



FIGHTING SUPERBUGS: THE PATH FORWARD

A SUBSCRIPTION-STYLE REIMBURSEMENT
MECHANISM TO BOOST AUSTRALIA'S ARSENAL
OF ANTIMICROBIAL MEDICINES

A report from Australia's National Roundtable on implementing
a pilot subscription model for novel antimicrobials in Australia

18 November 2024, Canberra

MTPConnect

AAMRNet
Australian Antimicrobial Resistance Network

 **evohealth**

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EXECUTIVE SUMMARY

Antimicrobial resistance (AMR) is a critical global health challenge, threatening the effectiveness of modern medicine and increasing the risk of untreatable infections. [1-4]

In Australia, recent policy reviews, notably recommendation 21 of the final report of the Health Technology Assessment (HTA) Policy and Methods Review, *Accelerating Access to the Best Medicine for Australians Now and into the Future*, have highlighted the need for a pilot subscription funding model to enable accessibility to new and novel antimicrobials, and to incentivise their development. [5]

In response, a roundtable was convened on 18 November 2024, made up of around 35 leaders in infectious disease management, from government, research, clinical practice and industry. Its goal was to develop a consensus on the design and implementation of an Australian pilot program. This roundtable drew on insights from global examples, particularly the recent experience of the United Kingdom (UK). [6] The roundtable was hosted by the Australian Antimicrobial Resistance Network (AAMRNet) and MTPConnect, and facilitated by Evohealth.

THERE WAS STRONG CONSENSUS FROM ROUNDTABLE PARTICIPANTS THAT A SUBSCRIPTION MODEL FOR NOVEL ANTIMICROBIALS CAN AND SHOULD BE ADOPTED IN AUSTRALIA.

THE UK SUBSCRIPTION MODEL PROVIDES A STRONG FOUNDATION FOR A PILOT PROGRAM IN AUSTRALIA. MANY ASPECTS CAN BE ADOPTED DIRECTLY, WHILE OTHERS WOULD REQUIRE ADAPTATION TO SUIT AUSTRALIA'S UNIQUE HEALTHCARE SYSTEM AND MEDICINES FUNDING ENVIRONMENT.

AUSTRALIA URGENTLY NEEDS IMPROVED ACCESS TO NOVEL ANTIMICROBIALS. BY LEVERAGING THE LESSONS LEARNED FROM THE UK MODEL AND PROGRAM AUSTRALIA CAN FAST TRACK THE DESIGN, ESTABLISHMENT AND IMPLEMENTATION OF THE PILOT PROGRAM WITHOUT DELAY.

The roundtable also agreed on ten key principles to guide the development of a pilot program and its implementation in Australia:

1

Collaborative development of the Australian pilot program should involve government, industry representatives and other stakeholders with key expertise, such as infectious disease clinicians.



2

Establish an expert group to validate the clinical criteria for Australia and assess the suitability of medicines for inclusion in the pilot.



3

Product eligibility and evaluation criteria prioritises World Health Organisation (WHO) priority pathogens, with flexibility to include pathogens of high unmet need in Australia and the Asia-Pacific region.



4

Medicines in the pilot are to be assessed using a multi-factor criteria model, separate from any existing Health Technology Assessment (HTA) processes.



5

Submissions to the pilot are to be via open market requests against the clinical and organisational eligibility criteria.



6

Contract terms are to balance incentive and risk for all stakeholders.



7

Supply of pilot medicines must be consistent with the established mechanisms and timelines of the Community Services Obligation (CSO).



8

The concept of robust antimicrobial stewardship (AMS) should underpin all aspects of the pilot program.



9

The pilot program must ensure clinical autonomy, with the place in therapy of pilot antimicrobials determined by the health services' respective Drug and Therapeutics Committee.



10

Evaluation criteria will be developed during the pilot program's planning to measure success against key indicators at the patient, clinical, and health system levels.





ABOUT THIS REPORT

PURPOSE OF THIS REPORT

This report provides a summary of the discussion at the Antimicrobial Subscription Model roundtable held in November 2024. Considerations and next steps discussed during the forum have been synthesised and summarised. The statements in this report do not necessarily represent the individual views of every attendee and were not the result of a formal consensus process.

PURPOSE OF THE ROUNDTABLE

The Australian Antimicrobial Resistance Network (AAMRNet) and MTPConnect hosted a roundtable on Monday 18 November 2024. The event was facilitated by Evohealth and involved key stakeholders from clinical, policy, patient advocacy and industry backgrounds.

The aim of the roundtable was to discuss the next steps required to implement a pilot subscription payment model for novel antimicrobials in Australia.

