



MTPConnect

MedTech and Pharma Growth Centre

Australian Antimicrobial Resistance Network (AAMRNet)

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EXECUTIVE SUMMARY

The Australian Antimicrobial Resistance Network - AAMRNet – is an Australian-first network bringing together key stakeholders from industry, clinicians and research to address the impact of antimicrobial resistance (AMR) on human health.

The network was established in 2020, delivering on a key recommendation of the report, [Fighting Superbugs: A Report on the Inaugural Meeting of Australia’s Antimicrobial Resistance Stakeholders](#), published by MTPConnect, the Growth Centre for the Medical Technology, Biotechnology and Pharmaceutical sector.

AAMRNet is operated by MTPConnect with cross-sector stakeholder investment and support.

Industry contributions provided by:

- Pfizer ANZ
- CSIRO
- MSD Australia
- GSK Australia
- Botanix Pharmaceuticals
- Recce Pharmaceuticals
- SpeeDx
- Medicines Australia
- Biointelect
- Monash Centre to Impact AMR

Partner organisations:

- DMTC Limited
- GARDP – Switzerland
- AusBiotech Ltd
- Roche Diagnostics Australia
- Menzies School of Health Research
- Formulytica Pty Ltd
- Epichem Pty Ltd
- BiomeBank
- LBT Innovations
- Microbio
- Incubator for Antibacterial Therapies in Europe (INCATE)
- Community for Open Antimicrobial Drug Discovery (CO-ADD)
- Monash Biomedicine Discovery Institute
- RESULTS International Australia

The COVID-19 pandemic and its health and economic impacts provide a stark reminder of the need to focus on Australia’s health security and has demonstrated the importance of strengthening preparedness for global health threats such as the one posed by AMR.

The threat of AMR to the health and welfare of Australians and the sustainability of our healthcare system cannot be underestimated. Only recently, CSIRO Biosecurity Research Director, Dr Paul de Barro, stated “it’s the biggest human health threat, bar none. COVID is not anywhere near the potential impact of AMR”¹.

The estimated annual impact of AMR on the Australian economy by 2050 will be between \$142 - \$283 billion². Globally, AMR is on track to claim 10 million lives per year and put at risk a cumulative US\$100 trillion of economic output if no action is taken by 2050³.

Australia’s *National Antimicrobial Resistance Strategy – 2020 & Beyond*⁴ has identified a range of priorities to help slow the development of AMR.

¹ The Guardian Australia (2020): <https://www.theguardian.com/world/2020/sep/10/superbugs-a-far-greater-risk-than-covid-in-pacific-scientist-warns>

² Superbugs to trigger our next global financial crisis, OUTBREAK consortium (2020)

³ Tackling drug-resistant infections globally. The Review on Antimicrobial Resistance Chaired by Jim O’Neill. (2016). https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

⁴ Australia’s National Antimicrobial Resistance Strategy – 2020 and Beyond, [Australia’s National Antimicrobial Resistance Strategy - 2020 and Beyond | Antimicrobial resistance \(amr.gov.au\)](#)

The key elements included in the National Strategy are all critical to address the impact of AMR and no one element on its own will solve this global crisis. However, despite best efforts around prevention, education, surveillance and antibiotic stewardship, AMR will continue to occur. As a result, novel antimicrobials, vaccines and companion diagnostics remain crucial tools for protecting the health of Australians. For example, companion diagnostics improve not only surveillance but stewardship and vaccines help reduce the burden of infectious disease and related use of antibiotics. And without effective antibiotics, it would simply be too dangerous to perform a range of other medical procedures such as some surgeries and cancer treatments.

Antimicrobials save lives, limbs, keep people out of hospital and shorten the length of stay for hospital inpatients.

A robust pipeline of new antimicrobials is central to combatting AMR, however the World Health Organisation has warned that the pipeline of antimicrobials is “insufficient to tackle the challenge of increasing emergence and spread of antimicrobial resistance”⁵.

There is a clear, critical, and established unmet need when it comes to the development and commercialisation of new antimicrobials.

There is widespread consensus that a combination of ‘push’ and ‘pull’ incentives are required to support new discovery, early clinical trials and, for medicines that show promise, suitable reimbursement assessment. Push incentives are critical to help early-stage R&D, but are on their own not enough. A stark reminder of this is Achaogen⁶, a small company that had benefitted from push incentives to gain FDA approval for its first product to treat complicated urinary tract infections. However, less than a year after launching their product, they filed for bankruptcy after sales of less than \$1 million over that time⁷. Key to overcoming this market failure will be finding ways to fully recognise the societal value of antimicrobials through de-linking payments to companies from the volume of antibiotics sold. Market-based or ‘pull’ incentives that assist developers to bring their products to the bedside are crucial to stimulate the development of new antimicrobials and ensure patient access.

