



Australian Antimicrobial Resistance Network

Submission: Health Technology Assessment
Policy and Methods Review
Consultation 2

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Health Technology Assessment Policy and Methods Review, Consultation 2.

The Australian Antimicrobial Resistance Network (AAMRNet), Australia's leading multi-stakeholder expert group on antimicrobial resistance (AMR), welcomes the opportunity to respond to the options proposed in the Consultation options paper within section 4.2. Approaches to incentivise the development of products that address AMR.

1. HTA Fee exemptions for products that address AMR.

The Australian Antimicrobial Resistance Network (AAMRNet) welcomes the Committee's acknowledgement that the cost burdens associated with lodging reimbursement submissions can be a barrier to market entry. As such we are supportive of the inclusion of antimicrobial health technologies as a HTA fee exemption in regulations.

For maximum impact, AAMRNet stresses that the fee exemptions for antimicrobial health technologies must apply to all HTA processes that occur across the entire lifecycle of a technology, which, as described in the Australian Government Review of Health Technology Assessment in Australia (2009)¹ involve:

- horizon scanning to identify new and emerging health technologies for governments and health systems for planning purposes;
- market regulation to assess the intrinsic safety and performance of therapeutic goods, as intended for use by manufacturers;
- HTA for reimbursement to assess the comparative safety, clinical and cost effectiveness of health technologies being considered for subsidy; and
- post-market surveillance to monitor the impact of technologies in routine clinical use.

AAMRNet also notes the Committee specifying the inclusion of organisms on the WHO bacterial/fungal priority pathogen list as being a criteria for qualifying for fee exemption. Whilst we agree that the list provides an appropriate starting point, limiting it to this list could result in pathogens of particular concern to Australia and our region being overlooked. This may create delays in and barriers to accessing lifesaving treatments for those infections. For example, in 2023, reports of *Mycobacterium Ulcerans* (Buruli Ulcer) cases in Australia were the highest ever recorded, and the disease has just been discovered by Australian researchers to be transmitted by mosquito bites from hosts including Ringtail possums². Treatment requires use of rifampicin (10 mg/kg) and moxifloxacin (400 mg) daily for a minimum of eight weeks and treatment can be lifelong in some cases. If Australian clinicians had access to other antibiotics, treatment and patient outcomes for this disease may be improved.

¹ <https://www.health.gov.au/sites/default/files/documents/2022/03/review-of-health-technology-assessment-in-australia.pdf>

² <https://www.nature.com/articles/s41564-023-01553-1>

We note Section 5 of the Options paper proactively addressing areas of unmet clinical need and gaps in funded access as an opportunity to inform Australian and regional priorities to address AMR through increasing access to antimicrobial health technologies.

AAMRNet also commends the Committee for recognising that HTA fee exemptions for products that address AMR “...would be appropriate as part of a broader set of incentives and reforms.” As described in AAMRNet’s original submission to this Review, and acknowledged in the Committee’s Options Paper, there is a widely acknowledged market failure that makes investment in the development and commercialisation of new antimicrobials loss making. This market failure is hindering equitable access to, and the research and development of new antimicrobials. At the heart of this market failure, is a reimbursement system where uptake is required to support commercial viability. We know that for antimicrobials, uptake is actively and appropriately discouraged by antimicrobial stewardship practices which are crucial to protect their effectiveness.

HTA fee exemptions, whilst helpful and welcome, are not sufficient to overcome this challenge and therefore on their own clearly insufficient to solve the market failure. Combining HTA fee exemptions with the urgent implementation of a reimbursement system that fully delinks payments from volume of sales is the key to overcoming this market failure and improving access to new antimicrobials for Australians, at the same time preserving stewardship.

AAMRNet supports the introduction of HTA Fee exemptions that apply to all HTA processes that occur across the lifecycle of a technology for products that address AMR, as part of a broader set of incentives and reforms that also includes the urgent establishment of a new reimbursement model that fully delinks payments from volume of sales.

2. HTA Policy and Guidance changes for products that address AMR.

AAMRNet welcomes the Committee’s acknowledgement “...that the current general approach to the HTA evaluation and HTA Committee recommendations in respect of antimicrobial health technologies may not be sufficiently flexible to support timely access and appropriate levels of availability to address population health needs.” We welcome proposals to examine how targeted changes to HTA policy and methods, including through the application of the STEDI (Spectrum, Transmission, Enablement, Diversity, and Insurance) value framework, could be applied in practice in Australia.

AAMRNet supports the proposal of the workshopping of variations to the standard HTA evaluation approach for health technologies that address AMR as part of a prospective work program and would welcome the opportunity to participate in that process. However, the urgent threat posed by AMR to the lives and health security of Australians demands immediate action. We need to move beyond workshopping towards implementation and as such, we are concerned that this work could further delay access to new and much needed antimicrobials.