The roundtable discussions were informed by the experiences of the UK pilot subscription model and subsequent implementation of a permanent model. Opening presentations described the global issue of market failure for antimicrobials. This was followed by a detailed session led by David Glover from National Health Service (NHS) England, describing the United Kingdom's (UK) antimicrobial subscription model pilot and its expanded scheme. This session aimed to provide a comparative framework for the roundtable discussion, and highlight lessons learned from international efforts. It was supplemented with an in-depth question and answer session. Focused 'break out' discussions then explored the clinical eligibility, evaluation, procurement, contracting, regulatory and policy considerations for implementing a subscription pilot program for novel antimicrobials in Australia.

ACKNOWLEDGEMENTS

The roundtable was supported by Pfizer ANZ and GSK Australia.

AAMRNet and MTPConnect would like to acknowledge the contributions of all the participants for their valuable insights and robust discussions on the day, and their continued advocacy in combatting AMR.

SPEAKERS

- **David Glover** - National Health Service (NHS), England
- **Andrew Bowskill** – AAMRNet

PARTICIPANTS

- **Dr. Richard Alm** – Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)
- **Christina Bareja** – Department of Health and Aged Care
- **Prof. Mark Blaskovich** – University of Queensland
- **Claire Callaghan** – National Aboriginal Community Controlled Health Organisation (NACCHO)
- **Dr. Chris Davis** – Griffith University
- **Elizabeth de Somer** – Medicines Australia (MA)
- **Lisa Dubé** – MTPConnect
- **Anne-Maree Englund** – Medicines Australia (MA)

PARTICIPANTS CONTINUED

- **Paul Field** – Global Antibiotic Research and Development Partnership (GARDP)
- **Ben Fitzsimmons** – Pfizer
- **Dr. Tony Gill** – Therapeutic Goods Administration (TGA)
- **Sarah Greenbaum** – Pfizer
- **Prof. Paul Griffin** – Mater Health Services
- **A/Prof. Tom Gottlieb** – Australian Society for Antimicrobials (ASA)
- **Catherine Haintz** – GSK
- **Jenny Herz** – Biointelect
- **Dr. Nadine Hillock** – University of Adelaide
- **Prof. Jon Iredell** – The Westmead Institute for Medical Research
- **Eric Johnsson** – GSK
- **Yuen Lai** – Pfizer
- **Prof. Christopher McDevitt** – Doherty Institute
- **A/Prof. Kerrie McDonald** – Australian Medical Association (AMA)
- **Dr. Angela Mina Vargas** - Department of Health and Aged Care
- **Prof. Branwen Morgan** – CSIRO
- **Dr. Alan Paul** – GSK
- **David Pullar** – GSK
- **Dr. Julian Rait** – Australian Medical Association (AMA)
- **Dr. Merrin Tulloch** – AstraZeneca
- **Dr. Phoebe Williams** – Australasian Society for Infectious Diseases (ASID), University of Sydney
- **Jacqueline Youssef** – Pfizer

FACILITATORS

- **Renaë Beardmore** - Evohealth
- **Deanna Mill** - Evohealth
- **Maggie Bawer** - Evohealth





WHY DO WE NEED A SUBSCRIPTION PAYMENT MODEL FOR NOVEL ANTIMICROBIALS IN AUSTRALIA?

MICROBIAL INFECTIONS ARE BECOMING HARDER TO TREAT

Antimicrobial resistance (AMR) is a global health crisis recognised as one of the top ten public health threats by the World Health Organization (WHO). [1] AMR occurs when microbes such as bacteria, viruses, fungi or parasites become unresponsive to medicines. Antimicrobials are essential for modern medicine, enabling safe surgery, chemotherapy, safer childbirth and treatment of common infections. However, resistance is emerging faster than ever, with pathogens developing resistance to new medicines in just 2–3 years. [7]

Antimicrobial resistance is already linked to 5,200 deaths each year in Australia, and this is projected to increase to 10,000 by 2050. It is estimated that by 2050 AMR could cause up to 10 million deaths each year globally if the issue is not addressed. [2-4] Without effective action, routine medical procedures will become life-threatening, and treatable infections could once again become fatal. Even with robust antimicrobial stewardship (AMS), drug-resistant pathogens will persist, leaving Australians increasingly vulnerable.

WE DO NOT HAVE ENOUGH ANTIMICROBIALS IN THE PIPELINE TO COMBAT AMR

The development of new antimicrobials is not keeping pace with the growing threat of AMR. Addressing this crisis requires 15 new antibiotics within the next decade, including treatments targeting priority pathogens identified by the WHO. [8] Yet, the pipeline is stagnating; only 12 antibiotics have been introduced globally since 2017, and no novel class has been developed in 35 years. [7, 9] Without urgent innovation, lives will continue to be needlessly lost.

The challenges in antibiotic development mirror those across other essential antimicrobial categories, all of which play a vital role in safeguarding public health.