Confirming the importance of pull incentives, on 13 December 2021 the G7 Finance Ministers released a statement on Actions to Support Antibiotic Development⁸ with a view to strengthening G7 preparedness against the “silent pandemic” of AMR. The statement notes that “different factors including market failure contribute to the lack of development of new antibiotics, with no new class of antibiotic coming to market for more than three decades.” It commits all G7 members “to expedite their implementation of existing strategies... and to take additional specific and appropriate steps to address the antibiotic market failure and create the right economic conditions to preserve essential existing antibiotics and ensure their access, strengthen AMR antibiotic R&D, and bring new drugs to market where they meet identified public health needs”.

The statement outlines possible steps including “exploring a range of market incentive options, with a particular emphasis on supporting relevant pull incentives, implementing new pilot projects, contributing to new national governance structures to develop economic strategies to strengthen antibiotic development, and exploring legislative and regulatory measures”.

The Standing Committee on Health, Aged Care and Sport, chaired by Trent Zimmerman MP, has also acknowledged the seriousness of the problem. In its report; [The New frontier – Delivering better health for all Australians](#), in which antimicrobials feature prominently, the Committee recommends the Australian

⁵ World Health Organisation, (2019), 2019 Antibacterial Agents in Clinical Development – An analysis of the antibacterial clinical development pipeline

⁶ <https://needham.bluematrix.com/docs/pdf/e821e131-b928-4b4d-86dd-63ec995e6e21.pdf>

⁷ Medicines Australia, Department-of-Health-Australias-Antimicrobial-Resistance-Strategy-2020-and-beyond.pdf (medicinesaustralia.com.au)

⁸ <https://www.g7uk.org/wp-content/uploads/2021/12/AMR-G7-Finance-Ministers-statement-on-supporting-antibiotic-development-final-13-Dec-2021.pdf>

Government takes strong action, including at Recommendation 27, which outlines several initiatives including:

- Consider future funding initiatives for novel drug discovery and support research and development partnerships in Australia. This would assist new drugs and novel medical technologies in early stage and pre-commercial development.
- In partnership with the states and territories, develop and implement a pilot scheme for value-based payments for new antimicrobial drugs.

The Australian Government has made substantial PBS savings relating to systemic anti-infectives over the past few years, saving almost \$2 billion or 65.5 per cent in 2019-20 when compared with 2016-17. There is therefore a significant opportunity to reinvest some of those savings, and direct targeted new investments, into initiatives to combat AMR.

With such a broad and engaged stakeholder base representing industry and research, AAMRNet is uniquely placed to drive impactful AMR initiatives. With targeted funding support, AAMRNet will take positive steps to deliver on several of the recommendations from Zimmerman inquiry. Its work will also help ensure Australians have fast access to the best medicines and send a strong message to the global community that Australia is committed to addressing this urgent public health challenge.

AAMRNet seeks an investment of \$3.55 million in three specific areas to support the National Strategy and enhance its work to combat AMR:

1. Ensure the sustainability of AAMRNet through the provision of new funding

- An investment of **\$1.5 million over three years** would ensure the sustainability of AAMRNet and enable it to operate sustainably, independent of MTPConnect
- Employ two highly qualified people to operate and drive the activities of AAMRNet
- The investment would build on the funding and in-kind contributions from MTPConnect through the Growth Centres Project Fund program and the financial and in-kind contributions provided by industry
- A sustainable AAMRNet would provide the Australian Government with critical access to the key opinion leaders working in the AMR sector in Australia.

2. Establish an AMR focused accelerator in Australia

- An investment of **\$1.8 million** over three years would enable AAMRNet to establish and operate an AMR-focused accelerator in Australia that could be fully endorsed by CARB-X (Combating Antibiotic-Resistant-Bacteria)⁹ and integrated into its Global Accelerator Network. CARB-X wrote to the Minister for Health in November 2020 confirming that it would expect to fully endorse any accelerator that was established with the support of the Australian Government. The proposed budget is comparable to the operating budgets of CARB-X accelerators in other countries, including the US and India.
- This investment would leverage work already being done by AAMRNet in collaboration with CSIRO and could generate a significant return to the Australian economy, including potentially more than \$50 million over five years in overseas funding into Australian biotechnology companies and research groups.