Australia has limited access to new antimicrobials, with only three of the 20 antimicrobials considered to be novel and listed in the US and/or the EU since 2011 currently registered for use in Australia. Any further delay in addressing this urgent unmet need puts the lives of Australians at risk from infections that are unable to be treated either in a timely manner, or at all. Therefore, the proposed workshop should be conducted in parallel with the urgent implementation of a fully delinked pilot subscription style reimbursement fund, and fee exemption for new antimicrobials in Australia, so as not to further delay equitable access to life-saving new antibiotics for Australians. This would also enable Australia to best leverage the work already done in the United Kingdom (UK) which has implemented a fully

delinked subscription style pilot reimbursement fund, setting the contract value at a level that reflects the principle of the UK paying its fair share of global pull incentive. The National Institute of Health and Care Excellence has since published its evaluation of the two antibiotics accepted into the pilot, both of which were shown to provide considerable value above the agreed cap of £10 million per year per drug.

In addition, novel antimicrobials, for use when all other alternative treatments are ineffective or unsuitable are products with high added therapeutic value (HATV) that address a high unmet clinical need (HUCN). To minimise any further delay in accessing urgently needed new antibiotics, a fully delinked subscription style reimbursement scheme for two new antibiotics could be implemented as a pilot in Australia by utilising the proposed bridging funding pathway, as outlined in section 4.1 of the Options Paper.

3. Funding and reimbursement-related changes to support availability of antimicrobials.

AAMRNet welcomes the Committee’s acknowledgement of the need for pull incentives to support availability of antimicrobials. We note the proposed option of workshopping incentive models and welcome the opportunity to work collaboratively with the Australian Government and stakeholders to design a flexible reimbursement policy in respect to antimicrobial products purchasing. We are concerned however, that the proposed workshopping would further delay the ability for Australians to receive timely access to the lifesaving antimicrobials they deserve. Such a delay compromises patient care and will continue to put Australia’s health security at risk.

AMR is already a leading cause of death worldwide³. It was estimated to be directly responsible for 1648 deaths in Australia in 2019⁴. That is around 40 per cent more than those who die on our roads each year. We also know that many more die from infectious causes that could potentially be treated with the right antibiotic, if accessible in a timely manner. For example, in Australia in 2017, over 8700 people died from sepsis⁵, a condition which, in 80 per cent of cases is caused by bacterial infection. Yet, as previously mentioned, Australia has limited access to new antimicrobials, with only three of the 20 antimicrobials considered to be novel and listed in the US and/or the EU since 2011 currently registered for use in Australia. A critical point to note is that none of these three are listed for subsidised access on the Pharmaceutical Benefits Scheme.

Lack of access to effective antimicrobials can also drive resistance, and crucially, makes it more difficult for clinicians to effectively treat their patients. The result is situations like this case of a premature baby girl in an Australian hospital who developed ventilator-associated pneumonia⁶. The baby was infected with the bacteria *Stenotrophomonas maltophilia* that was resistant to various Australian registered antibiotics, but susceptible to an antibiotic not currently registered here, and therefore only accessible via the Special Access Scheme (SAS). Accessing medicines via the SAS can delay appropriate treatment, which can sometimes be the difference between life and death. Fortunately, the hospital had stock on hand of the required antibiotic, as it was left over from another patient. The clinicians went ahead with treating the baby girl “off-label” with the unregistered antibiotic, and she quickly recovered. Her life

³ Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet 2022

⁴ Wozniak T, Nguyen A, Rollin A, Brock J, Bowskill A, Morgan B, Good N. (2022). Antimicrobial Resistance (AMR) Impact Report: How big is Australia’s AMR threat? Australia: CSIRO, MTPConnect

⁵ <https://www.australiansepsisnetwork.net.au/healthcare-providers/sepsis-epidemiology>

⁶ https://journals.lww.com/pidj/abstract/2023/11000/successful_use_of_cefiderocol_to_treat_a.17.aspx

was saved. She now has her whole life ahead of her, thanks to that antibiotic, and the resolve of her clinicians to obtain and use it, despite it not being registered for use in Australia.

As AMR worsens, there will be more cases like this. As befits a world-class health system, Australians would expect reliable and consistent access to a world-class suite of the latest antimicrobials, as people in the US and Europe are able to do. We must ensure our clinicians can confidently and legally use the most appropriate life-saving antimicrobials in a timely manner and not have to rely on good fortune, with 'left-over stock' available, to provide timely and life-saving treatment.

AAMRNet also questions whether a workshop to canvas options for a pull incentive for Australia is the appropriate next course of action. The Australian Government Department of Health and Aged Care has conducted an extensive consultation and review of pull incentives already. There is also considerable and widespread agreement and alignment amongst stakeholders that, in countries like Australia, the most appropriate mechanism to achieve equitable access to, and help support the R&D of new antimicrobials, is through the implementation of a subscription fund that fully delinks reimbursement from volume of sales^{7,8,9}. AAMRNet itself, as Australia's leading multi-stakeholder expert group on AMR, has done extensive work to bring consensus that such a mechanism is the best way forward. It was also recommended by the Parliamentary Standing Committee on Health Aged Care and Sport, in its report, *The New Frontier; delivering better health for all Australians*¹⁰, which specifically calls for the implementation of a pilot scheme for value-based payments for new antimicrobial drugs, taking learnings from the Australian Government's pilot scheme for payment for Hepatitis C drugs, as well as from overseas antimicrobial drug schemes.