THE MARKET IS FAILING AUSTRALIANS

There is a market failure that is actively disincentivising research and development (R&D) of new antimicrobial medicines. Despite the enormous societal costs of AMR and the urgent need for novel treatments, a viable market for novel antimicrobials does not exist in Australia. This market failure was acknowledged in The New Frontier Parliamentary inquiry report of 2021:



DESPITE THE HUGE SOCIETAL COSTS OF [AMR] AND URGENT NEED FOR ANTIMICROBIALS, THERE IS NO VIABLE MARKET FOR NEW ANTIBIOTICS IN AUSTRALIA.



– The New Frontier Parliamentary Inquiry^[3]

By their nature, antimicrobial medicines are designed mostly for short-term and occasional use in response to acute infection. [10] Novel antimicrobials are generally held in reserve and only used when drug-resistant infections occur. [11] This results in low sales volumes and poor commercial returns for pharmaceutical companies and drug developers, many of whom have withdrawn from the market as a result.

15 of the 18

largest pharmaceutical companies have **withdrawn from antibiotic research and development** in the last 30 years. [10, 12]

It takes
AUD\$1.5-3

billion and **10-15 years** to develop a new antimicrobial. [7, 11]

There was a
35%

reduction in the number of antibiotic **patents filed** between **2007** and **2012**. [13]

While the challenges are well understood, the solutions require a coordinated approach. Push incentives, such as grants and tax benefits are essential to support R&D. [14] **While pull incentives are needed to create a sustainable and attractive commercial market for manufacturers.** [12, 14-16]

A FULLY DELINKED SUBSCRIPTION PAYMENT MODEL CAN ADDRESS MARKET FAILURE

Encouragingly, the issue of market failure for antimicrobials has been widely acknowledged in Australia, and significant progress has been made in recent years to identify potential solutions. One solution is a pull incentive, by which reimbursement is fully delinked from the volume of sales and also recognises the inherent public health value of these medicines. [14, 15] This is known as a subscription payment model. Implementation of this would ensure adequate revenue and return on investment, if set at an appropriate amount.



WHAT IS A SUBSCRIPTION PAYMENT MODEL?

A fully delinked model that involves paying a fixed price to a company at regular intervals (e.g., annually) for access to an antimicrobial across the healthcare system, with the price delinked from patterns of use (i.e., sales). [17]

RECENT AUSTRALIAN REVIEWS AGREE ON THE NEED FOR A SUBSCRIPTION FUNDING MODEL

2021

The Australian Parliament's Standing Committee on Health, Aged Care and Sport, in the 2021 report *The New Frontier – Delivering Better Health for All Australians*, highlighted well-known challenges within the approval processes for new drugs and medical technologies, emphasising the urgent need for targeted action against AMR. [3] The report called for funding and regulatory reforms to support early-stage antimicrobial R&D, a pilot for value-based payments for new antimicrobials, and the promotion of existing R&D initiatives. [3]

2024

The final report of the Health Technology Assessment (HTA) Policy and Methods Review, *Accelerating Access to the Best Medicine for Australians Now and into the Future*, proposed concrete steps to establish a pilot program for a flexible reimbursement policy for novel antimicrobials. Recommendation 21 specifically called for developing, implementing and assessing the effectiveness of a pilot subscription fund for novel antimicrobials in the short term. [5]

HTA POLICY AND METHODS REVIEW RECOMMENDATION 21. APPROACHES TO INCENTIVISE DEVELOPMENT OF HEALTH TECHNOLOGIES THAT ADDRESS AMR.

The review recommends the Australian government implement measures to incentivise the development of antimicrobials including:

- 1 Exempting them from HTA fee requirements;
- 2 Developing a framework to inform changes to HTA policy and methods for antimicrobials;
- 3 Designing a flexible reimbursement policy for antimicrobials, including examining and testing multiple payment and incentive models including but not limited to full and partial price and volume delinking, advanced market commitments and guarantee-of-supply provisions; and
- 4 **In the short term, develop, implement and assess the effectiveness of a pilot subscription fund for novel antimicrobials. [5]**

With these calls in mind, the roundtable aimed to ensure that the proposed pilot is both practical and impactful, improving Australia's access to novel antimicrobials and at the same time helping address the urgent need to incentivise antimicrobial development and combat the rising threat of AMR.



DELINKING PRICE AND VOLUME IN THE UK

The UK has taken a pioneering role in addressing the market failure surrounding antimicrobial development, becoming the first country to adopt a fully delinked price-volume 'subscription' payment model for novel antimicrobials in 2024. [6]

This innovative approach was introduced following the success of a pilot program initiated in 2022, which demonstrated the feasibility of procuring novel antimicrobials based on the societal value rather than sales volumes. [6]

WHAT IS THE UK ANTIMICROBIAL SUBSCRIPTION MODEL?

The NHS pays a fixed annual subscription fee to a pharmaceutical company for access to novel antimicrobials. [6] The fee the pharmaceutical company receives is determined by the antimicrobial's evaluated value to the NHS. [6, 18, 19] The evaluation of the antimicrobial's value is an assessment of evidence to meet pre-determined criteria, not a typical quantitative health economic assessment (HTA). [6, 18]

HOW DOES IT WORK?

