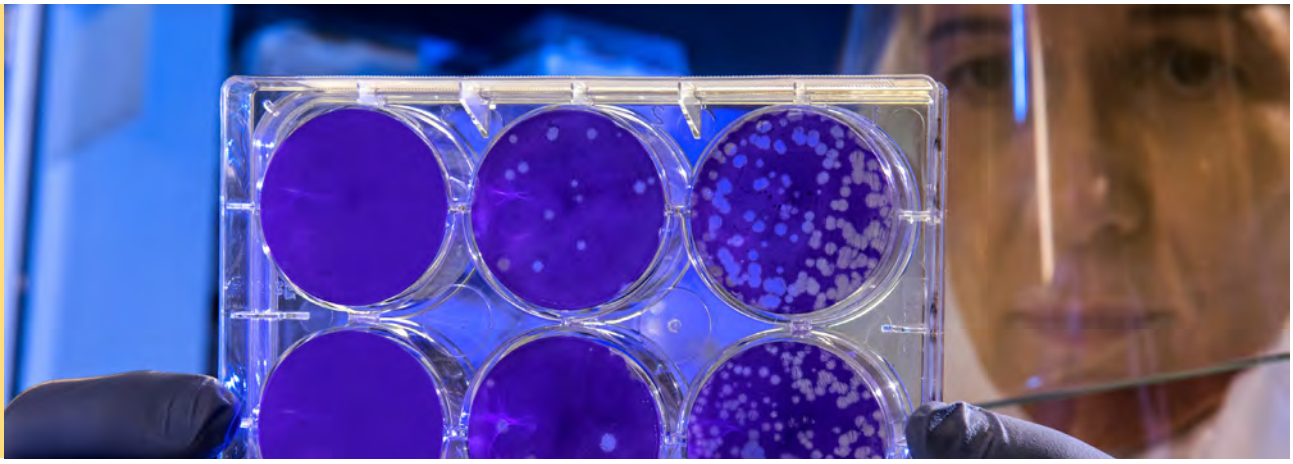
There are two types of strategies to overcome the market failure inhibiting the development of novel antimicrobials:

- **Pull incentives** make investment more profitable by creating conditions to ensure that a novel antimicrobial can be successfully commercialised, thereby 'pulling' investors into the market[9, 10]. These measures commonly delink revenues from sales volumes of antimicrobial products, which allows companies to recoup the costs of development without an increase in the prescription or use of antimicrobials (in line with principles of antimicrobial stewardship)[8, 33].
- **Push incentives** encourage early-stage R&D by reducing costs and financial risks, such as through research grants, tax incentives or funding subsidies. These measures 'push' novel antimicrobials through development and commercialisation so that successful candidates can be brought to market[9].

No single incentive alone will be sufficient to address the market failure for novel antimicrobials. A coordinated set of push and pull incentives is needed to target underlying causes of failure across each stage of the R&D lifecycle.

The following four focus areas must be considered in parallel to address the market failure for novel antimicrobials:

1. **Increasing market attractiveness;**
2. **Increasing and sustaining research funding;**
3. **Connecting Australia to a globally aligned research program; and**
4. **Creating an enabling environment for novel antimicrobials**.



1. Increasing market attractiveness

As long as drug developers receive volume-based payments for new antibiotics, investment will remain a high-risk and low reward proposition. A new payment model for novel antimicrobials is urgently needed – a model that delinks financial returns from their utilisation and that recognises their inherent public health value.

> *Despite the huge societal costs of antimicrobial resistance and urgent need for antimicrobials, there is no viable market for new antibiotics in Australia.*
>
> *– The New Frontier Report*[3]

There are a range of different pull incentives that could be implemented to increase the profitability and attractiveness of the market for novel antimicrobials (Table 1). Pull incentives 'delink' sales volumes of an antimicrobial drug from reimbursement incentives, thereby ensuring adequate market revenue[8, 33].

Table 1. Key examples of pull incentives

Pull Incentives	Definition
Market entry rewards (MERs)	A delinked model in which companies receive a fixed payment on their entry to the market[8]. Companies are paid for supplying a novel antimicrobial at a fixed volume. MER models can be fully delinked, partly delinked or combined with a value-based reimbursement strategy[6].
Subscription models	A delinked model that involves paying a fixed price to a company at regular intervals (e.g., annually) for use of an antibiotic across the healthcare system, with the price delinked from patterns of use. It is considered valuable for high-value and low-use antibiotics[34].
Transferrable exclusivity extension (TEEs)	Also known as tradeable vouchers, companies that meet certain criteria (e.g. efficacy against priority pathogens) receive a voucher, or TEE, upon regulatory approval that gives them a marketing exclusivity extension to fast-track the review process or extend patent life[8]. This can be applied to one of the company's own products or sold to another company, who could then apply it to any one of their products. It is a novel proposal considered to have sufficiently high value to incentivise R&D[33].
Patent extensions	Extension to patent period that prevents generic drugs from entering the market and increases the time that companies have to recover the costs associated with R&D[8].

Funding reform to incentivise the development of novel antimicrobials is gaining traction globally, including in Europe and the United States, which collectively account for more than 80 per cent of global pharmaceutical expenditure[4]. For example, the G7 Finance Ministers have released a *Statement on Actions to Support Antibiotic Development*, calling for the introduction of pull incentives to address antibiotic market failure and bring new medicines to market in line with public health needs[35]. Additionally, the *WHO Global Action Plan on AMR* calls for investment in new medicines, vaccines and diagnostic tools to treat drug-resistant infections, as well as national action plans for each country aligned to a common global direction[36].

Delinking payments from sales volumes

Subscription models have captured global attention as a potential solution to the market failure for novel antimicrobials. Sometimes referred to as 'the Netflix model', subscription models are an innovative funding approach that make a minimum supply of a novel antimicrobial available for a fixed annual price. This is a vastly different approach from the current (traditional) payment model, in which drug developers generate revenue based on the quantity of antibiotics purchased within a health system[34].

Subscription model pilots have been established in the United Kingdom[37] and Sweden[6] (see case studies below) with the aim to achieve two goals: to ensure that novel antimicrobials are made available for patients that develop drug-resistant infections, and to stimulate R&D of new therapies. Lawmakers in the United States (see case study on p. 16) are also considering the introduction of a subscription-like model through the proposed *PASTEUR Act* that is currently before Congress[12].

CASE STUDY

A DELINKED SUBSCRIPTION MODEL IN THE UNITED KINGDOM

The United Kingdom is the first country to trial a subscription model for novel antibiotics[7]. Recognising the limitations of traditional pricing approaches for these medicines, the National Health Service (NHS) and National Institute for Health and Care Excellence (NICE) jointly developed a national plan to fund novel antimicrobials based on their expected value to NHS patients.

