Australian Antimicrobial Resistance Network (AAMRNet)
2021-2022 Pre-Budget Submission, January 2021.

EXECUTIVE SUMMARY

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

The network was established on 24 September 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 industry contributions provided by:

- Pfizer ANZ
- MSD Australia
- GSK Australia
- Botanix Pharmaceuticals
- Medicines Australia
- Monash Centre to Impact AMR

Additional AAMRNet partners include:

- DMTC Limited
- Global Antibiotic R&D Partnership Foundation (GARDP – Switzerland)
- AusBiotech Ltd
- Roche Diagnostics Australia
- Menzies School of Health Research
- Formulytica Pty Ltd
- Epichem Pty Ltd
- 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. 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 A$142 billion and A$283 billion[2]. 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 2050[3].

[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. (22016). https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

The World Health Organisation (WHO) has said that the global pipeline of antimicrobials is insufficient to tackle the increasing challenge of AMR[4]. Incentives are clearly required to support new discovery, early clinical trials and, for medicines that show promise, suitable reimbursement assessment.
Australia's *National Antimicrobial Resistance Strategy – 2020 & Beyond*[5] has identified a range of priorities to help slow the development of AMR.

AAMRNet is uniquely placed to drive some of these priorities and is advocating for a seed investment of $2.8 million in three specific areas to support the National Strategy and initiate direct actions to combat the critical public health issue of AMR.

1. Conduct a National Capability Audit for AMR Research and Development

- An investment of **$800,000** for a capability audit to map Australia's existing research and development (R&D) capability in AMR, which AAMRNet would deliver in 2021.
- The Audit would focus on diagnostics, surveillance and novel/repurposed antimicrobials and associated technologies. It would scope strengths and weakness and pave the way for novel product development and regional and international collaboration.
- The results of the audit would inform the development of a *National AMR One Health Research and Development Agenda* which was foreshadowed in the Federal Government FY21 Budget.
- A key output of this investment is the 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. This dashboard data could be aligned with the existing Global AMR R&D hub, https://dashboard.globalamrhub.org/reports/investments/overview, 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.

2. Establish a CARB-X Accelerator in Australia

- An investment of **$1.5 million** over three years would enable AAMRNet to establish and operate a CARB-X (Combating Antibiotic-Resistant-Bacteria)[6] accelerator in Australia. 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.
- This investment could generate a significant return to the Australian economy, including potentially more than A$50 million over 5 years in CARB-X grants to Australian biotechnology companies and research groups and potentially A$10-20 million in foreign direct investment (FDI) from companies seeking to access Australian expertise and infrastructure for the development of AMR tools such as Phase 1 clinical trial capabilities.
- An Australian CARB-X accelerator would work with local small and medium enterprises (SMEs), research institutes and universities to craft high quality applications for CARB-X funding and support successful projects. We anticipate each additional Australian-based CARB-X award enabled by the

[4] World Health Organisation, (2019), 2019 Antibacterial Agents in Clinical Development – An analysis of the antibacterial clinical development pipeline
[5] Australia's National Antimicrobial Resistance Strategy – 2020 and Beyond, Australia's National Antimicrobial Resistance Strategy - 2020 and Beyond | Antimicrobial resistance (amr.gov.au)
[6] www.carb-x.org

Accelerator could fund over four researchers for up to five years, building Australia's capability and capacity in AMR research.

3. Invest in a Pilot Fund for Novel Antimicrobials

- AAMRNet proposes that the Australian Government allocate **$500,000** to scope and establish a model for an innovative reimbursement pilot program for novel antimicrobials for the Australian market, including the establishment of a Rapid Task Force to consider options for adapting international exemplars to the Australian context.

- New antimicrobials are urgently needed to treat drug-resistant infections and slow the growing threat of AMR, but the broken market for antimicrobials means that there is little incentive for companies to invest in this type of research and development.
- Novel reimbursement approaches are needed to stimulate investment to ensure a continuing pipeline of novel therapies.
- The model would be developed in collaboration with the AAMRNet and would consider relevant aspects of models being explored internationally, such as the United Kingdom's de-linked approach, whereby 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"[7] 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 deadly[8].

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 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"[9].

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 2050[10]. In Australia, the estimated annual impact of AMR on the economy by 2050 will be between A$142 billion and A$283 billion[11]. A recent Australian study showed that an increase in resistance to GP prescribed first line antibiotics from 21 - 50 per cent could see annual healthcare costs relating to urinary tract infections increase from A$1.1 billion to A$1.6 billion by 2030[12].