The UK subscription model for novel antimicrobial products involves a coordinated effort among national health bodies, contracting authorities, and the National Institute for Health and Care Excellence (NICE). [19]

The path to commissioning of antimicrobials via the subscription model differs from other medicines in the UK (Figure 1). The NHS England leads this process on behalf of all NHS agencies, managing tenders and acting as the main contracting authority. The NHS issues requests for submissions for novel products to be included in the subscription model, and the eligibility criteria may be adapted to target products that are specifically needed within the health system (e.g. priority pathogens for NHS). [19]

Organisations with antimicrobials that are expected to receive market authorisation to launch within 12 months of the submission invitation launch date, and those that already have relevant medicines in the market, can apply for a subscription style contract if they meet the clinical and organisational eligibility criteria. [19] Eligibility criteria for the UK model is included in Appendix 1.

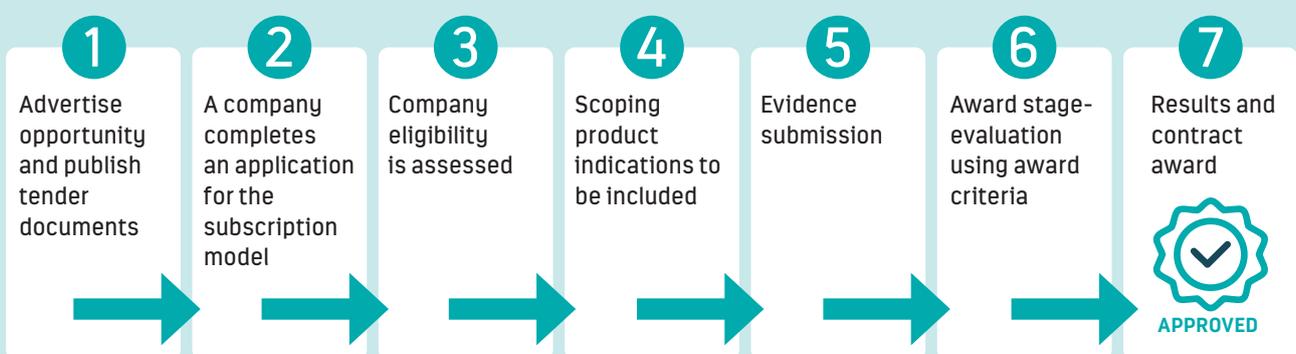


Figure 1 – The steps for commissioning antimicrobials in the subscription payment model in the UK

Source: [NHS England » Antimicrobial products subscription model: guidance on commercial arrangements](#)

If antimicrobial products meet this eligibility criteria, they are evaluated against 17 award criteria using a points-based scoring system. This determines the overall value of the antimicrobial to the NHS. [6, 18, 19] The total score gained assigns the product to one of four contract value bands (Table 1). Quantitative health economics are not used in this process and only those offering significant value qualify for a contract. [6, 18, 19] Details of the award criteria and scoring system provided in Appendix 2.

ANNUAL PAYMENT	POINTS SCORED AGAINST AWARD CRITERIA
Band 1: £20 million per year Breakthrough antimicrobials	Achieves ≥80% of max score against evaluation criteria
Band 2: £15 million per year Critical new antimicrobial	Achieves between 70% and 79% of max score against evaluation criteria
Band 3: £10 million per year Priority new antimicrobial	Achieves between 60% and 69% of max score against evaluation criteria
Band 4: £5 million per year Important new antimicrobial	Achieves between 50% and 59% of max score against evaluation criteria

Table 1 – Value bands linked to award criteria scoring system

Source: Reproduced from [NHS England > Antimicrobial products subscription model: guidance on commercial arrangements](#)

Contract information including the evaluation score and the agreed contract value band, together with the panel’s rationale for the score are published following the awarding of a contract. [19] Applicants can then seek clarification on what has been awarded and have up to 30 days to accept the contract offer. However, they cannot negotiate, nor are they consulted on the contract value. [19]

WHO EVALUATES THE ANTIMICROBIAL?

NICE plays a critical role in supporting this system by providing clinical expertise and evaluation through three main functions:

- 1 **Eligibility Panel:** NICE representatives assess the eligibility of products and organisations for subscription contracts. Eligibility criteria includes both clinical criteria and organisational eligibility criteria (see Appendix 1).
- 2 **Scope Recommendations:** Populations and indications to be included within the contract scope are defined by NICE and agreed between both parties before proceeding with the application.
- 3 **Evaluation Panel:** NICE recruits and oversees a standing panel of experts who evaluate products and submitted evidence against predefined award criteria.

The UK model provides a valuable blueprint for Australia, offering critical insights into designing and implementing a similar approach tailored to the unique challenges of the Australian healthcare landscape.