As part of the three-year pilot, the NHS paid £10 million per drug per year for access to two novel antimicrobials, ceftazidime-avibactam (Pfizer) and cefiderocol (Shionogi)[38]. These medicines are used to treat severe drug-resistant infections caused by gram-negative bacteria, and therefore address a critical unmet need for patients[6, 34].

In this way, the pilot tested the impact of value-based payments for guaranteed access to novel antimicrobials – as distinct from making payments for the number of packs sold[2, 37]. This approach provides predictable revenue for drug developers and guaranteed supply of medicines for patients[39].

The pilot has been proven a success, with the value provided under their HTA assessment shown to far exceed the £10 million per antimicrobial per annum that is currently being paid[40]. The NHS is now planning to expand the model across the whole of the UK, with tiered pricing of up to £20 million per year per antimicrobial available, depending on relative effectiveness and unmet clinical need, and pharmacological and health system benefit[41, 42, 43].

CASE STUDY

A PARTIALLY DELINKED SUBSCRIPTION MODEL IN SWEDEN

The Public Health Agency of Sweden (PHAS) is trialling a similar subscription model to the United Kingdom, in which suppliers of qualifying novel antimicrobials receive an annual value-based payment for a guaranteed supply of medicine. It is a partially delinked market entry reward model under which suppliers can receive volume-based sales *in addition to* receiving an agreed annual value-based payment. The model is reserved for those novel antimicrobials that have the highest clinical importance[8]. Regional health departments purchase antimicrobials from drug suppliers as per normal processes, and if the revenue from those sales is less than the agreed annual payment, the national body PHAS will pay the difference. If sales revenue exceeds the agreed annual payment, then a bonus of 10 per cent of the security stock amount is paid[39, 44]. Sweden is an important comparator to Australia due to its small market and federated healthcare system.

CASE STUDY

PROPOSED LEGISLATIVE REFORM IN THE UNITED STATES

The *Pioneering Antimicrobial Subscriptions to End Upsurging Resistance* (PASTEUR) Act is a proposed legislative change in the United States to incentivise the development of novel antimicrobials. Under the proposed Act, pharmaceutical companies will receive a contractually agreed annual payment (for terms ranging from five years to patent life) that reflects the value of a novel antimicrobial to the health system, taking into account both clinical need and the degree of novelty[12,6]. Unlike the United Kingdom pilot which considers HTA characteristics, determination of the payment amount under the PASTEUR Act would consider a drug's Target Product Profile characteristics[39].

The PASTEUR Act will reward innovation with higher payments for drugs that have novel mechanisms of action or a novel structure[12]. The Act is gaining strong bipartisan support with 65 co-sponsors of the bill at October 2022[45]. The Center for Global Development in 2022 estimates that globally, and over 30 years, the potential impact of the PASTEUR Act would be the saving of 9.9 million lives and showing a return on investment of 125:1[46].

The concept of **value-based payments** is a vital consideration that lies at the heart of design for a subscription model. Value-based pricing is an approach that aligns drug prices to their clinical benefit for patients, such as the quality-adjusted life years (QALY) gained from having a certain medicine available. For example, the United Kingdom paid up to £10 million per novel antimicrobial per year in its subscription model pilot. The final value was informed by a Health Technology Assessment (HTA) process assessing the expected benefits of each antibiotic to the NHS, giving consideration to the impact of five 'STEDI' factors on QALYs[38,39].

The STEDI Values of Antibiotics

- **Spectrum value:** Benefits of a narrow-spectrum (rather than broad-spectrum) agent;
- **Transmission value:** Benefits from preventing the spread of drug-resistant infections;
- **Enablement value:** Benefits of being able to treat infections to enable other forms of medical care (such as surgery, procedures or chemotherapy);
- **Diversity value:** Benefits from using varied antibiotics to minimise selection pressure;
- **Insurance value:** Benefits from having a suitable antibiotic in reserve should there be an urgent patient need.

Taking action on funding model innovation

Subscription models are not unprecedented in Australia's healthcare history, having been previously adopted for snake antivenom and Hepatitis C (Box 1). More recently, the Australian Parliament's Standing Committee on Health, Aged Care and Sport has recommended through *The New Frontier Report* that a subscription model pilot is trialled to accelerate the development of, and access to, novel antimicrobials[3]. Further, the Australian Government's *National AMR Strategy: 2020 and Beyond* acknowledges the importance of innovation to stimulate discovery and development, including alternate funding models[47].

> *In partnership with the states and territories, [the Australian Government] should develop and implement a pilot scheme for value-based payments for new antimicrobial drugs. This pilot should apply the lessons learned from the Australian Government's pilot scheme for payment for Hepatitis C drugs, as well as from overseas antimicrobial drug schemes.*
>
> *– The New Frontier Report*[3]

BOX 1: A HISTORY OF SUBSCRIPTION MODELS IN AUSTRALIA

A SUBSCRIPTION MODEL FOR HEPATITIS C TREATMENT

The Australian Government successfully trialled a five-year subscription model pilot for Hepatitis C treatment from 2015 to 2019. A lump sum payment of approximately AU$1 billion was paid to pharmaceutical companies for an unlimited supply of antiviral medicines. More than 47,000 patients were treated under the model in the first two years alone, with a three-fold increase in the number of patients seeking monthly treatment. It is estimated that the model reduced costs per patient by up to 85 per cent and improved patient access to care[48].

A MODEL FOR SNAKE ANTIVENOMS THAT PRIORITISES CONTINUOUS SUPPLY

The Australian Government established an agreement with CSL Seqirus in 2020 to ensure continued supply of snake antivenom in Australia. As the only manufacturer of antivenoms for Australia's deadliest snakes, this arrangement is of critical public health importance for Australian patients. Although only few vials of antivenom are typically administered each year, this agreement recognises the fundamental importance of having a steady supply of antivenoms available[49]. It is analogous to a subscription model in that the agreement prioritises availability and supply of medicine, rather than focusing on the number of vials used.

Should Australia continue to rely on traditional payment models for antibiotics, patients face a future in which common infections cannot be treated – with a commensurate increase in deaths. The window of opportunity to reform market conditions is closing, noting the urgency to develop 15 novel antimicrobials within a decade and the 10-to-15-year lead times to bring new antibiotics to market. The time is now to commence the design and establishment of a subscription model pilot for novel antimicrobials, drawing on the lessons from international experience to date and in line with the recommendations of *The New Frontier Report*.

