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Feasibility of de-linking reimbursement of antimicrobials from sales: the Australian perspective as a qualitative case study

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Background: There is a disparity in the economic return achievable for antimicrobials compared with other drugs because of the need for stewardship. This has led to a decline in pharmaceutical companies' willingness to invest in the development of these drugs and a consequent global interest in funding models where reimbursement is de-linked from sales.

Objectives: To explore the perspective of stakeholders regarding the feasibility of de-linked reimbursement of antimicrobials in Australia.

Methods: Semi-structured interviews were conducted with 18 participants sourced from the pharmaceutical industry and individuals representing public-sector payers or regulators. Interviews were transcribed verbatim, coded and thematically analysed using the framework method.

Results: Five key themes were identified in the interviews: funding silos are a barrier to de-linking reimbursement; varying levels of supporting evidence are (currently) required for funding depending upon setting; funding status or cost is used as a stewardship tool; a de-linked model may cost more; and concerns regarding governance and access to antimicrobials exist in the private sector.

Conclusions: Australia's current multi-tiered funding of medicines across different levels of government was perceived as a barrier to de-linked reimbursement. Participants felt that the responsibility for antimicrobial funding and stewardship should be integrated and centralized. Implementing a nationally funded de-linked reimbursement model for new antimicrobials would require a review of funding decision-making criteria, given that most MDR infections are off-label indications and could not then be funded through the Australian Pharmaceutical Benefits Scheme. Findings from this study could be applicable to other countries with reimbursement frameworks similar to Australia.

Introduction

Overuse and inappropriate use of currently available antimicrobial drugs is the leading cause of worsening antimicrobial resistance (AMR). Globally there is growing concern about the lack of new antimicrobial drugs in clinical development to treat MDR infections. While it is widely acknowledged that the current volume-based model of reimbursement is broken, there is uncertainty around how countries can adapt their regulatory and funding processes for antimicrobials in order to maintain a viable business model for manufacturers without inadvertently promoting overuse.[1,2] For pharmaceutical companies, the return on investment to shareholders is higher when prescription volumes are high. With AMR becoming a global threat to healthcare, interventions to reduce antimicrobial use and limit the risk of AMR have directly impacted the potential profit a company can make from marketing an antimicrobial drug. This has led to a marked decline in new antimicrobials being developed.

De-linking reimbursement from the number of units sold has been proposed internationally to reduce the incentive for companies to promote inappropriate sales.[3–6] The Australian Government has acknowledged that opportunities to support antimicrobial development need to be explored.[7] Various alternative reimbursement models have been proposed, including fully de-linked models where companies are reimbursed in pre-agreed lump-sum payments to the company irrespective of the number of prescriptions filled (Figure 1). Partially de-linked models have also been suggested. These include lower lump-sum market-entry