There is an opportunity for Australia to leverage the UK methodology to fast-track the establishment of a subscription model which would deliver timely and equitable access to novel antimicrobials while incentivising innovation in this vital area.



KEY CONSIDERATIONS FOR THE AUSTRALIAN PILOT

During the roundtable, participants identified key considerations to advance the implementation of a pilot subscription funding model for antimicrobials in Australia.

Drawing on the extensive expertise of those present, the roundtable aimed to achieve alignment on critical elements necessary for success.

There was strong consensus from roundtable participants that a subscription model for novel antimicrobials can and should be adopted in Australia.

The UK subscription model provides a strong foundation for a pilot program in Australia. Many aspects can be adopted directly, while others would require adaptation to suit Australia's unique healthcare system and medicines funding environment.

Roundtable attendees also agreed on **ten key principles** to guide pilot development and implementation in Australia. These principles emphasise practical adjustments to ensure the model's feasibility and effectiveness within Australia's healthcare landscape.

1

COLLABORATIVE DEVELOPMENT OF THE AUSTRALIAN PILOT PROGRAM BETWEEN GOVERNMENT, INDUSTRY REPRESENTATIVES AND OTHER STAKEHOLDERS WITH KEY EXPERTISE, SUCH AS INFECTIOUS DISEASE CLINICIANS.

Roundtable participants agreed that the development and implementation of a local pilot program must involve active engagement with relevant government, industry, clinical and expert stakeholder representatives to ensure that the program meets its objectives and is suitable for Australia. This open consultation, communication and dialogue should continue into any ongoing program post pilot.

The UK's subscription model was initiated by NHS England and NICE as part of the UK Government's 2019 National Action Plan for AMR. The pilot included extensive consultation with key stakeholder groups, including representatives from the innovative medicines sector to ensure that the program was viable and provided sufficient incentives for participation. Public consultation to gather feedback and refine the program was also necessary, as was the inclusion of external expertise to inform the clinical evaluation criteria.

2

ESTABLISH AN EXPERT GROUP TO VALIDATE THE CLINICAL CRITERIA FOR AUSTRALIA AND ASSESS THE SUITABILITY OF MEDICINES FOR INCLUSION IN THE PILOT.

Participants strongly supported establishing a similar group in Australia with expertise in infectious diseases, microbiology and health economics. This group will ensure the criteria are relevant, rigorous, and aligned with the pilot program's objectives. It will conduct a review of the UK clinical criteria and make any necessary adjustments to suit the Australian context.

The UK clinical criteria were collaboratively developed by NICE and NHS England, with input from clinical experts within the AMR Programme. They were further validated by clinical experts from the UK Government's Advisory Committee on Antimicrobial Prescribing, Resistance, and Healthcare Associated Infection. These criteria were informed by eligibility criteria from their pilot project, which assessed two antimicrobials under a new evaluation and payment model. Furthermore, insights from health economic analyses and expert committee deliberations were part of the pilot program. An expert panel convened by NICE continues to evaluate medicines against defined clinical criteria to determine their eligibility for subscription contracts (Appendix 2).

3**PRODUCT ELIGIBILITY AND EVALUATION CRITERIA PRIORITISES WHO PRIORITY PATHOGENS, WITH FLEXIBILITY TO INCLUDE PATHOGENS OF HIGH UNMET NEED IN AUSTRALIA AND THE ASIA-PACIFIC REGION.**

Participants agreed that the WHO's identified priority pathogens should be accorded high priority in Australia. However, they suggested that flexibility would be needed to ensure that vulnerable and priority populations were not excluded from the process. Examples given were that our First Nations population experience some uncommon health conditions, such as Rheumatic Heart Disease, which is routinely treated with the antibiotic benzathine penicillin G. Further, it was highlighted that much of Australia's multidrug resistant burden came from overseas infections and thus patterns of infection and disease from the Asia-Pacific region require consideration.

Participants also spoke of the importance of valuing novelty, and the need for the inclusion of criteria that were realistic and achievable for products where, for example, post-marketing data is limited.

In addition, while the pilot is unlikely to include a product with more than one indication initially, further consideration may be needed regarding the adoption of additional indications to address unmet patient needs in the future.

Pathogens considered a critical priority by the WHO are prioritised for inclusion in the UK model. The product evaluation criteria specifically assesses their effectiveness against the country's 'unmet needs' and 'effectiveness compared with UK best standard care'. This approach means the UK can contribute to combating pathogens of global and local needs.

4**MEDICINES IN THE PILOT ARE TO BE ASSESSED USING A MULTI-FACTOR CRITERIA MODEL, SEPARATE FROM ANY EXISTING HTA PROCESSES.**

Participants agreed that lessons learnt from the UK would be applicable in Australia and that an independent body should assess the value of antimicrobials to be included in the pilot independent of standard HTA committees and processes. This independence would streamline decision-making and prioritise factors unique to antimicrobials, such as stewardship and population level resistance mitigation.