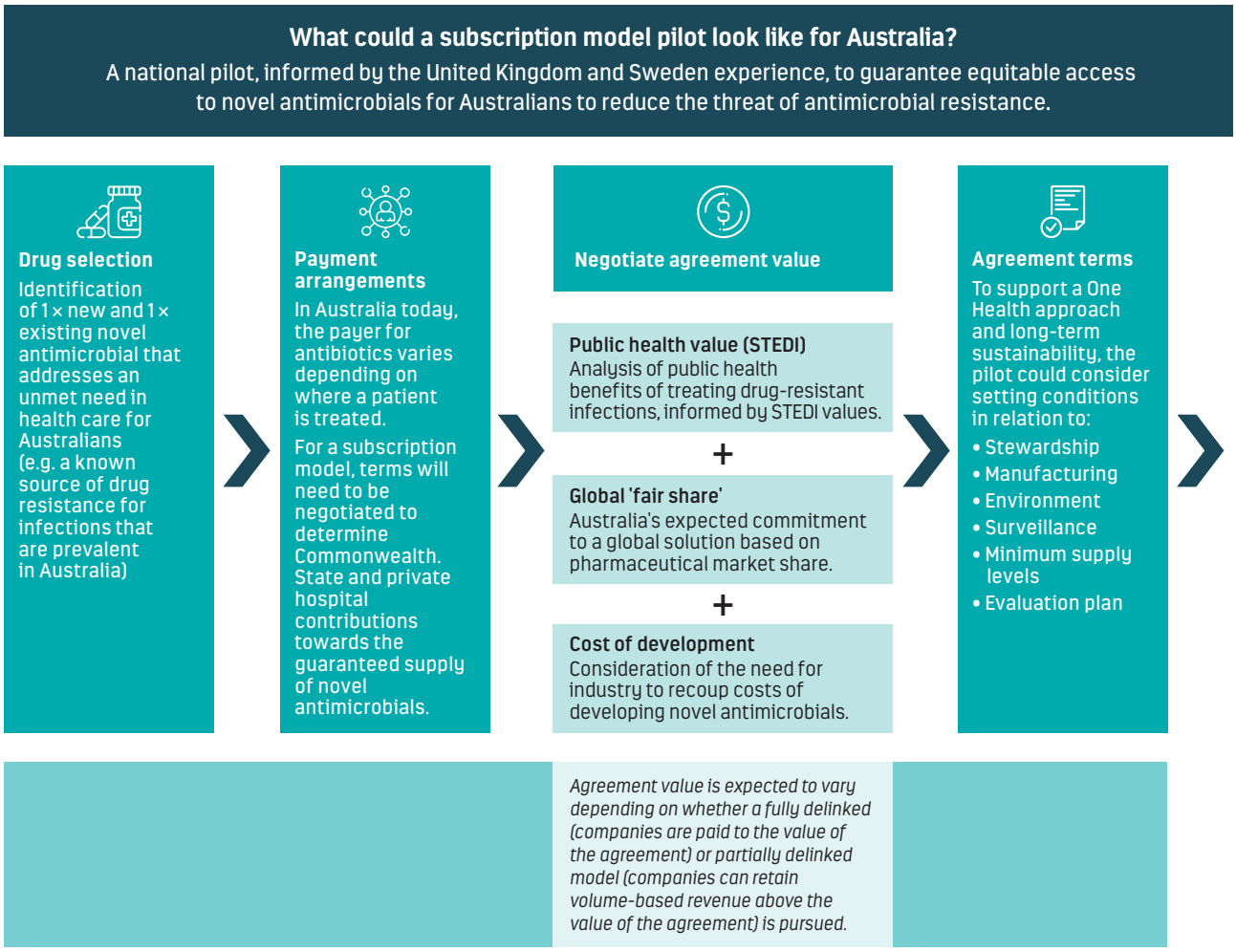
1 RECOMMENDATION **Pilot a subscription model in Australia for two novel antimicrobials.**

Design considerations for a subscription model pilot

Australia is fortunate to be able to draw on the experience of other healthcare systems in designing and implementing a subscription model pilot, including the United Kingdom and Sweden. In shaping the design of a pilot, consideration should be given to the following factors (Figure 3):

Figure 3.

Considerations for a subscription model in Australia



Drug selection: There should be clear eligibility criteria for participation, with a view to ensuring that novel medicines are made available to address unmet clinical needs for Australian patients with a focus on priority pathogens;

Payment arrangements: Design of a subscription model pilot will need to allow for differing payment arrangements currently in place for accessing antibiotics in primary care, public hospitals and private hospitals;

Agreement value: In negotiating the value of payments for novel antimicrobials under a subscription arrangement, consideration will need to be given to the public health value of having those medicines available to society; Australia's global 'fair share' contribution to combating AMR; and the cost of drug development (Box 2).

Agreement terms: A subscription model pilot presents an important opportunity to set terms around the use of novel antimicrobials in Australia. Consideration will need to be given to factors including AMS, manufacturing, environmental impacts, surveillance, minimum supply levels and pilot evaluation.

BOX 2: AUSTRALIA'S LOCAL CONTRIBUTION TO A GLOBAL PROBLEM

A great challenge in addressing the market failure for novel antimicrobials is determining how costs are shared on a global scale. No single country has the purchasing power to drive market reform alone, which means international alignment on introduction of pull incentives is critical.

While precise estimates vary, there is converging thinking that it costs around US$1 billion to bring a novel antimicrobial to market[38]. Therefore, to justify the cost and risk of antibiotic R&D, the combined value of subscription models for novel antimicrobials around the world would need to exceed this figure. In addition, post market costs, which, for new antibiotics, often exceed revenue due to stewardship practices, need to be considered[32]. To stimulate reinvestment in antibiotic R&D, it is estimated that a fully delinked global subscription model would need to be valued at between US$2.2 to US$4.8 billion over five to ten years, and a partially delinked model would require US$0.9 to US$2.6 billion[4, 38].

There has been extensive work to calculate a 'global fair share' – that is, the funding contribution each country would need to provide towards a subscription model[4, 25, 38, 56]. This could form the basis for the establishment of an Australian model.

By making a contribution to a collective action global problem, Australia has an opportunity to demonstrate leadership in tackling a global health emergency. It will also equip us to support less developed healthcare systems that are impacted by AMR, such as the Pacific region.

Strengthening market protections for innovative drug developers

Another challenge facing novel antimicrobials is the impact on revenues associated with competitor activity. Data exclusivity and market exclusivity are forms of market protection that can help reward innovation by delaying the registration and market entry of an equivalent competitor product[57].