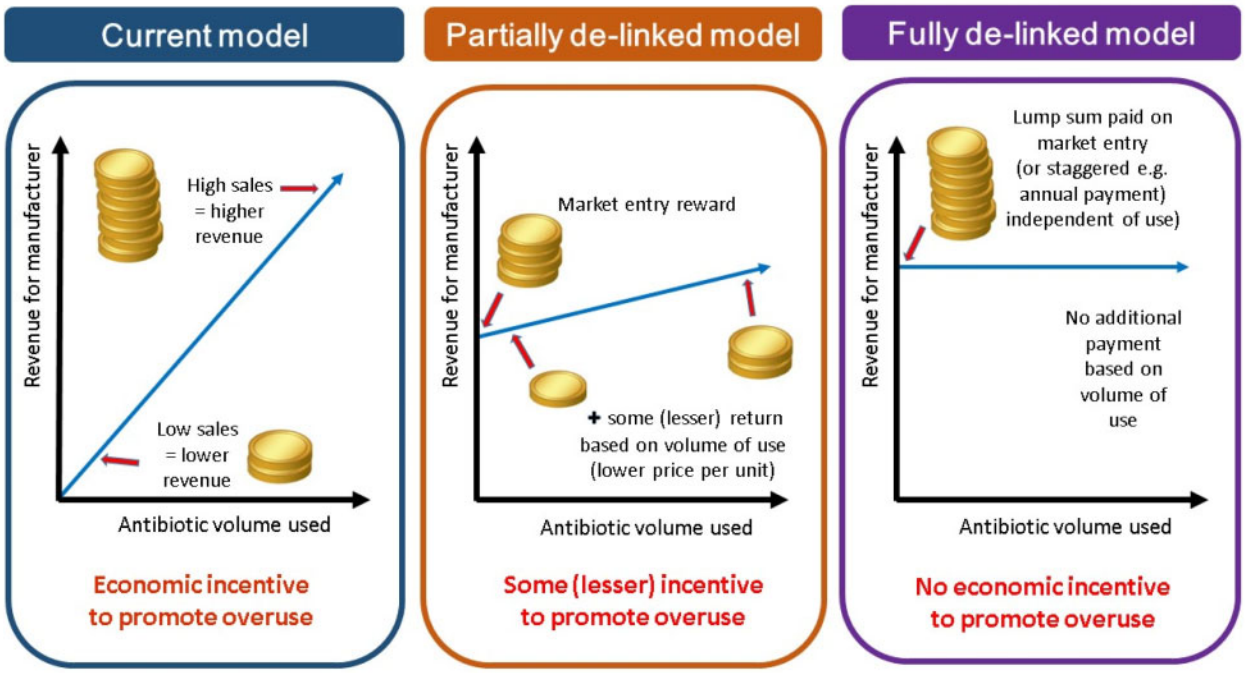

Figure 1. Simplified illustration of alternative reimbursement models.

rewards combined with some performance-based income, allowing future contractual payments to be linked to meeting certain predefined stewardship goals in addition to supply-chain security.[8–11] Sustainable solutions need to be a collaborative negotiation between manufacturers, regulators and payers. For manufacturers, economic reward for shareholders is the motivational goal, whereas for governments the aim is to allocate funding and resources to achieve maximum benefit for the population.

Australia has a universal healthcare system that is financed through a complex combination of Federal and State Government funding, in addition to private insurance and individual patient funds.[12] The proportion each contributes to the healthcare costs for an individual depends upon the healthcare setting (e.g. inpatient or outpatient), the clinical indication of the patient and the healthcare services provided. Medicines for patients in the community (non-hospital setting) are funded by the Federal Government via the Pharmaceutical Benefits Scheme (PBS).[13] Medicines administered to public hospital inpatients in Australia are funded by the state or territory governments, whereas medicines supplied to private hospital inpatients are funded by a combination of federal funding (for PBS-listed medicines), health insurance and patient funds. The complexity of funding sources for antimicrobials in Australia is illustrated in Table 1.

Recently there has been increased global investment ('push incentives') in research to discover potential new antimicrobials and repurpose older agents. Despite this increased investment, based on the current pipeline of drugs in various stages of research and development, it is estimated that no more than one new innovative drug active against a 'WHO priority pathogen'[14] will reach the marketplace in the next 5 years.[15] Investing in human trials

Table 1. Funding sources for antimicrobials in Australia

Setting	Funding of antimicrobial treatment
Public hospital inpatient	***State funded*** via hospital budget
Private hospital inpatient	If PBS-listed indication → ***Federally funded***; If antimicrobial registered in Australia but not PBS-listed indication → ***Health-insurer funded*** or ***patient funded***; If antimicrobial not registered in Australia → ***Patient-funded***[a]
Outpatients/ community setting	Oral antimicrobial treatment: If PBS-listed indication → ***Federally funded*** with ***patient co-payment*** (Note: Patient pays full cost where the cost of the antimicrobial is less than the set co-payment fee[b]); Non-PBS-listed indication (including off-label indications or unregistered antimicrobials) → ***patient funded***, or ***state funded*** (hospital budget) if prescribed on hospital discharge or in outpatient clinic; Outpatient Parenteral Antimicrobial Therapy (OPAT) → ***State funded*** (hospital budget), with ***federal reimbursement*** of the antimicrobial if PBS-listed indication

[a]Most health insurance companies do not cover unregistered drugs although some may cover inpatient treatment with unregistered antimicrobials depending on the policy.
[b]http://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee.

to establish clinical evidence of efficacy and safety for a new antimicrobial is considered a commercial risk, given that potential revenue will be limited by prescribing restrictions to minimize the risk of resistance. International research into methods to re-invigorate antimicrobial development has recommended that governments focus on regulatory and funding mechanisms ('pull incentives') to ensure industry has economic certainty once an antimicrobial is marketed.[15]

Although de-linked business models are a theoretical solution, implementation remains practically challenging, particularly given the global cooperation required. The UK national AMR plan includes the intention to explore de-linked funding of antimicrobials.[16] A subscription model is being trialled; however, there is a lack of transparency regarding the magnitude of the lump sums to be paid.[17] Concerns have been raised that lump-sum payments, irrespective of use, may facilitate distribution of public resources for private gain based on possibly over-inflated estimates of 'value' advocated by manufacturers.[6]

