Medicines Australia | Better health through research and innovation

5 April 2024

Australian National Audit Office
Attention: Alexandra Collins
Via email administrationofpbs@anao.gov.au

Re: ANAO audit of PBS Administration 2023–4 – Medicines Australia submission 2

Summary of key points

- The Department of Health and Aged Care (DoHAC) has implemented several measures to manage the cost of the PBS, most notably regular price reductions to older medicines that are reinvested into funding of new medicines.
- The flat growth in PBS spending, in contrast to other comparable programmes like the Medicare Benefits Schedule (MBS) and the National Disability Insurance Scheme (NDIS), demonstrates that these measures are working effectively.
- However, the DoHAC's focus on cost containment measures rather than investment in Australia's health has resulted in low prices for medicines in Australia, which has affected the time from registration to PBS listing for these medicines. Some medicines are not launched in Australia at all because it is not financially viable to do so.
- Therefore, while cost-containment measures may be effective at managing the cost of the PBS, they may not be 'appropriate' because they are affecting patient access to new treatments.
- Medicines Australia recommends that the focus shift to appropriate investment rather than cost containment.

Medicines Australia thanks the Australian National Audit Office (ANAO) for the opportunity to contribute a second response to the 2023–4 audit of PBS administration.

Medicines Australia leads the research-based medicines industry of Australia. Our members discover, develop and manufacture prescription medicines, biotherapeutic products and vaccines that bring health, social and economic benefits to Australia. Medicines Australia and its members are seeking to continue our collaborative partnership with the Australian Government to ensure that Australia's first-class health care system can continue to deliver lifesaving and life changing medicines to Australian patients.

In October 2023, Medicines Australia submitted a response to the ongoing ANAO audit based on the criteria under review at that time. In late 2023, the ANAO expanded the scope of the audit to include an additional criterion:

'*Has Health established appropriate arrangements to manage the cost of the PBS?*'

This document adds to Medicines Australia's previous response, specifically addressing the new criterion. Each of the four subpoints provided by the ANAO to Medicines Australia is addressed, along with some additional comments relating to capacity and capability within the DoHAC.

In addressing the additional criterion it is worth noting that investment in the PBS has not increased significantly in recent years, though there is a lack of transparency in reporting of disaggregated PBS spend, including F1, F2 and supply chain costs. In the 2023–2024 Federal Budget, the Government was expected to spend $19.1 billion on the PBS, with a compound annual growth rate (CAGR) of negative

0.46% in nominal terms.[1] The lack of growth in PBS investment contrasts with similar schemes such as the Medicare Benefits Schedule (MBS), which had an expected spend of $30.4 billion in the same Budget, with a CAGR of 6.2%;[2] and the National Disability Insurance Scheme (NDIS), with an expected spend of $41.9 billion and a CAGR of 11.2%.[3] PBS spend as a proportion of gross domestic product (GDP) has also declined and is projected to continue to decline over time, contrasted with the MBS.

The Federal Budget papers from 2023–2024 state that '*Expenses for the pharmaceutical benefits and services sub-function are expected to increase by 0.7 per cent in nominal terms and decrease by 7.0 per cent in real terms over the period 2023–24 to 2026–27. The decrease in real terms is primarily due to the impacts of existing pricing policies under the Pharmaceutical Benefits Scheme*'.[4] Over the longer term, PBS expenditure has grown from $10 billion to $13 billion over the past 10 years in nominal terms, but shrinking as a proportion of total Australian Government healthcare expenditure from 20% in 2012–13 to 17% in 2020–21.[5] These figures demonstrate that the measures currently in place to contain the cost of the PBS are more than adequately achieving this goal. As described below, however, this has contributed to Australian patients missing out on or experiencing delays in access to new, life-improving and life-sustaining treatments.

Since 2010, successive agreements between the Commonwealth Government and Medicines Australia and have generated savings to the PBS via price reductions, so that enduring savings measures are built into the system. Since 2020, the New Medicines Funding Guarantee has enabled the listing of medicines on the PBS without the need for new offsets because there are guaranteed savings of $2.8 billion over 4 years from statutory and other price reductions embedded into the system. Further, negotiations between the Department of Health and manufacturers frequently include risk-share arrangements (RSAs) that provide predictable, contained PBS spending on a case-by-case basis. However, it is unsustainable for savings to continuously pay for new medicines as advances in medical science find treatments and cures for some of the most difficult and hard to treat populations. Therefore, an improved balance between the generation of savings and investment in new medicines is required to maintain Australia as a first-launch country and improve time to access for new treatments, which are the shared goals of the Strategic Agreement between the Commonwealth and Medicines Australia 2022–2027.