The UK assessment process uses a multi-factor evaluation framework independent of traditional cost-effectiveness analyses and instead focuses on broader societal value. This approach allows for the inclusion of factors such as resistance patterns and public health impact. It also reflects the STEDI (i.e. Spectrum, Transmission, Enablement, Diversity, Insurance) values. It does not use quantitative health economic evaluations, such as those used in traditional assessments by the Pharmaceutical Benefits Advisory Committee.

5**SUBMISSIONS TO THE PILOT ARE TO BE VIA OPEN MARKET REQUESTS AGAINST THE CLINICAL AND ORGANISATIONAL ELIGIBILITY CRITERIA.**

Roundtable participants agreed that the simplicity and transparency of the UK submission process was beneficial for all stakeholders and that a similar open model could be readily established in Australia.

In the UK model, NHS England acts as the lead procurement authority and issues an open market invitation to pharmaceutical organisations to apply for a subscription model contract. Applicants are evaluated by a pre-determined set of clinical and organisational criteria. Clinical input is provided by NICE during the evaluation of submissions and when recommendations are made for the awarding of contracts. Outcomes of the process and the associated contract values are published publicly.

6**CONTRACT TERMS ARE TO BALANCE INCENTIVE AND RISK FOR ALL STAKEHOLDERS.**

The objective of the subscription model is to address some of the market failure associated with antimicrobial development. Doing so would provide surety in access to novel antimicrobial agents, and incentives to build a more robust pipeline of novel antimicrobial medicines. Achieving this requires a long-term approach. Given the development cycle for new medicines is approximately 15 years, it is essential that the subscription model provides sufficient incentive and acceptable risk mitigation for organisations to participate, and in turn operates within appropriate financial risk parameters for government.

As with the submission process, roundtable participants saw value in the simplicity and transparency of the contract terms used in the UK model. In the UK, contracts are initially issued for three years, with extensions available up to a total of 15 years. Contract values are awarded in one of four bands based on the assessment of the applicants against established evaluation criteria. Companies must meet key performance indicators, including delivery times to hospitals and surety of supply. Compliance with these indicators is reviewed throughout the contract term.

In regard to pricing there was consensus that a single national price should be negotiated for each contract rather than individual state and territories pursuing their own pricing. It was agreed that a block payment model, similar to the UK, be adopted. There are procurement models within the Australian health system that could be used as a model for this, such as the national vaccine procurement agreements.

The roundtable's discussions on the payment amount led to a figure of approximately \$12.5 million per contract, per year. This is comparable to the UK payments under its pilot program and aligned with the 2024 AAMRNet health and economic modelling for the implementation of a subscription model in Australia, details of which can be found in Appendix 3.

Because there are strong mitigations of risk in a national procurement contract, pricing policy and governance mechanisms such as Risk Share Arrangements and Managed Entry Schemes are not required. Special Pricing Arrangements should be maintained to enable access to some pilot antimicrobials, if required.

7**SUPPLY OF PILOT MEDICINES MUST BE CONSISTENT WITH THE ESTABLISHED MECHANISMS AND TIMELINES OF THE COMMUNITY SERVICES OBLIGATION (CSO).**

In Australia, delivery and therefore timely access to medicines is a challenge for rural and remote areas. This is addressed by the CSO, a funding pool established to ensure that all Australians have timely access to medicines by financially incentivising pharmaceutical wholesalers to deliver medicines within 24-72 hours of a pharmacy order regardless of pharmacy location. [20] There was agreement among roundtable participants that the supply of medicines under the pilot program should fit within the mechanisms of the CSO.

In the UK, a single procurement process exists across all four nations (i.e. England, Scotland, Wales and Northern Ireland), though each reviews and agrees to the eligibility and evaluation criteria prior to seeking applications. However, each nation can make amendments to address their specific requirements. Scotland, for example, amended its criteria on the time taken to supply its pilot medicines to allow for the challenges of accessing its many smaller islands and distant regions.

8**THE CONCEPT OF ROBUST ANTIMICROBIAL STEWARDSHIP SHOULD UNDERPIN ALL ASPECTS OF THE PILOT PROGRAM.**

Robust AMS is a shared responsibility of both government and organisations seeking to participate in the pilot program. The roundtable participants agreed that effective AMS should be included as a criterion in the organisational eligibility requirements for contracts. In addition, contract terms need careful consideration to include a deterrent for inappropriate use of antimicrobials, without deterring clinically appropriate use.

In the UK model, AMS is a core component of the organisational eligibility criteria for awarding contracts. Contracted organisations are required to reinforce appropriate behaviours including delinking remuneration incentives for sales teams from antimicrobial sales. They must also ensure that any campaigns in market are informative and educational, and must keep pilot coordinators informed of such activities.