As described above, we need to move beyond workshopping toward implementation and AAMRNet strongly advocates for the urgent implementation of a fully delinked pilot subscription style reimbursement fund for two new antimicrobials in Australia. Such a fund should be implemented without delay and can be done so by leveraging the learnings shared from the UK's experience.

As described in AAMRNet's original submission to this Review, a fully delinked subscription style reimbursement fund has already been successfully piloted in the UK. The pilot, which set a reimbursement level based on the UK paying its fair share of a global pull incentive, has been shown to be cost effective. The UK has shared its learnings from the pilot, and the model sets an appropriate and comparable example that Australia could implement quickly. Implementing such a mechanism as a pilot here would in the first instance, ensure Australia timely and equitable access to two cutting edge life-saving antibiotics for Australian clinicians to use when no other treatment is effective. It would also open up Australia to the broadest range of the latest antimicrobial medicines by incentivising pharmaceutical companies to bring current novel antimicrobials to Australia, and ensure Australia is playing its part in supporting innovation into new technologies to combat AMR.

The unmet need is clear and the need to address it is urgent, and should not be further delayed. Therefore, AAMRNet recommends the Committee propose the urgent implementation of a fully delinked pilot subscription style reimbursement fund for two new antimicrobials in Australia, and any further workshopping should be used to refine the details of the implementation of the pilot.

⁷ https://globalamrhub.org/wp-content/uploads/2023/09/Pull_IncentivesGUIDE_DRAFT_2023-09-01.pdf

⁸ https://www.mtpconnect.org.au/images/MTPC_AAMRNet_Superbugs_Report%202023.pdf

⁹ https://www.cca-reports.ca/wp-content/uploads/2023/09/Overcoming-Resistance_digital_FINAL_2.pdf

¹⁰ https://parlinfo.aph.gov.au/parlInfo/download/committees/reportrep/024755/toc_pdf/TheNewFrontier-DeliveringbetterhealthforallAustralians.pdf;fileType=application%2Fpdf

4. Do you have further comments or concerns to add specific to this topic that should be considered?

AMR is widely acknowledged as one of the most critical and urgent threats to human health that exists, and AAMRNet welcomes the HTA Review Committee's acknowledgement of the seriousness of the threat posed by AMR and the market failure that challenges antimicrobial product availability.

As described in AAMRNet's submission to the first consultation and outlined in the above responses, overcoming this market failure will be critical for the Committee to achieve its stated goal of delivering Australians equitable, timely, safe, and affordable access to a high-quality and reliable supply of medicines for all Australians. This is particularly relevant for antimicrobials, as not only are they needed to treat infection, but they are also required to support common healthcare interventions such as childbirth and elective surgery, as well as others including cancer treatments and organ transplants.

Whilst the Committee's options outlined are welcome, Australia will continue to suffer from limited access to new antimicrobials, thereby placing its health security and the lives of Australians in jeopardy, unless urgent action is taken and initiatives to overcome the market failure are implemented without delay.

AAMRNet strongly urges the Committee that the implementation of a fully delinked pilot subscription style reimbursement fund for two new antimicrobials in Australia, at a level based on the global fair share principle, is urgently needed to improve Australia's access to new antimicrobials and help protect its health security.

Combining such a mechanism with HTA Fee exemptions applied to all HTA processes occurring across the lifecycle of a technology for products that address AMR, would enable the Committee to deliver on its goal of providing Australians equitable, timely, safe, and affordable access to a high-quality and reliable supply of medicines for all Australians.

About AAMRNet

AAMRNet is Australia's leading multi-stakeholder expert group committed to combating the urgent global threat of AMR. AAMRNet is a public-private partnership, established and operated by not-for-profit MTPConnect, Australia's life sciences innovation accelerator.

AAMRNet leverages MTPConnect's networks and resources, and its reputation as an independent and trusted voice for the sector. It brings together experts from industry, clinicians, and research. AAMRNet is operated by MTPConnect with cross-sector stakeholder investment and support from Pfizer ANZ, CSIRO, GSK Australia, Recce Pharmaceuticals, MSD Australia, Botanix Pharmaceuticals, SpeedX, Medicines Australia, Tenmile, Biointelect, Monash Centre to Impact AMR and Bugworks Australia. Its members and stakeholders include universities, not-for-profits, researchers, SMEs and large multinational companies, industry peak bodies, clinicians, government, and regulators. AAMRNet is the only body in Australia able to provide whole-of-sector representation and is therefore uniquely placed to provide a unified voice to support and promote Australia's role in the global fight against the urgent threat of AMR and help inform government priorities and strategies.

The network also has strong links to the Australian Government and international not-for-profit organisations dedicated to developing and delivering new or improved treatments and diagnostics.

Through its partnerships and engagement with key international stakeholders, AAMRNet is established as the key organisational contact point for access to Australian AMR expertise.

AAMRNet is ideally placed to work closely with the Australian Government to deliver progress on its commitment to combat AMR. We would welcome the opportunity to discuss and collaborate with the Australian Government further on this issue.

For further information about this submission, please contact [REDACTED]