Any new funding model needs to guarantee availability of the antimicrobial when needed, as patient outcomes are dependent on timely administration, particularly for life-threatening infections. Lack of economic return has been cited as an underlying causative factor in the increasingly frequent problem of antimicrobial shortages both in Australia and globally.[18,19]

Medicines 'formularies' are used by Australian hospitals to ensure constancy of supply and contain procurement costs of medicines.[20,21] Hospital formularies are typically managed by multidisciplinary drug and therapeutics committees. Formulary decisions should ideally consider cost-effectiveness but are typically motivated by budget impact, i.e. a local reduction in medicine costs, and may fail to adequately assess system-wide clinical benefits or cost reductions.[22,23] Some states in Australia have moved to state-wide formulary decision-making to improve equity of access and standardize care between hospitals.[24–27]

This study was designed to explore the feasibility and practicalities of implementing a de-linked funding model for antimicrobials in Australia, from the perspectives of policymakers/payers and the pharmaceutical industry.

Methods

Design and setting

The context of this study was the Australian healthcare system, which is a universally funded public health system sitting alongside a privately funded health sector. The Australian setting was chosen as a case study, to provide the context of a high-income country with multi-tiered healthcare funding and a relatively small economic market globally. A qualitative approach using in-depth semi-structured interviews was chosen to explore nuances within and between the views of participants.[28] Interviews followed an interview guide (available as Supplementary data at *JAC-AMR* Online) based upon a search of published and grey literature, with open-ended questions allowing participants to determine the nature of their responses, enabling additional explanation or provision of examples. Interviews were conducted by the first author, either face-to-face or via video- or phone-conferencing.

Recruitment of participants

Nine participants from the pharmaceutical industry and nine policymakers were recruited between July and December 2018. Recruitment was initially purposive to select key stakeholders, with additional participants recruited by snowball sampling[29,30] until thematic saturation was achieved; that is, until no new themes pertaining to the study objectives were identified within the final interviews.[31,32] Stakeholders from the pharmaceutical industry represented six companies, ranging from large multinational companies to small–medium companies, in addition to a representative from Medicines Australia.[33] Industry participants were senior employees working in managerial or policy roles within companies currently developing or marketing antimicrobial medicines in Australia, as well as medical managers and market entry specialists. Policymakers included federal government policymakers, state government employees involved with state-wide formulary decision-making and members or ex-members of the Australian Pharmaceutical Benefits Advisory Committee (PBAC) or advisory committees to the Australian regulator, the Therapeutic Goods Administration (TGA).

Analysis

Interviews were recorded and transcribed verbatim, with speech idiosyncrasies (such as 'you know', 'sort of' or 'um') removed for ease of reading. Names were de-identified at the point of transcription and replaced with a study number to anonymize the individual and their workplace or associated role. Data collection and analysis were conducted simultaneously, with deductive (predefined) as well as inductive coding and creation of new codes when required.

The transcripts were coded and thematically analysed using NVivo® software (version 12, QSR International Pty Ltd) in accordance with the framework method of qualitative data analysis.[34] Transcripts were read and re-read by the first author to allow familiarization with the data and an initial coding framework developed following the initial interviews, in consultation with two other authors. These initial codes were categorized into potential themes, which were refined with the addition of new data. Minor themes linked by a common distinct idea or subject were grouped together as a major theme. Any differences in interpretation were resolved through discussion amongst the authors.

Ethics

This research was approved by the University of Adelaide Human Research Ethics Committee (Approval H-2018-136). Participants were provided with written information regarding the study and informed consent was obtained.

Results

Themes

A dominant theme addressed the issue of how to translate the clinical value of an antimicrobial into a monetary value and this is discussed elsewhere (N. T. Hillock, T. L. Merlin, J. Karnon, J. Turnidge, J. Eliott, unpublished data). Five further themes drawn from the data and pertaining to alternative methods of reimbursement are discussed below.

Theme 1: funding silos for medicines and healthcare are a barrier to de-linking reimbursement

Many participants were aware of de-linked funding models proposed internationally but most agreed that implementation would be challenging, citing the complexities of multiple funding sources for medicines in Australia as a barrier.

The divide between the perceived responsibilities of different levels of government was evident in the responses from both policymakers and stakeholders from industry (Table 2).