9

THE PILOT PROGRAM MUST ENSURE CLINICAL AUTONOMY, WITH THE PLACE IN THERAPY OF PILOT ANTIMICROBIALS DETERMINED BY THE HEALTH SERVICES' RESPECTIVE DRUG AND THERAPEUTICS COMMITTEE.

Roundtable participants emphasised the importance of preserving clinical autonomy in Australia, allowing clinicians to make context-specific decisions, ensuring alignment with local clinical priorities and infection patterns. Examples highlighted that if a new antimicrobial demonstrated a more favourable adverse event profile or was suspected to be more efficacious than existing treatment options, clinicians wanted the flexibility to use it without it being automatically restricted to last-line therapy. Paediatric populations were also noted as a challenge given they are often excluded from clinical trials. Consequently, guidance on their use in this situation is lacking and typically reliant on clinician experience until observational studies become available. Participants emphasised the importance of considering these factors in ensuring optimal patient outcomes and informed decision-making.

In the UK model, NICE provides clinical guidance on the place of antimicrobials in therapy following their evaluation. This guidance considers the evidence assessed during evaluation and offers recommendations on clinical use. This clinical guidance also advises seeking specialist input from microbiologists and infectious disease clinicians before use. Further it recommends local governance practices, such as Drug and Therapeutics Committees, guide their inclusion in local formularies and use in practice. This approach balances adherence to national guidelines with local flexibility.

10

EVALUATION CRITERIA WILL BE DEVELOPED DURING THE PILOT PROGRAM'S PLANNING TO MEASURE SUCCESS AGAINST KEY INDICATORS AT THE PATIENT, CLINICAL, AND HEALTH SYSTEM LEVELS.

Participants agreed that Australia's pilot should include clear, well-defined key performance indicators at the patient, clinical, and health system levels where possible. These metrics should evaluate the pilot program's effects on access to novel antimicrobials, stewardship outcomes, and system-wide improvements, while ensuring transparency and accountability.

In addition, an Australian pilot program should specifically aim to enhance access to novel antimicrobials and stimulate innovation in antimicrobial R&D. Success should be measured through indicators such as equitable access, usage patterns, and supply chain performance, as well as improved patient outcomes and contributions to global antimicrobial resistance mitigation efforts. Participants agreed that these criteria should be developed at the beginning of the pilot program so that relevant data can be included in contracts with the pharmaceutical company and participating health sites. Additionally, they suggested that existing surveillance resources such as the Australian Group on Antimicrobial Resistance (AGAR) National Resistance Surveillance program (AGAR-NRS) could be leveraged for some of the data collection purposes.

In the UK pilot program, evaluation criteria were to demonstrate that health economics could be used to appropriately value antibiotic products and that a delinked payment model could be used to pay for them. Complementary independent audits and research were designed to measure other metrics such as access to antimicrobials, resistance trends, and public health outcomes. The ultimate objective of the model was to provide sufficient revenue to create a 'pull incentive' to stimulate R&D and increase the number of antimicrobials brought to market. It was not possible to measure success in this regard because of the insufficient timespan to discern a change and the scale of the revenue offered by the UK was not designed to compensate for the entire global market.

➤ FIGHTING SUPERBUGS: THE PATH FORWARD

The roundtable outcome was clear - there is no time to waste in the fight against superbugs.

A subscription model is critical for supporting R&D for new antimicrobials and a market for their adoption and use in the health system.

The UK has trialled and implemented a successful, fully delinked subscription model.

By leveraging the learnings of the UK model, we have the opportunity to adapt and fast track a model tailored for Australia, with a framework that promotes good antimicrobial stewardship, fits into our current medicines and procurement frameworks, and most importantly provides a viable solution to addressing market failure for novel antimicrobials.

This is good for Australian patients.



ADAPT THE UK SUBSCRIPTION MODEL AS HOLISTICALLY AS POSSIBLE.

All participants in the roundtable agreed that the UK model was comprehensive, simple and applicable to Australia. Though it was recognised that certain amendments may need to be considered in Australia, it was also agreed much of the work has been done. Multiple reports have recommended a subscription model over several years, most notably the recent HTA Policy and Methods Review, *Accelerating Access to the Best Medicine for Australians Now and into the Future*. [5] There is no need for Australia to 'reinvent the wheel', investing further resources or exploring options when a suitable model exists. Rather we should expedite the planning and implementation of a local pilot program based on the UK model to enable quick and efficient implementation.