⁹ www.carb-x.org

- An equally important role for an Australian AMR-focused Accelerator integrated into the CARB-X Global Network would be to attract foreign direct investment (FDI), promoting Australia’s R&D capabilities in AMR to all companies that receive CARB-X grants, including biotech and diagnostic companies in the US and Europe. Bugworks (India), for example, has received CARB-X funding and recently established an Australian subsidiary to support a Phase I clinical trial for its new antibiotic. The proposed accelerator would seek to facilitate more of these kinds of FDI outcomes.
- Additionally, the Accelerator would develop a publicly accessible dashboard for researchers, public health organisations and public and private funders and investors (from Australia and globally) to follow current strengths in Australia’s AMR R&D pipeline as it relates to human health. This dashboard data could be aligned with the existing [Global AMR R&D hub](#), ensuring visibility of Australian AMR R&D for attracting funding from beyond our shores. The funding would also enable the dashboard to be maintained by AAMRNet for three years.
- CARB-X is a global non-profit partnership supported by several donor countries and philanthropies such as the Bill & Melinda Gates Foundation and the Wellcome Trust. CARB-X is dedicated to accelerating the development of new therapeutics, vaccines, and diagnostics to combat AMR. It supports a global network of accelerators and has total US\$480 million to invest, typically up to US\$8 million for selected projects.

3. Invest in a Pilot Fund for Novel Antimicrobials

- An initial investment of **\$250,000** would enable AAMRNet to scope and design a model for an innovative reimbursement pilot program for novel antimicrobials fit-for-purpose for the Australian market.
- The investment would leverage existing work being done by the Australian Government Department of Health, as well as the expertise and networks of AAMRNet. It would also align strongly with a key recommendation of the Standing Committee on Health Aged Care and Sport’s report; *The New frontier – Delivering better health for all Australians*.
- The model would be developed in collaboration with AAMRNet and would consider relevant aspects of models being explored internationally, such as the UK’s de-linked approach where reimbursement is not linked to the value of the antimicrobials sold, but rather to their broader value to society.
- The pilot fund would provide access, and support the appropriate use of novel antimicrobials for clinicians to prescribe to the right patient at the right time. It would also encourage investment in AMR R&D and would demonstrate Australia’s leadership in the face of a looming global health crisis.

ABOUT ANTIMICROBIAL RESISTANCE (AMR)

AMR occurs when bacteria, parasites, viruses, or fungi change to protect themselves from the effects of the antimicrobial drugs that are designed to destroy them. It has been described by the Centers for Disease Control and Prevention (CDC) as “one of the biggest public health challenges of our time”¹⁰ and the WHO has cautioned that it is possible that a “post-antibiotic era” may be coming, where minor infections – currently easily treated with common antibiotics – may become deadly¹¹.

¹⁰ <https://www.cdc.gov/drugresistance/index.html>

¹¹ World Health Organization. 2014. Antimicrobial Resistance Global Report on Surveillance. https://apps.who.int/iris/bitstream/handle/10665/112642/9789241564748_eng.pdf;jsessionid=FAA9126AD29D83C9BD29A1B8EA167FD8?sequence=1

The Australian Group on Antimicrobial Resistance (AGAR) described AMR as “...a risk to patient safety because it reduces the range of antimicrobials available to treat infections. It also increases morbidity and mortality associated with infections caused by multidrug-resistant organisms. AMR may also limit future capacity to perform medical procedures such as organ transplantation, cancer chemotherapy, diabetes management and major surgery because of a lack of effective antimicrobials”¹².

AMR is on track to claim 10 million lives per year globally and put at risk a cumulative US\$100 trillion of economic output if no action is taken by 2050¹³. In Australia, the estimated annual impact of AMR on the economy by 2050 will be between \$142 - \$283 billion¹⁴. A recent Australian study showed that an increase in resistance to GP prescribed first line antibiotics from 21 to 50 per cent could see annual healthcare costs relating to urinary tract infections increase from \$1.1 - A\$1.6 billion by 2030¹⁵.

Serious concern exists that AMR may worsen due to the COVID-19 pandemic. A US multicentre study reported that 72 per cent of COVID-19 patients received antibiotics even when not clinically indicated¹⁶ and antibiotic use was shown to be very high (91.3 per cent) in patients with COVID-19 admitted to intensive care/high dependency units¹⁷.

Drug resistant infections are a growing and silent pandemic and combatting this threat will require a long-term global One Health approach that includes ensuring a robust pipeline of novel antimicrobials, as highlighted in Australia’s National Antimicrobial Resistance Strategy – 2020 and Beyond¹⁸, the USA National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025¹⁹ and The Wellcome Trust’s report on “The Global Response to AMR”²⁰.