Table 2. Quotes illustrating division in perceived responsibilities of levels of government

Quote
In general in health across Australia we've got problems with multiple silos and multiple different areas of funding and almost sort of stealing money from one area. A lot of it is false economics where the big picture is you've got a certain amount of money, and whether it's Commonwealth money or state money. (State policymaker)
Antimicrobials that are for emerging resistant organisms are in smaller groups and it could be hospital only, so therefore it may be a state budget thing more so than a Commonwealth budget matter. (Federal policymaker)
There is a bit of divide between what happens in the commonwealth-funded space in terms of prevention [of resistance] versus what can kind of happen at the hospitals. I think it is going to become an increasing problem and I think we probably do need to relook at the funding models of some these [interventions]. . .taking into account the increasing complexity of patients and their conditions they have. (State government policymaker)
So that is where I think it gets really difficult, because as it stands most of the antibiotics we are talking about the government are not paying for. The state hospitals are paying for it. (Pharmaceutical industry stakeholder)
There is always that tension between the state and federal budget, and if Pharma comes to the federal and says 'please pay us money for new antibiotics, and you are currently not paying anything but we want some money', so you know, we will never win that battle on our own. (Pharmaceutical industry stakeholder)

Table 3. Illustrative quotes—varying levels of evidence required for funding depending on payer

Quote
The lack of cost-effectiveness constraints around the non-PBS marketplace increases the chance that manufacturers would license a drug with the TGA irrespective of whether they put it forward for the PBS or not. (Ex-PBAC member)
Because you're not going down the PBS road. . .they're (public hospitals) freer to use what they need to use. (Industry representative, policy role)
If you get regulatory approval, it's based on whatever trials you've got, whereas a lot of those drugs are used off-label. (Industry representative, market access)

In general, participants felt a more centralized funding of antimicrobials would be beneficial, particularly industry stakeholders who were generally in favour of federal funding of hospital antimicrobials. Most policymakers agreed, suggesting that centralized funding of antimicrobials, similar to the funding of vaccines or blood products, may remove cost-shifting incentives:

> 'It would be a lot simpler if the funding was less split between the states and the federal [government]'.

Some industry stakeholders acknowledged that with hospital- or state-based tendering, there can be marked variation in antibiotic prices between hospitals and states and that a nationwide tendering system may remove price differentials between states. State policymakers favoured centralized tendering for generic antibiotic supply, stating, 'It would make sense that we've all got the same price'. There was concern, however, about awarding a tender to a single supplier due to possibly increasing the risk of shortages:

> 'You offer a 100% to that company, but then you run that risk . . . where that one company can no longer supply and then you get into shortages and unavailability because the other players, that in a competitive market are there, have just gone away and they don't do it at all anymore'. (PBAC member)

Some participants felt that federal management and funding of generic antimicrobials would prevent local stockpiling if there was a shortage, 'because then you're removing the free-for-all that happens when something goes out of stock'.

Opinions varied regarding centralization of funding and supply for new drugs. Some participants felt there was a need for local hospital management to allow for flexibility in rare or complex infections:

> 'In principle a common formulary is good; the time bringing it all together and the need to have flexibility in certain circumstances are an impediment'. (Federal policymaker)

Theme 2: varying levels of evidence (currently) required for funding depending upon the setting

A further perception was that new antibiotics were generally destined for use in the hospital system and that access to funding in the public hospital system was a less rigorous process than for federal funding of these medicines through the PBS, where evidence of value for money (cost–utility) is required (Table 3).

Participants agreed that it would be difficult for new drugs targeting MDR infections to attain the level of evidence required to support a regulatory (market approval) decision and, without regulatory approval, access to federal subsidy for the medicine is not possible in Australia. One industry participant emphasized the challenges with obtaining clinical trial evidence for treatment of MDR infections and the ethical issues arising if a patient is randomized to 'standard of care' when there is a risk the infection may be resistant to current treatment options:

> 'Let's say multi-drug resistant *Acinetobacter baumannii*, right? That's an area with great unmet need. If trials were to be done on new agents, then they would want to have not a trial against susceptible *Acinetobacter* because that's not where they want to use it'. (Pharmaceutical industry stakeholder)

One policymaker acknowledged the difficulties regarding changing resistance patterns affecting efficacy, saying, 'We have trial data that's generated. . .we can approve it at a point in time and the difficulty is it may be difficult to replicate these studies at a later time'.