ABBREVIATIONS

ABBREVIATIONS	DESCRIPTION
AGAR	Australian Group on Antimicrobial Resistance
AGAR-NRS	Australian Group on Antimicrobial Resistance National Resistance Surveillance program
AMR	Antimicrobial resistance
AAMRNet	Australian Antimicrobial Resistance Network
HTA	Health Technology Assessment
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
R&D	Research and Development
SAS	Special Access Scheme
STEDI	Spectrum, Transmission, Enablement, Diversity, Insurance
TGA	Therapeutic Goods Agency
UK	United Kingdom
WHO	World Health Organization



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APPENDIX 1 – ELIGIBILITY CRITERIA

The UK antimicrobial subscription model product and company eligibility criteria ensure that only high-value products are considered for subscription contracts. [19]

Key product eligibility criteria include:

- **Clinical need:** The antimicrobial must be active against WHO-designated priority pathogens. In particular, those that are designated as critical. [19]
- **Company criteria:** These include agreement to contractual terms on supply surety, antimicrobial stewardship (i.e. sales force stewardship – responsible sales and promotion), performance reporting and payment terms. Additionally, they must demonstrate compliance with antibiotic manufacturing standards to reduce resistance and environmental impact. Additionally contracts are tied to probity requirements of demonstrating financial stability to support contract execution, and adherence to public contract standards, including commitments to social value initiatives such as Net Zero emissions. [19]

Products meeting these criteria advance to an award stage, where they are further evaluated against detailed criteria to determine eligibility for a subscription-style contract and associated payments.



APPENDIX 2 – EVALUATION CRITERIA

The UK product evaluation criteria assess the value of an antimicrobials relative clinical effectiveness, pharmacological benefits and health system benefits. [18] These criteria balance assessing the clinical need for the antimicrobial both locally and globally.[18]

There are 17 evaluation criteria grouped into three categories:



Figure 2 displays the 17-evaluation criterion and their respective weights. “An overall product score is calculated by multiplying each criterion score (between 0 and 100) by the criterion weight (between 0 and 1) and summing across all of the criteria.”[18]

A company will submit evidence (e.g. clinical trial data, systematic literature reviews) to demonstrate their product’s performance against each criteria. [18] The NICE evaluation panel then review and consider the strength, quality and relevance of the submitted evidence and assign points for that criterion. These are then scored as outlined above. [18]

	CATEGORIES	CRITERIA	WEIGHTS
	RELATIVE EFFECTIVENESS & UNMET CLINICAL NEED 45%	<ul style="list-style-type: none"> • 1A: Activity against WHO bacterial priority pathogens • 1B: Activity against resistance mechanisms • 1C: Activity against UK unmet needs • 1D: Effectiveness compared with current UK best standard care 	<ul style="list-style-type: none"> 12.2% 10.4% 11.2% 11.2%
	PHARMACOLOGICAL BENEFIT 25%	<ul style="list-style-type: none"> • 2A: Chemical entity novelty • 2B: Target site novelty • 2C: Drug exposure at the site of infection • 2D: Absence of cross-resistance • 2E: Absence of rapidly emerging resistance • 2F: Impact on gut microbiome 	<ul style="list-style-type: none"> 4.5% 4.0% 4.5% 4.5% 4.0% 3.5%
	HEALTH SYSTEM BENEFIT 30%	<ul style="list-style-type: none"> • 3A: Adverse events • 3B: Drug-drug interactions • 3C: Formulation of delivery of therapy • 3D: Dose frequency • 3E: Product stability and storage • 3F: Monitoring requirements • 3G: Reduced hospital-led care 	<ul style="list-style-type: none"> 5.4% 3.9% 4.5% 4.5% 2.7% 3.6% 5.4%

Figure 2 – UK criteria for evaluation on an antibiotic for contract award

Source: [A new model for evaluating and purchasing antimicrobials in the UK | NICE Advice service | Life sciences: how to get your product to market | What we do | About | NICE](#)



APPENDIX 3 – AAMRNET HEALTH AND ECONOMIC IMPACT MODELLING

Drawing on learnings from the successful UK antimicrobial subscription model pilot, [21] AAMRNet has proposed a pilot for Australia that would see the Australian Government provide a revenue guarantee of \$12.5 million per antimicrobial per year. The selected antimicrobials would then be purchased by hospitals around Australia, at an agreed price set at a level to support robust AMS practices. The value of those sales would then be deducted from the \$12.5 million annual revenue guarantee, enabling the cost of the pilot to be shared between the Federal, and State and Territory Governments.

The value of the proposed pilot program was calculated by taking the figure generally agreed internationally as the optimal size for a global pull incentive for a fully delinked global subscription program, which has been calculated at US\$2.2 to US\$4.8 billion, with a best estimate of US\$3.1 billion. [22]

Using this best estimate, AAMRNet has calculated an appropriate value for the pilot of \$12.5 million per antimicrobial, per year, for Australia. This approximately reflects Australia's share of the cost of a global pull incentive being shared across the G20 Nations on a gross domestic product basis. The total cost for access to two antimicrobial over the four years of the pilot would be \$100 million.

Implementing a pilot as proposed has conservatively been shown to save around 350 lives, provide around \$400 million in benefit and show a return on investment well over 4:1.

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Figures have been calculated using modelling adapted from that developed by Rachel Silverman Bonnifield at the Center for Global Development and Adrian Towse at the Office of Health Economics.

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