Medicines Australia submitted responses to both the first and second rounds of consultation for the ongoing HTA Policy and Methods Review. Our submissions to those consultations touch on many of the industry's experiences relating to the DoHAC's arrangements to manage the cost of the PBS and may be read as companion documents to this response for additional context.

Assessment of the cost-effectiveness of medicines listed on the PBS (e.g., PBAC assessment, post-market review)

There are many mechanisms in place to manage the cost of the PBS, including movement of medicines from formulary 1 (F1) to formulary 2 (F2) when generic or biosimilar medicines are listed on the PBS,

[1] Budget 2023–2024. Budget Strategy and Outlook. Budget Paper No. 1. Table 6.8.2. Available at https://budget.gov.au/content/bp1/download/bp1_2023-24_230727.pdf. Accessed 27 March 2024.
[2] Budget 2023–2024. Budget Strategy and Outlook. Budget Paper No. 1. Table 6.8.1. Available at https://budget.gov.au/content/bp1/download/bp1_2023-24_230727.pdf. Accessed 27 March 2024.
[3] Budget 2023–2024. Budget Strategy and Outlook. Budget Paper No. 1. Table 6.9.2. Available at https://budget.gov.au/content/bp1/download/bp1_2023-24_230727.pdf. Accessed 27 March 2024.
[4] Budget 2023–2024. Budget Strategy and Outlook. Budget Paper No. 1. Page 211. Available at https://budget.gov.au/content/bp1/download/bp1_2023-24_230727.pdf. Accessed 27 March 2024.
[5] Medicines Australia. Funding Innovative Medicines Whitepaper. May 2023. Available at https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/06/Funding-Innovative-Medicines-1.pdf. Accessed 3 April 2024.

with accompanying price reductions; price disclosure for medicines in F2; and statutory and administrative price reductions at various defined points in a medicine's life cycle. These mechanisms have been introduced in consultation with Medicines Australia and with the broader medicines industry, and are designed to deliver savings to the PBS that can be reinvested in funding newer medicines. However, these mechanisms have impacted patient access to effective treatment.

Cost-containment versus investment in innovation: HTA methods that devalue new medicines and the impacts on patient access

The price reduction policies in place have flow-on effects to the prices of newer medicines being evaluated by the PBAC. The health technology assessment (HTA) process requires that sponsors present a comparison of a new treatment with a treatment already funded on the PBS. Frequently, this means that new medicines are compared with older medicines in F2, which have undergone one or more price reductions since being listed on the PBS. The periodic reduction in value of the older medicine means that the newer medicine is benchmarked against a low-priced alternative. This means that the price of the new medicine is determined based on demonstration of the incremental benefit against a reduced incremental cost (in cases where an efficacy advantage can be demonstrated), resulting in low prices for new medicines in Australia.

Where an efficacy advantage is not demonstrated, the existing interpretation of Section 101 (3b) of the National Health Act by the DoHAC – that is, that the PBAC is legally bound under this Section to price benchmark new medicines to the lowest-cost comparator – further devalues new treatments.

In some cases, the prices that new medicines attract in a setting where they are benchmarked against low-cost medicines means that it is financially challenging or even economically unviable for sponsors to achieve reimbursement of medicines in Australia. For medicines that are reimbursed in Australia, the time from registration to reimbursement is, on average, 466 days (Medicines Matter report, 2022). This is below the OECD average, longer than countries with comparable HTA systems, and places Australia thirteenth in the top 20 OECD countries in terms of time to access to new medicines.

There are also a number of medicines that are not launched in Australia for an extended period or at all. Recently, Medicines Australia commissioned an analysis of medicines that were registered for use in either the USA or Europe (or both) during the period from 2015 to 2020, that are (1) not registered in Australia; (2) registered but not reimbursed in Australia; or (3) registered and reimbursed for some but not all possible indications. This analysis identified 193 medicines that were either not available in Australia at all, not reimbursed, or not reimbursed for all potentially eligible patients. Of these:

- 85 are considered high-priority based on clinical need and a lack of alternative treatments
- 99 are for orphan conditions (54 of which are considered high-priority)
- 56 are for the treatment of cancer (27 of which are considered high-priority)
- 24 are anti-infective medicines, including novel antibiotics and antifungals (17 of which are considered high-priority).

While the reasons that these medicines have not been launched in Australia vary, one common theme heard from sponsor companies is that the HTA environment in Australia does not always support the commercial viability of bringing these medicines to market. Low prices driven by HTA policies and methods that focus on cost-containment rather than investment in innovation, coupled with policies that further erode prices over the life-cycle of a medicine, mean that in some cases medicines sponsors opt not to seek registration or reimbursement of some medicines.