Data exclusivity protects an innovator company's safety and efficacy data used to seek regulatory approval of a new pharmaceutical product. It prevents competitors from using that data when applying for the approval of a generic version of the same pharmaceutical product with the same regulatory agency for a defined period of time[58]. For Australia, it means the data package submitted by the innovator company to the Therapeutic Goods Administration (TGA) remains confidential for five years from the time the medicine is registered on the Australian Register of Therapeutic Goods Administration (ARTG)[57]. The long lead-times often required to bring a new antibiotic to market (particularly for novel products), means that a patent on its own could be insufficient to recoup the significant cost of R&D[8]. Data exclusivity runs parallel to a patent and protects the innovative firm's investment in clinical trials and data collection, regardless of the length of time required to bring the drug to market.

Market Exclusivity grants the innovator company the exclusive right to market their product for a defined period of time following regulatory approval[57].

Australia's data exclusivity provisions fall short of protections provided by key comparable jurisdictions such as the European Union, Canada and the United States[3, 59]. In Australia data exclusivity only applies to a new active ingredient, and regulatory approval may still be sought by a competitor during the data exclusivity period[57]. Also, if the confidentiality of the information is not maintained, for example through the publishing of the clinical trials results, protection may be forfeited[61]. Australia has no market exclusivity provisions[57].

Many comparable jurisdictions also allow for additional, flexible provisions depending on designation and target population that are either directed at or may be of benefit to novel antimicrobials. For example, in the United States, Generating Antibiotic Incentives Now (GAIN) aims to stimulate the development and approval of new antibacterial or antifungal drugs by providing an additional five years of market exclusivity for products defined as Qualified Infectious Disease Products (QIDPs). This takes the total market protection for a new chemical entity with QIDP designation to 10 years. It also provides for prioritised review and grants Fast Track designation[61, 62]. In Japan, orphan drugs typically receive additional protection[63]. In the EU and Canada, data exclusivity provisions are supplemented with additional periods of market exclusivity for all new products, as wells as flexible add-ons depending on patient population targeted (see table below).

Table 2: International comparison of data and market exclusivity laws

Country	Data exclusivity	Classification
Australia	5 years (Data package supplied to TGA is kept confidential)	New active ingredient
US[64]	5 years	New chemical entities (NCE)
	3 years	New indication
	7 years	Orphan Drug
	+ 6 months	Paediatric Exclusivity
	+ 5 years (Market exclusivity)	Generating Antibiotic Incentives Now (GAIN)
	12 years	Biological products
Europe[65]	8 years (Data exclusivity)	All products
	+ 2 years (Market exclusivity)	All products
	+ a further year (Market exclusivity)	For significant therapeutic benefit over other therapies
	10 years (Market exclusivity)	Orphan products
	+2 years	If compliant with a paediatric Investigation Plan
Japan[63]	Market protection is provided by the requirement for generic drugs to go through re-examination of safety	
	Up to 6 years	New indication drugs (includes dosages and administration)
	6-10 years	New drugs (including orphan, new administration routes for known drugs)
Canada[66]	8 years (6 years data exclusivity + 2 years marketing exclusivity)	New drug
	+ 6 months	Paediatric drugs (for clinical trials in paediatric populations)
China[67]	6 years	New drugs
New Zealand	5 years	New drugs

In the Australian Government's *The New Frontier Report*, data exclusivity is identified as a potential barrier to access to novel drugs including antimicrobials[3]. Recommendation 27 calls for the extension of the data exclusivity period in Australia from five to ten years for novel drugs and vaccinations[3].

Transferrable exclusivity extensions (TEEs) are another mechanism being considered by governments around the world to increase market attractiveness for novel antimicrobials. TEEs enable companies to benefit from an extended period of marketing exclusivity for a product. One proposal being considered in Europe, would, upon regulatory approval of an eligible new antimicrobial, award a TEE voucher to the developer of that drug, which can be used to extend the period of marketing exclusivity on one of its own products, or be sold to another company for use on one of their products[8, 33, 68].

Flexible options that strengthen regulatory data protection (such as longer data exclusivity periods or TEE schemes) reward innovation and encourage companies to bring novel antimicrobials into new markets. Given the significant challenges with bringing novel antimicrobials to market in Australia, these should be considered alongside other pull incentives (such as a subscription model pilot).

2 RECOMMENDATION **Strengthen existing, and introduce additional, flexible data exclusivity extension options for novel antimicrobials in Australia.**

2. Increasing and sustaining research funding

A shortfall in access to sufficient research funding for early-stage research and discovery is consistently identified as one of the most significant barriers in the development of novel antimicrobials. In the drug discovery stage, researchers often struggle to secure adequate funding to generate the volume of research needed to identify promising candidates for new antimicrobial medicines and technologies.

> *The quantum of funding that has been available is insufficient to support the volume of idea stimulation needed. You need to have some failures, so there has to be enough money to make bold choices.*
>
> **– Researcher**

There is then the ongoing challenge of sustaining funding as drug developers navigate pre-clinical development, clinical trials and regulatory approval. Around the world, several companies have been forced to abandon promising candidates due to a lack of sustained funding[2]. For example, Achaogen (antibiotics developer) invested over AU$1 billion to bring a new antibiotic to market for complicated urinary tract infections. However, by the time FDA approval was granted, Achaogen did not have sufficient funds to successfully commercialise and went into bankruptcy[2].

Australian Government funding opportunities

The Australian Government has recognised the importance of targeted research funding to address AMR. For example, Australia's *National Antimicrobial Resistance Strategy 2020 and Beyond*, endorsed by the Council of Australian Governments (COAG), has two overarching goals: to minimise the development and spread of AMR and to ensure continued availability of effective antimicrobials[47].

In addition, the Medical Research Future Fund (MRFF) and National Health and Medical Research Council (NHMRC) provide essential research funding to support antibiotic R&D, both of which identify AMR as a research priority[69]. However, there is a commonly held view among researchers that the magnitude of funding made available to AMR projects in recent years has been insufficient[55]. For example, under the MRFF, only AU$30 million over 10 years has been allocated from a AU$6.3 billion budget – equating to 0.48 per cent[70].

Global investment

On a global scale, several players are making significant investments to transform the R&D landscape for antimicrobials. This acknowledges that the quantum of funding available is far from adequate to generate the volume of research needed to tackle AMR, as well as the immense public health consequences of failing to act.