Industry stakeholders believed government had a role to assist with collection and assessment of outcome data:

> 'I think we have a good commitment to generating real-world data and to supporting clinician-generated data. But should the responsibility be totally on Pharma?'

Policymakers were generally supportive of clinical outcome registries, but were more cautious regarding fast-tracking reimbursement processes:

> 'We've got examples in other areas where fast-tracking of drugs has actually led to quite poor outcomes'.

New drugs targeted at an unmet need were likely to be high cost, but participants felt they would likely be approved for individual patients at hospital level despite this:

> 'You are going to have some extremely high-cost antibiotics, extremely costly antibiotics that you will have extremely tight restrictions on. . .while clearly for an antibiotic you would expect it to be almost instant approval but it may still necessarily rely on some central level of approval'. (PBAC member)

Theme 3: funding status used as a stewardship tool

A further theme, particularly among policymakers, was that the current 'user-pays' funding model allows cost to be used to control use. As one participant put it, 'paying for something does act as a suitable disincentive for overuse as well'. Some policymakers felt that having hospitals pay for antimicrobials is a good incentive to keep utilization rates down, particularly for high-volume generic drugs. Some industry participants also recognized that not being funded on the PBS prevented inappropriate use in the general practice (GP) setting. One industry participant used the example of oral linezolid, saying 'If a GP could prescribe it. . .potentially that leads to some misuse of a drug that should be reserved'. Some participants felt that separation of payment from use (de-linking) would remove the cost barrier that can be used to prevent overuse.

Although cost could be currently used as a tool to prevent overuse, other participants pointed out that the appropriateness of antimicrobial use can be adversely influenced by the cost, because some of the least appropriate antimicrobials are often the cheapest. 'So it might be the right drug to use in that patient, but because it's too highly priced then they will look for another option'. Antimicrobial drugs are not priced according to their impact on resistance selection and sometimes the broader-spectrum drugs are cheaper than the narrower-spectrum ones:

> 'At the moment. . .the hospital pharmacy budget pays for antimicrobials. So if you have the choice between hypothetically a new agent, which may be more appropriate from a stewardship perspective, or something which is cheap, both of which is going to work in that patient, but one has a higher societal cost. . .they would have to go with the cheaper agent, because that's the precedent for their hospital budget'. (Pharmaceutical industry, medical manager)

Theme 4: concerns about a de-linked model costing more

Non-industry participants expressed concerns that a de-linked method of reimbursing companies for antimicrobials would cost more than the current funding of antimicrobials in Australia. To fund antimicrobials via a de-linked model and still incentivize new products, payment is made even if the drug is not used. One policymaker gave an analogy of 'a bit like the EU paying farmers not to farm'. Uncertainty about the amount a country should pay, and how a new product would be assessed for value to that country's population, was a prominent theme. Participants felt that the impact Australia could have on incentivizing antimicrobial development was insignificant in a global context due to its small market size.

There was general agreement across stakeholders that increasing AMR will mean increasing costs associated with infections that are more difficult to treat, but drug procurement costs seemed more visible to payers than the consequences of resistance in the future.

> 'I think the problem with the de-linked model I guess is finding. . .a cost-efficient price, and so we could end up just paying a lot more for antibiotics with little benefit'. (PBAC member)

Theme 5: governance of, and access to, antimicrobial use in the private hospital or community sector

Most stakeholders believed that the current funding of medicines in Australia results in inequity of access in the private hospital sector (Table 4). Participants agreed that in private hospitals there is an incentive to give preference to PBS-listed antimicrobials over non-PBS antimicrobials, because they are federally funded, particularly if a health insurer does not cover the cost.

Participants believed that if a patient needed a high-cost, non-PBS-funded antibiotic, they would need to be transferred to the public sector for hospital-funded access:

> 'I think most patients who need high-cost antibiotics, they end up accessing it one way or another. . .and if it can't happen through the private sector, potentially a lot of that gets transferred into the public sector'. (PBAC member)

It was felt that the only way to ensure equity of access to new antimicrobials in the private hospital setting would be for antimicrobials to be federally funded across all settings:

> 'Clearly if the PBS found a way to approve the use of drugs under specific indications and clearly that's a role that may occur in the private sector. . .that would definitely improve access in terms of those that saw a way to get approved'. (Ex-PBAC member)

Discussion

New antibiotics are destined predominantly for the public hospital setting, which is funded by the state governments in Australia, where the level of evidence required to obtain funded access is