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 indicated[13] and antibiotic use was shown to be very high (91.3 per cent) in patients with COVID-19 admitted to intensive care/high dependency units[14].

Drug resistant infections are a growing and silent pandemic and combating this threat will require a long-term global One Health approach that includes ensuring a robust pipeline of development of novel antimicrobials, as highlighted in Australia's National Antimicrobial Resistance Strategy – 2020 and Beyond[15], the USA National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025[16] and The Wellcome Trust's report on "The Global Response to AMR"[17].

The world is responding to the threat through 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 newly announced 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.

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[7] https://www.cdc.gov/drugresistance/index.html
[8] 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
[9] Australian Group on Antimicrobial Resistance; Sepsis Outcome Programs, 2018 Report
[10] Tackling drug-resistant infections globally. The Review on Antimicrobial Resistance Chaired by Jim O'Neill. (22016). https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf
[11] Superbugs to trigger our next global financial crisis, OUTBREAK consortium (2020)
[12] OUTBREAK consortium. A One Health antimicrobial resistance economic perspective (2020). Sydney, Australia: UTS
[13] GARDP. Learning from COVID-19 to Tackle Antibiotic Resistance (2020). https://gardp.org/uploads/2020/11/GARDP-Learning-COVID19-Tackle-AMR-En.pdf
[14] MTPConnect. 2020. 'Fighting Superbugs: A Report on the Inaugural Meeting of Australia's Antimicrobial Resistance Stakeholders'
[15] 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
[16] USA National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025 (Oct 2020) https://aspe.hhs.gov/pdf-report/carb-plan-2020-2025
[17] 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

1. CONDUCT A NATIONAL CAPABILITY AUDIT FOR AMR RESEARCH AND DEVELOPMENT

Australia has high-quality research capabilities, however there is a lack of co-ordination of AMR research, particularly into novel antimicrobials, diagnostics and surveillance.

Since the time of Howard Florey, Australia has been a strong contributor to global antimicrobial research. The Australian AMR R&D ecosystem produces high quality research, a skilled R&D workforce and entrepreneurial talent. However, a lack of accessible and connected information about our R&D capabilities and expertise between knowledge generators, knowledge investors and knowledge users throughout the pipeline is slowing collaborative efforts and reducing leveraging opportunities.

The '*WHO Global Action plan on antimicrobial resistance 2015'*[18] and *'Australia's National Antimicrobial Resistance Strategy: 2020 and beyond*'[19] aim to tackle AMR by strengthening knowledge and evidence base through surveillance and research and by increasing investment in new medicines, diagnostic tools, vaccines and other interventions and improving AMR communication, education and training.

AMR R&D stakeholders in Australia have heeded this call. Universities, medical research institutes, SMEs, hospitals, public health organisations and industry are recognising the need for coordinated action through networks such as AAMRNet. These stakeholders seek to collaborate, coordinate and leverage AMR R&D synergies. However, efforts are hampered by an ill-defined landscape of AMR R&D capabilities, expertise and research workforce. A comprehensive audit of Australia's current research capabilities in new diagnostics, surveillance, preclinical models, new antimicrobial materials and technologies, and social and communication research has not been conducted. Interactions between AMR knowledge generators and knowledge users are piecemeal and rely on network contacts. Investors lack ready access to information about what new diagnostic technologies and antimicrobials are being researched and their technology readiness levels. For SMEs in sectors as diverse as advanced manufacturing and food and agriculture, a failure to access antimicrobial expertise can be detrimental to their R&D programs. Pharmaceutical and biotechnology companies express difficulties in accessing specialised preclinical models in which to test new technologies[20]. This is a convergence point for them and fundamental researchers.

Many Australian universities are actively pursuing AMR research, much of which goes beyond the search for the next drug and drug stewardship. This 'next gen' AMR research seeks to develop new diagnostic technologies, novel antimicrobials such as phage and nano-surfaces and new therapeutic strategies such as precision-personalised artificial intelligence (AI) modelled dosing and drug repurposing. Another exciting frontier in 'next gen' AMR research are approaches that reverse AMR evolution, with the potential to extend the useful lifetime of current drugs, enabling increased return on investment. Research into social and behavioural drivers of AMR, as well as enhanced surveillance in clinical and environmental settings such as water and agriculture are also recognised by AMR stakeholders as essential to supporting AMR policy and technology innovation and implementation. However, ready access to R&D pipeline knowledge has been hampered due to a lack of collective information about AMR R&D in Australia.