- **CARB-X,** a global not-for-profit public-private partnership, has up to US$850 million available to invest between 2016-2032. CARB-X has provided non-dilutive funding to over 90 projects across 12 countries to accelerate development of novel antimicrobials by fuelling the pre-clinical development pipeline. CARB-X has made initial investments in Australia to support AMR research at the University of Queensland, SpeeDx, a Sydney based diagnostic company, and most recently, the University of Melbourne's Doherty Institute[25, 71].
- The **AMR Action Fund,** the world's largest public-private partnership investing in the development of new antimicrobial therapeutics has set an ambitious goal of bringing 2-4 novel antibiotics to market by 2030. The Fund is backed by investment from leading global pharmaceutical companies, the WHO, the European Investment Bank and Wellcome Trust[72].
- **GARDP** is a not-for-profit organisation established by the WHO focused on the development of treatments that target those drug-resistant infections posing the greatest threat to human health[73].

The commitments being made by these players (and many others seeking to reduce the threat of AMR) underscore the importance of globally aligned and coordinated push incentives. AMR is a global problem that requires collective action solutions.

Opportunities for reform

The identification of AMR as a research priority by the MRFF and NHMRC is undoubtedly a step in the right direction for increasing the volume of funding dedicated to AMR projects. However, further action is needed to ensure that Australia can play its part in contributing to a global research program that is powered to deliver the required 15 novel antibiotics within the next decade. Greater investment is needed to enable higher volumes of early-stage research, both to discover new therapeutic options and to ensure promising candidates can be sustained over a decade or more to reach commercialisation.

3 **RECOMMENDATION** **Increase the quantum of AMR research funding in Australia.**

3. Connecting Australia to a globally aligned research program

A strong and steady research pipeline is critical to enable the development of novel antimicrobial medicines. Australia must play its part in **fostering a targeted research program that is connected to and aligned with** research efforts on a global scale and contribute to a global collective action problem, whilst taking advantage of the expertise, resources and infrastructure available internationally. Australia has a collective public health responsibility to contribute to a global research program.

Directing AMR funding to where it is needed most

Start-up accelerators play a critical role in improving the likelihood of success for early-stage research and therapeutic candidates. Accelerators provide funding, mentorship and support across the R&D lifecycle. An AMR-focused accelerator in Australia would provide an opportunity to concentrate expertise and coordinate funding across the sector to strengthen the pipeline of novel antimicrobial medicines and technologies. Any accelerator should strengthen relationships with and leverage the expertise and infrastructure of existing players on a global scale such as CARB-X[71]. Contributing to CARB-X, a major global player, would also enable Australia to directly leverage from its investments and strengthen global efforts. A globally connected Australian AMR accelerator would address a point of failure in R&D by supporting a path to commercialisation for Australian AMR research.

4 **RECOMMENDATION** **Establish and appropriately fund an Australian AMR accelerator as well as contribute to and leverage global initiatives such as CARB-X.**

Incentivising R&D in Australia

Australia has a strong reputation for high-quality research capabilities, particularly in the early stages of discovery and pre-clinical development. As new medicines candidates progress to clinical trials, Australia offers an attractive value proposition to pharmaceutical companies and startups. The **R&D Tax Incentive** is a valued Australian Government initiative that encourages innovation by providing a refundable tax offset for R&D entities with an aggregated turnover of less than AU$20 million per annum[74]. A non-refundable tax offset, available for all other entities, is based on the company tax rate plus a two-tiered premium calculated on the theoretical R&D expenditure as a proportion of total expenditure in the financial year[75]. Similarly, the **Clinical Trial Notification (CTN) scheme** is reported as a drawcard to conduct clinical trials in Australia as it reduces the cost and effort needed to submit applications as well as time to commence and conduct a trial[55]. Phase I to III clinical trials can cost upwards of AU$130 million for antibiotics, which is a significant burden, so such measures are important in offsetting cost and risk to drug developers[2].

> *The Clinical Trial Notification (CTN) Scheme is critical for attracting international investment in antibiotic research in Australia, but more people need to know about them.*
>
> **– Biotech representative**

The CTN Scheme offers competitive advantage for Australia to attract international investment, including clinical trials for novel antimicrobials[76]. Yet many individuals and companies overseas are not aware of the scheme and its benefits. Promoting the scheme internationally presents significant opportunities to support job creation and economic activity whilst encouraging sorely needed antibiotic R&D.

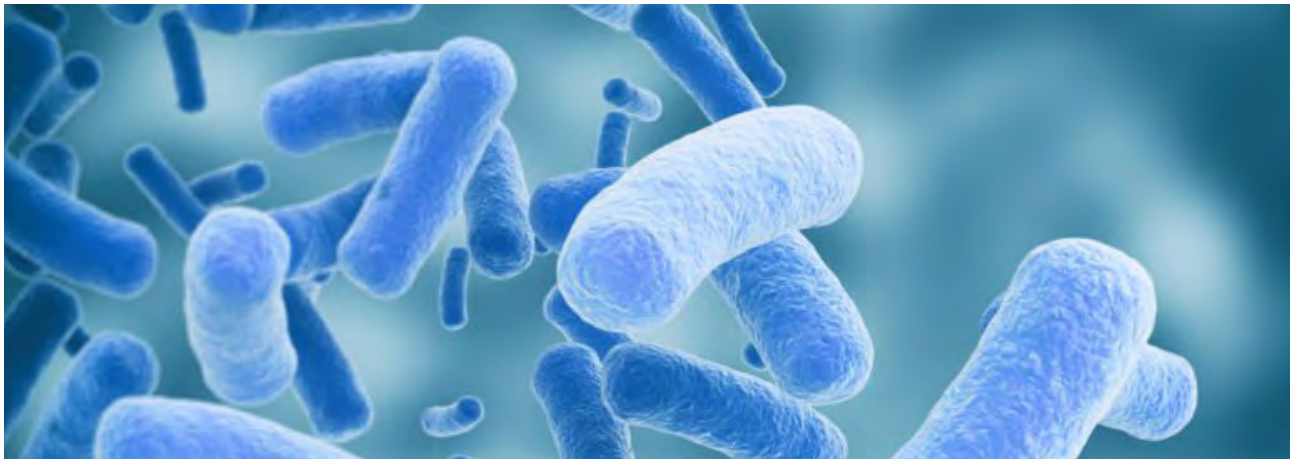
CASE STUDY

INTERNATIONAL INVESTMENT

Bugworks (India), having received funding from CARB-X potentially totalling US$3.6m, recently established an Australian subsidiary to support a Phase I clinical trial program in Adelaide for its new antibiotic. Trials such as this can involve a direct spend of around AU$3-4 million and provide high value jobs for up to 15 professionals[77].