The world is recognising and responding to the threat as demonstrated by the aforementioned G7 statement and numerous global and regional AMR-related alliances. These are public-private partnerships involving industry, government and not-for-profit organisations and include CARB-X, the Global Antibiotic R&D Partnership (GARDP), the Foundation for Innovative New Diagnostics (FIND) and the AMR Action Fund, a partnership of over 20 leading biopharmaceutical companies which expects to invest more than US\$1 billion to bringing 2-4 new antibiotics to patients by 2030.

¹² Australian Group on Antimicrobial Resistance; Sepsis Outcome Programs, 2018 Report

¹³ Tackling drug-resistant infections globally. The Review on Antimicrobial Resistance Chaired by Jim O’Neill. (2016). https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

¹⁴ Superbugs to trigger our next global financial crisis, OUTBREAK consortium (2020)

¹⁵ OUTBREAK consortium. A One Health antimicrobial resistance economic perspective (2020). Sydney, Australia: UTS

¹⁶ GARDP. Learning from COVID-19 to Tackle Antibiotic Resistance (2020). <https://gardp.org/uploads/2020/11/GARDP-Learning-COVID19-Tackle-AMR-En.pdf>

¹⁷ MTPConnect. 2020. ‘Fighting Superbugs: A Report on the Inaugural Meeting of Australia’s Antimicrobial Resistance Stakeholders’

¹⁸ Australia’s National Antimicrobial Resistance Strategy – 2020 and Beyond, Publications Number: 12589 <https://www.amr.gov.au/news/australias-national-antimicrobial-resistance-strategy-2020-and-beyond>

¹⁹ USA National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025 (Oct 2020) <https://aspe.hhs.gov/pdf-report/carb-plan-2020-2025>

²⁰ The Wellcome Trust. The Global Response to AMR. Momentum, success, and critical gaps. November 2020 <https://wellcome.org/reports/global-response-amr-momentum-success-and-critical-gaps>

FUNDING REQUEST IN DETAIL

1. Ensure the sustainability of AAMRNet through the provision of new funding

AAMRNet is a collaboration of leading stakeholders committed to addressing the impact of AMR on human health. Its members and stakeholders include universities, not-for-profits, researchers, SMEs and large multinational companies, industry peak bodies, clinicians, patients, government, and regulators. As the only body in Australia able to provide whole-of-sector representation, AAMRNet is uniquely placed to promote Australia's role in the fight against AMR and help inform government priorities and strategies.

MTPConnect has supported the establishment and operations of AAMRNet through a commitment of \$300,000 from its Growth Centres Project Fund Program. This, combined with matched funds from industry partners of over \$400,000, will support the activities of AAMRNet until 30 June 2023. This commitment demonstrates significant opportunity for government to leverage any future funding of AAMRNet with existing industry funds obtained via membership fees.

AAMRNet aligns its activities closely with current Australian Government priorities. Including:

- The National Preventive Health Strategy, which identifies AMR as an emerging threat where Australia may wish to increase its preparedness.
- The National Manufacturing Priorities, which includes medical products.
- The Medical Research Future Fund (MRFF), which describes the need for collaborative, multidisciplinary research in AMR, "critical".
- The National AMR Strategy, which outlines seven objectives to address AMR, including greater engagement and collaboration.
- The Department of Industry Science Energy and Resources (DISER) Industry Growth Centre Initiative by working, as it relates to AMR, to:
 1. optimise the regulatory and clinical trials environment,
 2. boost commercialisation through increasing collaboration,
 3. improve access to global alliances, supply chains and markets,
 4. improve management and workforce skills.

AAMRNet is taking significant action on delivering on its strategic priorities to combat AMR. Current actions include:

1. In collaboration with DMTC and Biointelect; undertaking an audit of Australian AMR R&D capability,
2. in collaboration with CSIRO, scoping the establishment of a potential Australian AMR focused accelerator,
3. in collaboration with CSIRO, developing a report on how we better measure the real impact of AMR on mortality in Australia,
4. the formation of a working group on pricing and reimbursement to consider new and innovative funding models and ways of better valuing antimicrobials to support patient access, incentivising R&D, translation, and commercialisation, and,
5. working to develop a report on the impact of AMR on indigenous and remote populations.

These activities have relied largely upon goodwill and existing industry funding as the formation of the steering committee, development of strategy and agreement of the terms of reference have not been resource intensive. However continued rollout of the work program, including stakeholder engagement, communications, outreach and education, and policy development, will be resource and time intensive.

Membership fees will cover some expenses but as there are few industry participants with significant financial capacity. Maximising the full potential of AAMRNet, and leveraging the existing funds provided through MTPConnect, will require additional external funding.