Industry and academia have also identified high risk but potentially game-changing fundamental discoveries which require greater public funding support to prevent 'shelving' and enable them to be developed to a

[18] No time to wait: securing the future from drug resistant infections- report to the secretary general of the United Nations April 2019
[19] Australia's National Antimicrobial Resistance Strategy - 2020 and Beyond Published 13 March 2020 https://www.amr.gov.au/resources/australias-national-antimicrobial-resistance-strategy-2020-and-beyond

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

point where they are de-risked enough to be commercially attractive to the biotechnology sector. We also know that access to specialised *in vivo, in vitro* and *in silico* preclinical models and expertise developed in early-stage research is a stage of the pipeline that could strengthen MTP sector AMR R&D.

To maximise the impact of Australia's AMR R&D efforts, a means of better connecting AMR knowledge generators, knowledge investors and knowledge users is urgently needed. A national capability audit that maps Australia's AMR R&D stakeholders, capabilities, workforce, funding support and opportunities for collaboration would be the first step to strengthening AMR R&D in Australia.

The benefits of a national AMR R&D capabilities audit are:

- provide a central repository of knowledge to AMR R&D stakeholders throughout the R&D pipeline, for effective and timely coordination of interests
- provide an understanding of R&D 'choke-points': knowledge/structural/funding barriers that prevent new antimicrobial knowledge making its way through the innovation pipeline
- improve ease and speed of collaboration and enable stakeholders to quickly uncover R&D synergies, expertise and duplication to speed and effectively direct R&D time, labour and money investment
- assist investors, decision and policy makers to align Australia's AMR R&D endeavours with the global R&D landscape and understand alignment to national strategies and action plans
- provide a model for AMR R&D leadership in the Asia Pacific region
- better understand more effective interactions between public and private funding of AMR innovations
- better understand Australia's current R&D workforce expertise and be mapped against the Asia Pacific region and global context, and identify workforce vulnerabilities
- Promote One Health collaboration through better recognition of the role of the R&D community
- Enable other stakeholders, such as the defence sector, to quickly ascertain antimicrobial capabilities for Chemical, Biological, Radiological and Nuclear (CBRN) responses.

An $800,000 investment would enable AAMRNet, with its broad sectoral and industry representation, to coordinate with key public and private stakeholders on a national capability audit of Australian AMR R&D. The Audit would be conducted over 6 to 12 months and comprise the following:

- a project initiation phase to agree scope approach and project governance
- a desktop research phase to identify key organisations and complete an initial mapping of capabilities and capacity by identifying existing funding streams, reviewing patents filed with IP Australia, relevant conference proceedings, consortia and working groups, and reviewing and cross-checking existing overviews of the AMR R&D landscape in Australia
- a capability audit using state-based focus groups, an online survey and interviews using a structured questionnaire to gather qualitative information on capabilities
- gathering of new data on key areas of interest including workforce, technology readiness, existing collaborations, research focus, access to funding, bottlenecks and challenges in AMR R&D, key contacts and specific defence-relevant capabilities, such as antimicrobial capabilities for CBRN responses
- the 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 AMR Australia's R&D pipeline. This dashboard data could be aligned with the existing Global AMR R&D hub, https://dashboard.globalamrhub.org/reports/investments/overview, 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 a period of 3 years.

2. ESTABLISH A CARB-X 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 leader in AMR research.

AAMRNet is proposing to establish a CARB-X accelerator in Australia that would be fully endorsed by CARB-X and integrated into its global network, which includes accelerators in India, Germany, the UK and four in the USA. CARB-X has written to the Minister for Health and Aged Care confirming their intention to integrate an 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 CARB-X's growing portfolio of 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.

The impact of an Australian accelerator would include;

- the creation of at least two high-value jobs; the Accelerator would employ two people with experience of antibacterial product development who could mentor and guide Australian CARB-X grant applicants, and promote Australian R&D capabilities to international CARB-X funding recipients
- greatly improved likelihood of success for Australian applicants for CARB-X grants (up to A$15 million per project); there have been approximately 12 Australian-based applications to CARB-X but only the recent University of Queensland (UQ) application was successful. A CARB-X 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)
- the 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 CARB-X applicants. 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 quality of data required to meet the evaluation by the CARB-X review panel.