It is notable that a globally connected Australian AMR accelerator (as per recommendation four), would be ideally placed to promote the strengths and advantages of conducting AMR R&D in Australia. Thereby helping attract overseas companies to access Australian service providers, infrastructure and expertise, and to conduct their clinical trials activities here.

5 RECOMMENDATION Continue to promote R&D investment in Australia, including through raising awareness of the CTN scheme and R&D Tax Incentive.



4. Creating an enabling environment for novel antimicrobials

Streamlined regulatory approval processes

Any new medicine or health technology requires regulatory assessment by the TGA to ensure it is safe and effective for Australian patients. As with other medicines, the timeframe for antibiotic developers to navigate regulatory approval increases the cost, effort, risk and duration of R&D. Depending on the country and regulatory process being applied, approval of new therapies typically takes up to 11 months[78]. During this time, developers are unable to generate revenue to offset R&D costs.

Several countries are exploring approaches to simplify regulatory approval, including for novel antimicrobials, that reduce barriers to development and patient access[2]. For example, the United States has introduced priority review vouchers to accelerate the regulatory review process for certain medicines (including those that relate to public health emergencies)[2]. Priority review pathways (e.g., accelerated assessment) have also been introduced by the European Medicines Agency (EMA) to facilitate earlier access for novel antimicrobials[79].

In Australia, there are some mechanisms for accelerated regulatory approval processes for certain medicines. For example, medicines that are eligible for orphan drug designation (that is, they have a single indication for a serious condition in a small patient population) can have regulatory approval fees waived[80]. A priority registration pathway is also available for new and novel prescription medicines that can shorten review timeframes by up to three months[81]. While these pathways could be used to accelerate the introduction of novel antimicrobials, the options are non-specific and fragmented. Further coordination is required.

6 RECOMMENDATION **Provide accelerated pathways and reduce barriers for the regulatory approval of novel antimicrobials in Australia.**

Fit-for-purpose reimbursement pathways

In Australia, all new medicines undergo HTA to assess benefit and value, with a view to informing pricing and reimbursement decisions. HTA is a fundamental component of the Australian healthcare system to ensure safe and equitable access to medicines and other health technologies.

HTA has been identified as a barrier to the introduction of novel antimicrobials in Australia. Specifically, novel antibiotics in Australia are often considered to be undervalued due to the availability of low-cost generics[3]. For example, the Australian Parliament's *The New Frontier Report* has acknowledged that it will be challenging to bring novel antimicrobials to the Australian market due to reference pricing policy which will impede a drug developer's ability to realise a commercial return[3]. This means Australian patients are at risk of being unable to have timely or affordable access to lifesaving medicines should they develop a drug-resistant infection.

Likewise, enabling HTA to explicitly consider the value that a novel antimicrobial will bring to Australian society is critical. The HTA Review being undertaken in 2022-23[82] is the appropriate vehicle to consider the evolution of our HTA framework for novel antimicrobials, commensurate with other advanced health systems globally. For example, in the United Kingdom, the NHS, as part of its assessment of the pilot model for antimicrobials, has shown that the value provided under their HTA assessment has far exceeded the £10 million per antimicrobial per annum paid under the pilot[40], and is now in the process of expanding the program.

> *Australia's HTA system needs to take into consideration rare disease and develop robust pathways that provide equity and access to treatments and therapies that don't fit neatly into the current system such as…antimicrobials.*
>
> *– The New Frontier Report*[3].

7 **RECOMMENDATION** **Develop fit-for-purpose HTA pathways for antimicrobial medicines as part of the HTA Review currently underway.**

Elevating the profile of AMR in healthcare policy

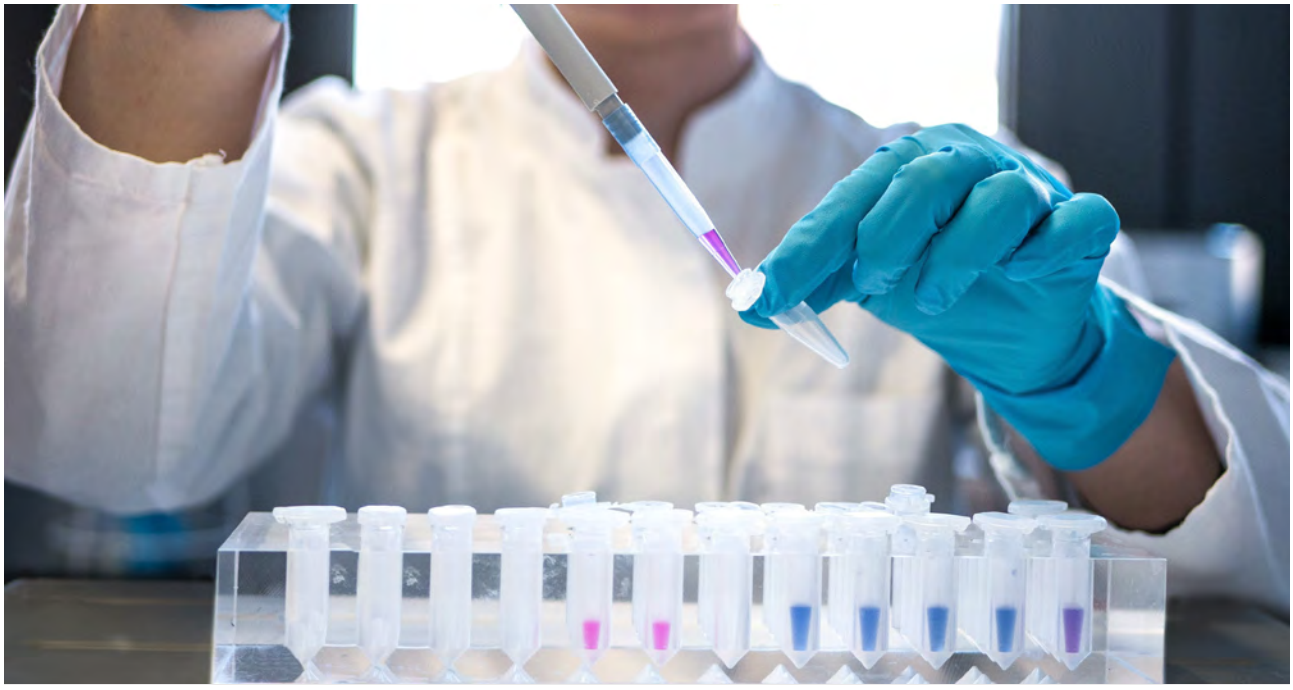
While there is growing recognition of AMR as an important health issue, to date there has been insufficient investment and public attention focused on this developing public health emergency. To increase both public attention and targeted funding to combat AMR, it is recommended that AMR is recognised as a National Health Priority Area (NHPA).