AAMRNet has demonstrated efficient and judicious use of funds to achieve significant milestones. This has been done through in-kind contributions from motivated supporters and partners. Projects undertaken by AAMRNet that require funding undergo robust screening. Proposals by members and partners are assessed and prioritised by a diverse steering committee chaired by MTPConnect and comprising leading Australian AMR experts, ensuring expenditure aligns with the aims, objectives, and priorities of AAMRNet as outlined in the terms of reference.

Building on MTPConnect's achievements as a trusted and independent voice to inform government on key issues, challenges and opportunities, AAMRNet has demonstrated it has the skills, knowledge and experience to provide advice to the Australian Government; through policy submissions, providing evidence to the Parliamentary inquiry into approval processes for new drugs and novel medical technologies, assisting the Department of Health with nominations to the AMR Youth Ambassador network and providing the sector with a "one-stop-shop" for engagement and communication on AMR - all within its first year.

With Australian Government funding for the Industry Growth Centre Initiative set to end at the end of Financial year 2022-2023, additional funding for AAMRNet is required to ensure it can continue to deliver on its ambitious workplan, provide advice on AMR to the Australian Government, and be the co-ordinated voice for action on AMR as it relates to human health in Australia.

2. Establish an AMR focused Accelerator in Australia

Early-stage R&D at research and academic institutions is supported by current government research funds, including specific funding for AMR by agencies administering the Medical Research Future Fund (MRFF) and less so by the National Health and Medical Research Council (NHMRC). However, while connections between the research sector and industry are improving, closer collaboration would facilitate product development, capture the value of the investment in the research, and position Australia as a global leader in AMR research.

AAMRNet is partnering with CSIRO to scope the establishment of an Australian AMR accelerator with the aim to be fully endorsed by CARB-X and integrated into its global network, which includes accelerators in India, Germany, the UK and the USA. CARB-X has written to the Minister for Health and Aged Care confirming its intention to integrate the proposed Australian accelerator into its network should the Australian Government support the initiative. CARB-X accelerators are designed to provide scientific, technical, and business support to CARB-X-applicants and funded product developers, with the accelerator network acting as a one-of-a-kind source of knowhow and expertise in antibacterial drug development, diagnostics, business strategy and other areas essential to supporting early development research projects. Importantly the Australian accelerator would be the only CARB-X endorsed accelerator in the Western Pacific Region, expanding Australia's international AMR profile and connections.

In addition, the proposed accelerator would provide assistance and advice to Australian organisations looking to access other sources of overseas funding such as the Novo Repair Fund, AMR Action Fund, and others.

Australian Government support of the proposed AMR Accelerator would further leverage not only the work AAMRNet is doing with CSIRO on scoping a potential accelerator, but also the additional work it is doing with DMTC and Biointelect to audit Australia's capabilities in AMR R&D. The audit is critical, as whilst it is widely known that Australia has high-quality research capabilities, and that many Australian universities and SMEs are actively pursuing AMR research, there is a lack of co-ordination of this research. To maximise the impact of these efforts, a means of better connecting AMR knowledge generators, knowledge investors and knowledge users is urgently needed, and a national capability audit that maps Australia's AMR R&D

stakeholders, capabilities, workforce, funding support, and opportunities for collaboration is an important first step to strengthening AMR R&D in Australia. A publicly accessible dashboard for researchers, public health organisations, and public and private funders and investors (from Australia and globally) aligned with the existing Global AMR R&D hub, would add significant further value to the audit, enabling the ability to follow current strengths in Australia’s AMR R&D pipeline and ensuring visibility of Australian AMR R&D for attracting funding and investment from beyond our shores.

The impact of an Australian AMR accelerator would include:

- The creation of at least two high-value jobs; the Accelerator would employ two to three people who could mentor and guide Australian applicants to overseas funding opportunities, and promote Australian R&D capabilities to international organisations looking to access Australian expertise and infrastructure, including clinical trials capabilities. These accelerator employees would have experience in the development and commercialisation of AMR products, and an ability to integrate into CARB-X investment processes should the accelerator be endorsed by CARB-X and incorporated into its global network.
- Greatly improved likelihood of success for Australian applicants for overseas funding opportunities including CARB-X grants (up to A\$15 million per project); there have been approximately 12 Australian-based applications to CARB-X but only the relatively recent University of Queensland (UQ), and Speedx applications have been successful. A CARB-X endorsed Australian AMR accelerator will increase this ratio of success by improving the quality of submissions and we would expect that CARB-X would fund at least two projects per year in Australia (approximately A\$2-3million p.a. per project).
- Facilitation of Foreign Direct Investment (FDI); a major goal for the Accelerator would be to promote Australian fee-for-service capabilities to overseas companies seeking drug screening, pre-clinical and clinical development of novel therapeutics, diagnostic development, anti-bacterial vaccine R&D, and other support and expertise that is available in Australia. We believe the value of these FDI projects could be in the order of A\$10-20 million over three years including overseas companies conducting their Phase 1 clinical trials in Australia.
- Integration of the Community for Open Antimicrobial Drug Discovery (CO-ADD) into the operations of the Accelerator, providing practical and validated antimicrobial testing support to Australian applicants for overseas funding and investment. CO-ADD is internationally recognised for helping develop new antibiotics and is included on the Global AMR R&D Hub Dashboard alongside programs such as CARB-X and IMI ENABLE. It is operated out of the same UQ group that received CARB-X funding, so would ensure that Australian applicants had the appropriate type and quality of antimicrobial data required to meet the evaluation by the CARB-X review panel. Furthermore, CO-ADD has recently taken over the Shared Platform for Antibiotic Research and Knowledge (SPARK), a global antibiotic knowledgebase established by the Pew Charitable Trusts, so could help facilitate open access sharing of Accelerator data.
- Development of a publicly accessible dashboard for researchers, public health organisations, and public and private funders and investors (from Australia and globally) to follow current strengths in Australia’s AMR R&D pipeline as it relates to human health. This dashboard data could be aligned with the existing [Global AMR R&D hub](#), ensuring visibility of Australian AMR R&D for attracting funding from beyond our shores. The funding would also enable the dashboard to be maintained by AAMRNet for 3 years.

An investment by the Australian Government of **\$1.8 million** over three years in an Australian AMR focused accelerator would leverage the work that AAMRNet is already doing in its collaborations with CSIRO, DMTC and Biointelect, and could generate a significant return to the Australian economy. Including potentially more than \$50 million over five years in overseas sourced funding to Australian biotech companies and research groups, and potentially \$10-20 million in FDI from companies seeking to access Australia’s deep

capabilities in AMR R&D. In addition, it is expected that each additional Australian-based CARB-X award enabled by the Accelerator could fund over four researchers for up to 5 years, building Australia’s capability and capacity in AMR research.

3. Invest in a Pilot Fund for Novel Antimicrobials

AAMRNet is proposing the Australian Government allocate sufficient funding to develop and implement an innovative reimbursement pilot program for novel antimicrobials for the Australian market. An initial investment of **\$250,000** would enable AAMRNet to scope and develop a model for the pilot.

This is a unique opportunity for government, clinicians, researchers, and industry to work together on practical solutions for a pressing health issue. A simple, pragmatic approach can be found which would signal Australia’s commitment to tackling the growing threat of AMR and ensuring we are at the cutting edge of this effort globally.

AAMRNet would leverage the expertise and networks of its supporters and partners to bring together key relevant stakeholders to consider options for adapting international exemplars to design a model for a pilot fit for purpose for Australia.

Why a new funding model is needed

DRIVE-AB (Driving Re-InVEstment in R&D and responsible AntiBiotic use) was a public-private, collaborative multinational consortium funded by the European Innovative Medicines Initiative to recommend options to stimulate innovation and responsible use while ensuring global access to novel antibiotics to meet public health needs. Its final report highlighted that “new economic models that create incentives for the discovery of new antibiotics and delink the return on investment from volume of sales are long overdue”²¹.

Australia, like other countries, has multiple challenges facing companies that invest in the development of novel antimicrobials:

- Uptake of novel antimicrobials is slow as they are typically held in reserve by healthcare practitioners until resistance to older treatments has emerged. This immediately limits the usage of a new product and the recouping of any research and development costs.
- There is no nationally consistent reimbursement system for antimicrobials in Australia. There are multiple payers with regard to novel antimicrobials and the payer will depend not only on the PBS status of the drug, but also on individual patient circumstances. For example, State Governments will bear the cost of treatment for public hospital inpatients. In the private hospital system however, the cost could be borne by the patient, the insurance company, the hospital, or the Federal Government when the antimicrobial is listed on the PBS and prescribed in accordance with PBS restrictions.
- The need for hospitals to manage their budgets means that the use of novel antimicrobials can be discouraged for financial reasons, even when they may be a more clinically appropriate treatment for a patient than a generic antimicrobial²².
- Novel antimicrobials are generally undervalued by reimbursement systems relative to the benefits they bring to society as indispensable, life-saving drugs. This is because of the existence of low-cost, often generic comparators which are still effective for many but not all infections, and the inherently narrow focus of health technology assessment (HTA) on direct health costs and benefits. While it may be appropriate for most therapies to maintain that narrow focus, the societal benefits

²¹ DRIVE-AB, Novel business models needed to revive reinvestment in antibiotics
http://drive-ab.eu/wp-content/uploads/2015/07/Novel-business-models-needed-to-revive-reinvestment-in-antibiotics_Ursula_Biotechnology-Journal.pdf

²² Bhatti, T et,al 2018, A Perspective on Incentives for Novel Inpatient Antibiotics: No One-Size-Fits-All, Journal of Law, Medicines and Ethics, p60

of having a supply of novel antimicrobials requires a broadening of the HTA perspective. Indirect costs, such as delays in surgical procedures for patients with AMR, need to be considered in estimating the value of new antibiotics. Additionally, longer term direct health costs associated with development of complications of AMR, such as patient readmissions to hospital and extended lengths of hospitalisation need to be considered in HTA.