An investment of $1.5 million over three years in an Australian CARB-X accelerator could generate a significant return to the Australian economy, including potentially more than A$50 million over five years in CARB-X grants to Australian biotech companies and research groups and potentially A$10-20 million in FDI from companies seeking to access Australia's deep capabilities in AMR R&D. In addition, 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 $500,000 to scope and establish a model for the pilot, including the establishment of a Rapid Task Force outlined below. The pilot would be developed in collaboration with AAMRNet.

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.

In the first instance, a Rapid Task Force (RTF) is needed to bring together relevant stakeholders to consider options for adapting international exemplars to the Australian context. The RTF would benefit from including the Australian Government (DoH), state departments of health, industry, public hospital infectious diseases experts, private health insurers and experts in health technology assessment. The RTF could consider payment models (including subscription type payment), selection criteria for pilot participation, health technology assessment needs and the processes by which these elements would be combined.

The following sections outline why a new approach is needed and some of the key concepts that could be covered in the proposal.

Why a new funding model is needed

DRIVE-AB, a public-private, collaborative multinational consortium that seeks to recommend options to stimulate innovation and responsible use while ensuring global access to novel antibiotics to meet public health needs, has 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 national reimbursement system for antimicrobials in Australia. They are purchased by individual hospitals and other healthcare organisations which can have constrained budgets.
- The need for hospitals to manage their budgets means that the use of novel antimicrobials can be discouraged, even when they may be a more appropriate treatment for a patient than a generic antimicrobial[22].
- Novel antimicrobials are generally undervalued by reimbursement systems relative to the benefits they bring to society as indispensable, life-saving drugs, because of the low-cost comparator, which is often generic.

[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

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.

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

In order to stimulate the 'broken market' a new approach to funding is required. 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. Elements of both these new approaches could be considered by the above RTF 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 value[23] which takes into account their full value to society, including transmission value, insurance value, diversity value, enablement value, novel action value and spectrum value. This work is ongoing, as they are trying to establish a balance between the difficulty of the task, the complexity of the modelling required and the 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 Australia (see Appendix A)[24].

Proposed principles for an Australia pilot

The following principles could be considered by the above Task Force for inclusion in an Australian pilot. They combine aspects from both the UK and the Swedish model.

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.

[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.* EEPRU, 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>

[24] Health Technology Analysts 2020, Federal Fund for Novel Antimicrobials

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 the WHO[25] and is a major emerging AMR threat in Australia[26]. 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, 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.

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.

[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

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 by MTPConnect with the support of Pfizer ANZ, MSD Australia, GSK Australia, Botanix Pharmaceuticals, Monash Centre to Impact AMR and Medicines Australia. AAMRNet aims to provide 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.

Since its formation, AAMRNet has been 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, Anne-Maree Englund from MSD Australia and Elizabeth de Somer from Medicines Australia.