The NHPAs is a set of 10 priorities requiring government focus and attention:

- arthritis and musculoskeletal conditions;
- asthma;
- cancer control;
- cardiovascular health;
- dementia;
- diabetes mellitus;
- injury prevention and control;
- mental health conditions;
- obesity; and
- medicine safety[83].

While the medicine safety priority area includes AMS, it does not explicitly promote timely access to new and novel antibiotics[83]. Moreover, it should be acknowledged that to some extent the 10 NHPA's are dependent on the availability of readily available and effective antibiotics. The inclusion of AMR as a NHPA would be an important step towards improving funding, coordination and awareness of AMR initiatives as a collaborative effort between Commonwealth and State Territory Governments.

8 **RECOMMENDATION** **Identify AMR as Australia's 11th National Health Priority Area.**



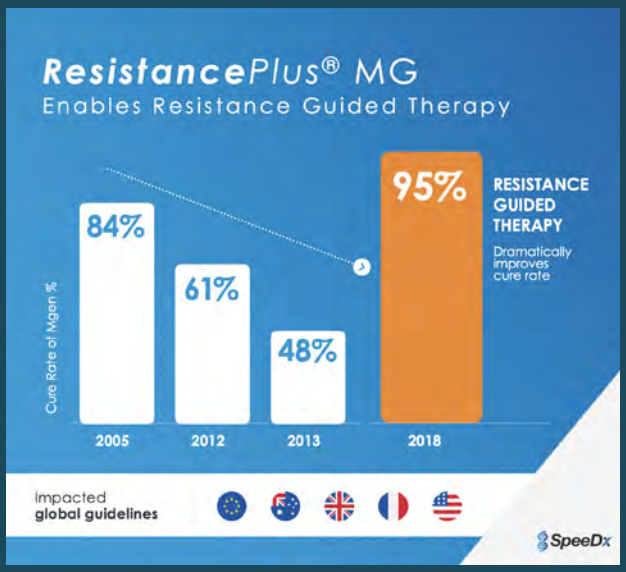
Maintaining antimicrobial stewardship

AMS is a critical pillar of the fight to combat AMR. Any future funding reform must not compromise the appropriate prescribing and use of antibiotics and other antimicrobial medicines. Rapid diagnostics that improve the detection of bacterial infections are showing promise to slow the spread of drug-resistant infections and enable effective treatment[2]. Identifying a bacterial infection as quickly as possible and commencing suitable treatment is a key pillar of AMS.

CASE STUDY

RAPID POINT-OF-CARE TESTING FOR BETTER ANTIBIOTIC PRESCRIBING

Several countries are making strides in developing diagnostic technologies that will enable more effective use of existing antibiotics to combat AMR. For example, SpeeDx is an Australian molecular diagnostics company that is developing point-of-care tests to detect chlamydia and gonorrhoea within 60 minutes. Critically, these tests will also be able to test for resistance to commonly used antibiotics such as cefixime, ciprofloxacin and azithromycin. If successful, such tests could be used in clinical practice to improve antibiotic prescribing – both by making sure that patients have a confirmed bacterial infection before commencing treatment and informing the selection of the most appropriate antibiotic for the patient on the basis of the pathogen[84].



Companion diagnostics alone are not sufficient to prevent or treat drug-resistant infections, but they will play an important role to curb the spread of AMR. As technologies develop, our healthcare system must be prepared to adapt to change. This includes change to our clinical systems, HTA processes, policy, and funding to incorporate rapid point-of-care testing for suspected bacterial infections. Rapid tests will need to undergo HTA through the Medical Services Advisory Committee (MSAC) to be funded through the Medicare Benefits Schedule (MBS). Training, policy development and process change will also be needed to support consistent use in primary care. The hospital sector will also require access, as well as testing for patients at home in the future.

9 **RECOMMENDATION** **Encourage uptake of timely point-of-care testing for antimicrobial infections.**

SUPPORTING OUR PACIFIC NEIGHBOURS IN COMBATING AMR

AMR is a global collective action problem, yet not all countries have the same capacity to contribute to a global solution. The impacts of AMR are disproportionately high in low- and middle-income countries (LMIC), including in Australia's neighbouring Pacific region.

Across the Pacific, there is a higher burden of infections and a lower supply of antimicrobials relative to Australia. This reflects a range of factors including level of healthcare funding, interrupted supply chains and fewer regulations to govern the appropriate use of antibiotics[50]. For example, Samoa is reported to have the highest use of antimicrobials and consequently high reliance on penicillins when compared to other developing countries[51].

In addition, as COVID-19 has demonstrated, microbes know no borders, and the close interconnectedness of Australia, New Zealand and the Pacific means that AMR pathogens can move freely between countries.

Around the world, there is recognition of the responsibility that wealthier countries have to support LMICs in fighting AMR. To this end, several global programs have been introduced that could be leveraged in the Pacific region as part of the global solution to address AMR, including through better supporting access to much needed new antimicrobials.

For example:

- **Indo-Pacific Centre for Health Security:** The Department of Foreign Affairs and Trade (DFAT) administers a range of programs that foster health security in the Pacific region, ranging from lab strengthening and product regulation to access to new medicines[52].
- **Combat AMR:** An initiative led by the Doherty Institute and funded through a grant from the Indo-Pacific Centre for Health Security, COMBAT AMR is a consortium of organisations from around the world that seeks to address the threat of AMR in Pacific Island countries. It offers training, mentoring and capacity building and operates across Fiji, Samoa, Solomon Islands and Papua New Guinea. At this stage, it has a focus on infection control, AMS, laboratory capacity, surveillance and animal health, but does not support access to novel antimicrobials[53]. However, it shows promise and potential for future expansion.
- **SECURE:** Global Antibiotic Research and Development (GARDP), a leading global organisation accelerating the development and access to treatments for drug-resistant infections, has developed a collaborative initiative called SECURE in partnership with WHO to provide access to essential antibiotics and support pandemic preparedness in vulnerable populations. Participating countries will be able to access new antibiotics for drug-resistant infections together with older antibiotics that are not as widely available or are disrupted frequently by supply chain issues[54].
- **SpeeDx:** SpeeDx, an Australian-based company that specialises in molecular diagnostic solution, has partnered with the Kirby Institute to support capacity building efforts in Papua New Guinea for COVID testing and pandemic support. There is some potential for future expansion to supporting diagnostic testing for AMR in future[55].

A WAY FORWARD: ENSURING AUSTRALIA IS CAPABLE TO COMBAT THE RISE OF DRUG-RESISTANT INFECTIONS.