- Precision medicine is more important than ever in antimicrobial therapy but is powerfully disincentivised by regulatory processes based on clinical indications. Developing a precise therapy for a specific bacterial pathogen is economically unattractive but is necessary to control the collateral selection pressure that is driving AMR development.

New funding approaches in the UK, Sweden and the US provide exemplars for Australia to consider

In order to stimulate the ‘broken market’ a new approach to funding is urgently needed. The UK recently launched a pilot program using a ‘de-linked’ model in which companies are paid an annual subscription fee to supply as much or as little of an antimicrobial as required. This results in more predictable revenue for the manufacturer and coverage for the health system in the event of disease outbreaks. In other words, companies are paid for antimicrobials based on their expected value to the health system, as opposed to the actual volume used.

In Sweden, a new reimbursement model is being piloted which aims to ensure the availability of new antibiotics of special medical value. Pharmaceutical companies that enter into contracts and fulfill the requirements for availability will be guaranteed a certain annual income at the national level. Regions will continue to buy and pay as usual for the products. If the actual income from regions to the companies is lower than the guaranteed income for a given year, the difference will be paid from the national level. If, on the other hand, revenue from the sales exceeds the guaranteed level for a given year, the company received 10 per cent of the value of the guaranteed annual compensation for fulfilling availability requirements.

In the US, the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (Pasteur) Act also proposes a model that would provide market incentives for life-saving antimicrobial therapies. Under this Act, the US government would provide a subscription payment similar to the UK model, but larger (proportionate to the relative size of the US economy) and based on clear Target Product Profile characteristics rather than the HTA used by the National Institute for Health and Care Excellence (NICE). Antibiotic developers would be paid annual, contractually agreed amounts for a duration ranging up to the antimicrobial’s patent life. The government would offer developers an upfront payment for access to their eligible antimicrobial and would consider the clinical need and novelty of the therapy. Under this proposal, patients in the US insured by national payer plans (Medicare or Medicaid) would have access to Pasteur Act antimicrobials at no additional cost to the government. The PASTEUR Act would also provide education on stewardship to facilitate appropriate use of new antimicrobials. A decision on the Act is expected before the end of 2022.

Elements of all these new approaches could be considered for possible incorporation into an Australian pilot.

A Pragmatic Valuation Approach

Countries around the world are looking at how to tackle the challenge of bringing novel anti-infectives to market. The UK has already spent several years developing a workable model to determine the expected value²³ which takes into account their full value to society, including spectrum value, transmission value, enablement value, diversity value and insurance value (STEDI). This work is ongoing, as they acknowledge the need for balance between the difficulty of the task, the complexity of the modelling required and the

²³ Rothery, C., Woods, B., Schmitt, L., Claxton, K., Palmer, S., Schulper, M., 2018, *Framework for Value Assessment of New Antimicrobials. Implications of alternative funding arrangements for NICE Appraisal*. EEPURU, Policy Research Unit in Economic Evaluation of Health & Care Interventions, viewed 17 December 2019 <<http://www.eepru.org.uk/wp-content/uploads/2017/11/eepru-report-amr-oct-2018-059.pdf>>

use of expert opinion. Australia, through AAMRNet, could consider these developments and how these might be pragmatically adapted for use within Australia's HTA processes.

A recent report which reviews the available data on the burden of AMR estimates that \$10 million per year would be appropriate to fund a novel antimicrobial for a pilot in Australia²⁴.

Proposed principles for an Australia pilot

The following principles could be considered for inclusion in an Australian pilot.