Table 4. Illustrative quotes—inequity of access in the private sector

Quote
Inequity of access—once you start quoting costs like that then it really comes down to a decision of a bunch of people sitting around a table at each hospital or Network (Local Health Network) as to whether the Network will bear that cost, and in the private system there's a much more defined accounting system. (Ex-PBAC member)
The biggest difference we see between public and private, is private is a lot more restricted in terms of what they spend. (Industry representative)
The PBS, non-PBS thing. . .again could potentially be an issue with, for the patient, because if they're presented with a perhaps not the most appropriate medication that's going to cost them $6, versus the most appropriate medication which might cost them $100, then that's going to be a barrier to appropriate prescribing. (Pharmaceutical industry, policy manager)

lower than required for federal reimbursement on the PBS. In addition to challenges assigning a monetary value to a lump-sum payment for an antimicrobial, most participants in this study felt that hospital or state budgets were insufficiently flexible to accommodate negotiating either a fully de-linked lump-sum payment or market-entry reward as part of a partially de-linked model. Federal funding of all antimicrobials was considered an alternative model (a federally funded national formulary), which participants felt could assist with market stability and remove price discrepancies between the states, but they raised some concerns regarding flexibility and the ability to cater for local differences in antimicrobial epidemiology.

Although current funding of healthcare in Australia is multi-tiered, there are examples of nationwide funding of some resources, such as that of blood products through the National Blood Authority (NBA). The NBA is federally funded with a national inventory system that allows local health services to enter their inventory levels, to limit waste and ensure the product is available where it is needed.[35]

Concerns about increased costs were expressed by non-industry participants. Participants in this study also raised concerns about equity of access and the governance of stewardship in the private hospital setting currently and agreed that federal oversight and funding could improve equity.

Limitations

Our sample of policymakers included funding decision-makers at the Australian federal and state level, but only two states were represented, despite attempts to recruit participants from two other states with state-wide formulary processes. States without a state-wide drug formulary were not represented. While the majority of participants were recruited by purposive sampling to ensure a representative sample, some participants were recruited by snowball sampling, which may increase the risk of selection bias.

Conclusions

The adoption of a de-linked reimbursement model for antimicrobials in Australia would require a system-wide transformation of funding. Fragmented silos of funding and split responsibility for consequences of future resistance were highlighted by stakeholders as a significant barrier to implementing a de-linked reimbursement model. With current funding silos, there is not one single 'funder' responsible for the patient outcome, nor the outcome regarding the impact on AMR in the future. The economic burden of MDR infections sits largely with hospitals as patients with these infections are predominantly treated in the hospital setting. Hospitals have antimicrobial prescribing policies aimed at reducing resistance; however, there is no economic incentive to consider the long-term impact of formulary decisions on future resistance and the consequent economic burden in future decades; the economic drivers for hospitals are to keep current medication costs at a minimum and enable patient discharge as soon as possible. De-linking reimbursement from sales would require moving towards a more centralized (federal) funding model to remove silos of responsibility regarding the management of AMR, including the funding of antimicrobials. Increased federal governance over the access and use of antimicrobials in the private sector would also be required.

In addition, to implement a nationally funded de-linked reimbursement model for new antimicrobials, the evidentiary support for reimbursement would need to be more flexible than current PBS requirements, given that many MDR infections are off-label indications (i.e. medical conditions not approved by the national drug regulatory body). Governments need to consider adaptive methods of collecting sufficient evidence for federal reimbursement of novel antimicrobials, or for reimbursement of older antimicrobials for novel indications, with consideration of the wider public health impact.

This study provides a unique insight into the perspective of stakeholders regarding the feasibility of an alternative de-linked model of reimbursement for antimicrobials in Australia. While the larger markets of the USA, Europe, Japan and China are driving the public investment into antimicrobial development, the methods of reimbursement and regulatory controls regarding usage differ among these large market players. Australia is representative of smaller, high-income countries with complex, multi-tiered reimbursement structures for medicines. Findings from this study could be applicable to other countries with reimbursement frameworks similar to the Australian model. De-linked funding for antimicrobials requires a collaborative international approach, necessitating significant policy and funding reform within countries in order for it to succeed globally.

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Transparency declarations

T.L.M. is the director of Adelaide Health Technology Assessment, University of Adelaide. All other authors: none to declare.

Supplementary data

The Interview guide and Reviewer reports 1 and 2 are available as Supplementary data at *JAC-AMR* Online.

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