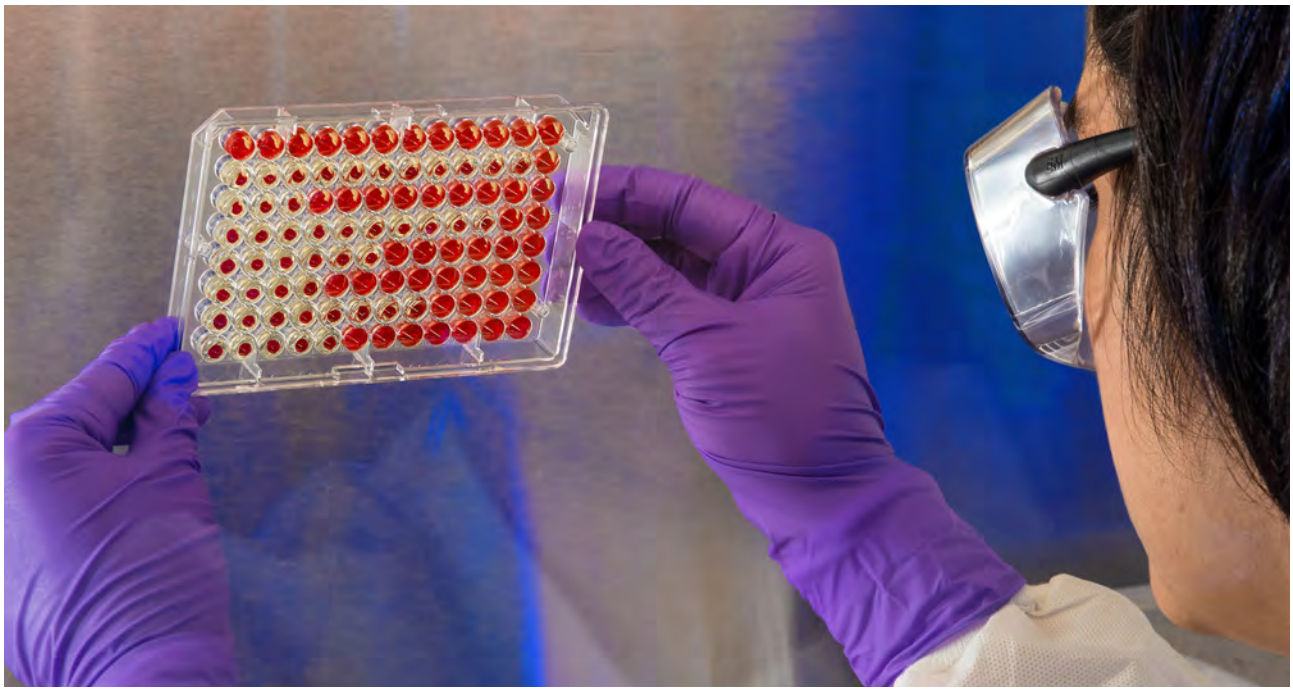
We are in a fight against superbugs. The continued and accelerating spread of drug-resistant infections that cannot be treated with today's medicines presents an immense risk to human, animal and environmental health within a generation[22]. By 2050, ten million people per year globally will die from infections that are treatable today and the associated economic impacts will be stark. There is an urgent need to both strengthen and accelerate our efforts to combat AMR, in line with a 'One Health' approach and with efforts underway globally.

Combating AMR will not be possible without the development of novel antimicrobial medicines that are effective in killing or weakening drug-resistant pathogens. And yet, there is clear and well documented evidence of a market failure that is hindering their development and subsequent commercialisation.

The costs of R&D are too high and the commercial returns currently too low to justify investment in infectious disease medicine, particularly compared to other therapeutic areas. Intervention is urgently needed to change how we fund and pay for antibiotics and other antimicrobial medicines.

There is recognition around the globe that no country can combat AMR alone. It is a collective action problem that will require coordinated and aligned actions on an international scale[7, 3]. Research collaborations, streamlined regulatory approval pathways and a commitment to contributing a 'global fair share' to innovative payments models will be key to success.

It is clear that this problem cannot be overcome with a single solution alone, and a spectrum of targeted actions is needed to foster and sustain innovation across every stage of the R&D pipeline for novel antimicrobials. As the window is closing to protect our future and those of the next generations to come, the time to act is now.



Summary of recommendations

This report has presented nine evidence-based recommendations to equip Australia in preparing to fight the rise of drug-resistant infections. These have been informed by a comprehensive review of academic and grey literature; interviews with subject matter experts across industry, government and healthcare; and the contributions of an expert project steering committee.

1. Pilot a subscription model in Australia for two novel antimicrobials.
2. Strengthen existing, and introduce additional, flexible data exclusivity extension options for novel antimicrobials in Australia.
3. Increase the quantum of AMR research funding in Australia.
4. Establish and appropriately fund an Australian AMR accelerator, as well as contribute to and leverage global initiatives such as CARB-X.
5. Continue to promote R&D investment in Australia, including through raising awareness of the Clinical Trial Notification (CTN) scheme and R&D Tax Incentive.
6. Provide accelerated pathways and reduce barriers for the regulatory approval of novel antimicrobials in Australia.
7. Develop fit-for-purpose HTA pathways for antimicrobial medicines as part of the HTA Review currently underway.
8. Identify AMR as Australia's 11th National Health Priority Area.
9. Encourage uptake of timely point-of-care testing for antimicrobial infections.

ABBREVIATIONS

Abbreviation	Description
AMR	Antimicrobial resistance
AMS	Antimicrobial stewardship
ARTG	Australian Register of Therapeutic Goods
CARB-X	Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator
COAG	Council of Australian Governments
CTN	Clinical Trial Notification
DFAT	Department of Foreign Affairs and Trade
EMA	European Medicines Agency
FDA	US Food and Drugs Administration
GARDP	Global Antibiotic Research and Development Partnership
HTA	Health Technology Assessment
MBS	Medicare Benefits Schedule
MER	Market Entry Reward
MRFF	Medical Research Future Fund
MSAC	Medical Services Advisory Committee
NHMRC	National Health and Medical Research Council
NHPA	National Health Priority Area
NHS	National Health Service (United Kingdom)
NICE	National Institute for Health and Care Excellence
PHAS	Public Health Agency of Sweden
QALY	Quality-adjusted life years
QUM	Quality use of medicine
R&D	Research and development
STEDI	Spectrum, Transmission, Enablement, Diversity and Insurance
TEE	Transferrable Exclusivity Extension
TGA	Therapeutic Goods Administration
WHO	World Health Organization

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