1. The pilot could use the **de-linked model** whereby an annual subscription fee is paid regardless of the amount of antimicrobial used.
2. The pilot should be **jointly supported by the Australian and State and Territory Governments**. The National Blood Authority provides an example of a joint funding model.
3. The pilot could be reserved for up to five drugs which treat organisms for which the impact of resistance is high in the hospital setting. For example, carbapenem-resistant *Pseudomonas aeruginosa* is a priority 1 pathogen according to the WHO²⁵ and is a major emerging AMR threat in Australia²⁶. Novel antibiotics to treat this pathogen are available but they are expensive compared to cheaper generic options so can be under-used, even when they are the most appropriate choice.
4. The pilot should ensure **equity of access** to the chosen drugs across metropolitan, regional, rural and remote Australia, in all states and territories.
5. The pilot should support **the AMS principle of using the right drug for the right patient**, for the right organisms, at the right dose, at the right time, so that usage is always based on clinical need and appropriate use rather than the cost of an antibiotic.
6. The pilot should recognise the **broader social value** of making novel antibiotics available, including the STEDI values, while at the same time preserving their use according to AMS principles.
7. The pilot should act as a signal to industry that the government is willing to create **a stable market for novel antimicrobials**.
8. The pilot should establish **Australia as an AMR policy leader** by providing an example for other countries to follow to help address the growing, global threat of AMR.
9. Metrics should be developed and aligned on across all stakeholders to measure the outcomes of the pilot, such as hospitalization/ healthcare costs in the respective region. The outcomes will help to refine, if needed, the design of the pilot moving forward.
10. The pilot should support international efforts through bodies like the G7, G20 and Global Leaders Group on AMR to assist in establishing environmental standards for the manufacture of antibiotics through incentives and standards in the purchasing and reimbursement of antibiotics by the Australian and State and Territory Governments.

The short-term benefit of such a pilot is that up to five novel antibiotics could be available for clinicians to prescribe to the right patient at the right time with no budget constraints.

The long-term benefit of such a pilot is that it would send a strong signal to the market that there is a reliable return for investing in research and development decisions and would also set an example for other countries to do the same.

²⁴ Health Technology Analysts 2020, Federal Fund for Novel Antimicrobials

²⁵ <https://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en/>

²⁶ Williamson, Deborah. A., Howden, Benjamin P., Paterson, David L., 2019, *The risk of resistance: what are the major antimicrobial resistance threats facing Australia?* Medical Journal of Australia

AAMRNet is committed to working with government to help re-stimulate the market for these crucial therapies and is most appropriate due to the combined national and international expertise of its members and stakeholders.

ABOUT AAMRNET

AAMRNet, Australia's first Antimicrobial Resistance network, was launched on 24 September 2020. It is an industry-led, inclusive collaboration of stakeholders, all committed to addressing the impact of antimicrobial resistance (AMR) on human health. In response to a key recommendation of the report, "Fighting Superbugs"²⁷ AAMRNet was established and is operated by MTPConnect with the support of Pfizer ANZ, CSIRO, MSD Australia, GSK Australia, Botanix Pharmaceuticals, Recce Pharmaceuticals, SpeeDx, Biointelect, Monash Centre to Impact AMR and Medicines Australia. AAMRNet provides a unified voice to support and promote Australia's role in the global fight against the growing threat of drugs resistant infections.

To successfully combat AMR, collaboration is crucial, and the key stakeholders are many and varied. AAMRNet includes and engages with key relevant Australian and global stakeholders across the health and medical research sector, the biotechnology and pharmaceutical industry, clinicians, government, and regulators. The result is the only Australian network that links all these key stakeholders together.

AAMRNet is guided by a steering committee co-chaired by Dr Dan Grant and Andrew Bowskill from MTPConnect and comprising experts from industry and academia including Professor David Paterson from The University of Queensland Centre for Clinical Research, David Grolman from Pfizer ANZ, Paul Field from GARDP, Julie Phillips from Opal Biosciences, Professor Geoff Coombs from the Australian Society for Antimicrobials, Jenny Herz from Biointelect, Simon Jessup from MSD Australia and Elizabeth de Somer from Medicines Australia.

AAMRNet is ideally placed to work closely with the Australian Government to deliver progress on its commitment to combat AMR.

For further information in relation to this submission please contact:

Andrew Bowskill, Co-Chair AAMRNet
MTPConnect Director of Stakeholder Engagement for Queensland
Level 7, 37 Kent Street, Woolloongabba QLD 4102
Telephone: +61 423 644 044
Email: andrew.bowskill@mtpconnect.org.au

²⁷ MTPConnect. 2020. 'Fighting Superbugs: A Report on the Inaugural Meeting of Australia's Antimicrobial Resistance Stakeholders'



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MedTech and Pharma Growth Centre

CONTACT US FOR FURTHER INFORMATION

PHONE	+61 3 9070 8298
EMAIL	info@mtpconnect.org.au
HEAD OFFICE	Ground floor, Suite 2 155 Cremorne Street Cremorne VIC 3121 Australia <small>See our website for other locations</small>

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