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

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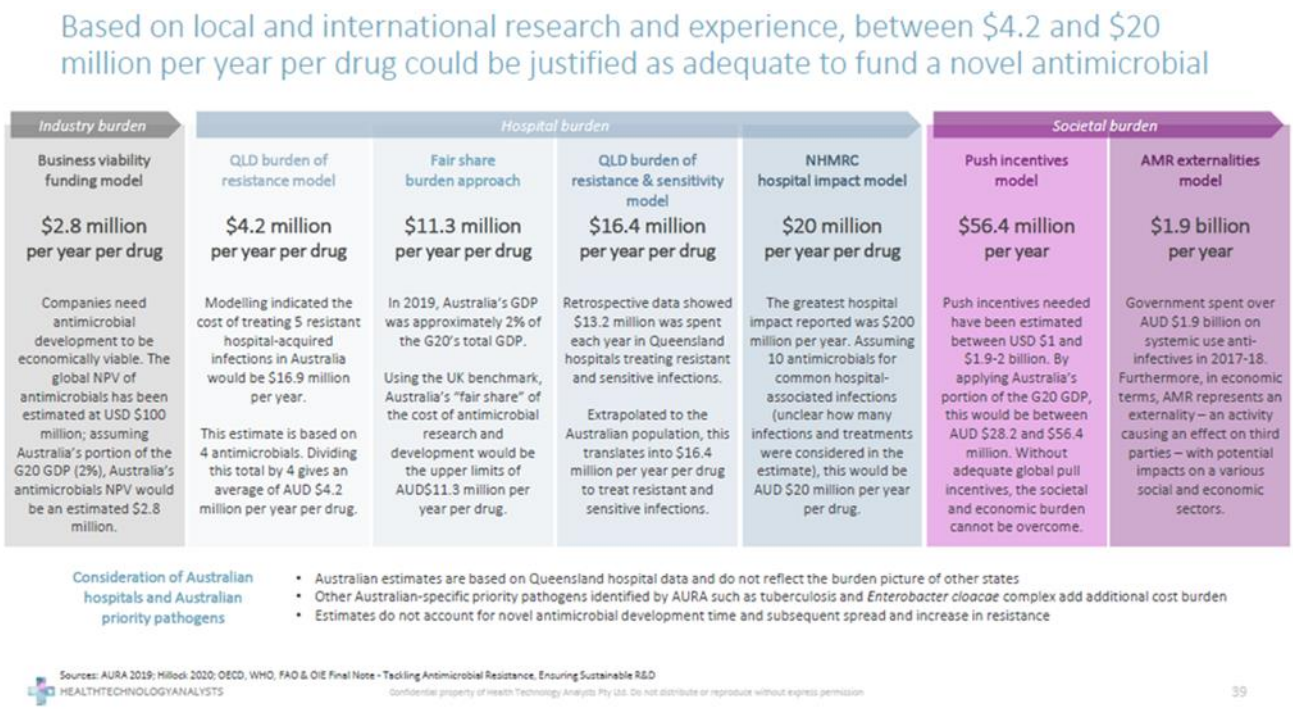
[27] MTPConnect. 2020. 'Fighting Superbugs: A Report on the Inaugural Meeting of Australia's Antimicrobial Resistance Stakeholders'

APPENDIX A


Based on local and international research and experience, between $4.2 and $20 million per year per drug could be justified as adequate to fund a novel antimicrobial
Industry burden
Hospital burden
Societal burden
Business viability funding model
$2.8 million per year per drug
Companies need antimicrobial development to be economically viable. The global NPV of antimicrobials has been estimated at USD $100 million; assuming Australia's portion of the G20 GDP (2%), Australia's antimicrobials NPV would be an estimated $2.8 million.
QLD burden of resistance model
$4.2 million per year per drug
Modelling indicated the cost of treating 5 resistant hospital-acquired infections in Australia would be $16.9 million per year.
This estimate is based on 4 antimicrobials. Dividing this total by 4 gives an average of AUD $4.2 million per year per drug.
Fair share burden approach
$11.3 million per year per drug
In 2019, Australia's GDP was approximately 2% of the G20's total GDP.
Using the UK benchmark, Australia's "fair share" of the cost of antimicrobial research and development would be the upper limits of AUD$11.3 million per year per drug.
QLD burden of resistance & sensitivity model
$16.4 million per year per drug
Retrospective data showed $13.2 million was spent each year in Queensland hospitals treating resistant and sensitive infections.
Extrapolated to the Australian population, this translates into $16.4 million per year per drug to treat resistant and sensitive infections.
NHMRC hospital impact model
$20 million per year per drug
The greatest hospital impact reported was $200 million per year. Assuming 10 antimicrobials for common hospital-associated infections (unclear how many infections and treatments were considered in the estimate), this would be AUD $20 million per year per drug.
Push incentives model
$56.4 million per year
Push incentives needed have been estimated between USD $1 and $1.9-2 billion. By applying Australia's portion of the G20 GDP, this would be between AUD $28.2 and $56.4 million. Without adequate global pull incentives, the societal and economic burden cannot be overcome.
AMR externalities model
$1.9 billion per year
Government spent over AUD $1.9 billion on systemic use anti-infectives in 2017-18. Furthermore, in economic terms, AMR represents an externality – an activity causing an effect on third parties – with potential impacts on a various social and economic sectors.
Consideration of Australian hospitals and Australian priority pathogens
• Australian estimates are based on Queensland hospital data and do not reflect the burden picture of other states
• Other Australian-specific priority pathogens identified by AURA such as tuberculosis and Enterobacter cloacae complex add additional cost burden
• Estimates do not account for novel antimicrobial development time and subsequent spread and increase in resistance
Sources: AURA 2019; Hillock 2020; OECD, WHO, FAO & OIE Final Note - Tackling Antimicrobial Resistance, Ensuring Sustainable R&D
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