Further, the way in which the current system assigns value to new medicines specifically precludes a consideration of some of the flow-on effects of new treatments, thereby further reducing their value. This is inconsistent with moves by the Albanese government towards better understanding the broader factors affecting Australians' wellbeing, as outlined in the Measuring What Matters Framework. HTA submissions to evaluate the cost-effectiveness of new medicines do not quantify the impact of these medicines on elements like the subsequent ability of patients to return to work and thereby reduce dependence on social welfare; reductions in costs to State and Territory governments via reductions in hospitalisations and other State- and Territory-funded health services; or productivity gains from patients being able to contribute to the economy as a result of new treatments, all of which are outcomes highly valued by people living with medical conditions. More appropriate valuation of these secondary effects of new medicines would contribute to an environment more conducive to the launch of new treatments in Australia.

Key to the methods employed within the Australian HTA system to manage the cost of the PBS is the issue of uncertainty. Uncertainty is inherent in any forward-looking cost-benefit analysis, including HTA. Tools implemented to help manage cases where uncertainty is high, such as managed access programmes (MAPs), have not been widely taken up for various reasons: difficulty in gaining agreement between sponsors and the DoHAC upfront; high risk for all stakeholders; administrative burden for both the DoHAC and sponsors; and the need for a seamless 'exit strategy' if data from the MAP do not support continued supply of the medicine on the PBS, to name a few. A revised MAP structure with more balanced risk and a defined process for managing these issues could improve the uptake of MAPs.

The HTA Policy and Methods Review currently being undertaken may address some of these issues through reforms implemented as a result of the Review.

Post-market reviews

Medicines Australia addressed the issues relating to post-market reviews (PMRs) in the first response to this consultation. We note that an updated PMR framework has since been published that may address many of the industry's concerns about the process for conducting PMRs. The new framework aims to reduce the time taken for each PMR, and has some significant improvements in scope, transparency and consultation compared with the original framework. However, how this will impact the outcome of PMRs remains to be seen. Historically, PMRs have frequently led to price reductions for PBS-listed medicines, with few examples of a price increase if the review shows a better-than-expected improvement in efficacy or cost-effectiveness.

Manage the prices of PBS medicines (e.g., price negotiations with sponsors, statutory price reduction mechanisms)

Some aspects of pricing negotiations between sponsors and the DoHAC work well. The opportunity to assign both published and effective prices through special pricing arrangements (SPAs), for example, is a key feature of the Australian HTA system. SPAs allow many new medicines to proceed to a PBS listing, when they otherwise could not for reasons relating to international price referencing. Similarly, indication-based pricing is a unique feature of the Australian HTA system that incentivises sponsor companies to bring new medicines to the Australian market and should be retained. Indication-based pricing means that a single medicine used to treat more than one condition can be assigned a different PBS price for each condition it is used to treat, allowing sponsors to retain the value of their medicines.

However, some aspects of pricing negotiations could be improved. This section will discuss some of these.

Post-recommendation pricing negotiation processes

In recent years, some measures have been put in place to help expedite the PBS listing of medicines following a positive recommendation by the PBAC. For example, pricing pathways were introduced that were designed to facilitate faster pricing negotiations, and thereby reach a PBS listing more quickly. However, these have not all delivered improvements in time to PBS listing.

An analysis of time from TGA registration to PBS listing for PBAC recommendations made between March 2021 and March 2023 found that, on average, post-recommendation processes took 194 days, or just over 6 months. Experiences reported by sponsor companies indicate that at least some of the reason for this length of time relates to the steps following a positive recommendation needing to be undertaken sequentially rather than concurrently. This can be further exacerbated by the need to repeat steps in certain cases, for example where there are errors in the spreadsheet modelling the cost to the Commonwealth that are not identified until late in the process. This can result in the need to repeat earlier steps as the final cost of listing the new treatment on the PBS is recalculated, which impacts RSA caps and necessitates addition correspondence between sponsors and the DoHAC. This issue is explored further in the section below discussing capacity and capability of DoHAC staff. A more defined process, with fixed timepoints for each milestone and some steps running concurrently rather than in parallel, could help to reduce the post-recommendation timeframe.

Further, Pricing Pathway A (a facilitated pathway in which complex submissions are assigned a case manager to help sponsors and the DoHAC navigate the path to a PBS listing) has not always expedited the process. Sponsors report that the case managers assigned are not always empowered to make decisions, meaning additional input and approval is required by more senior staff within the DoHAC, thereby delaying progress. While implemented with good intentions, in practice Pricing Pathway A has not facilitated faster or more efficient PBS listings following a positive PBAC recommendation.

Combination medicines

Some new medicines, particularly oncology medicines, seeking PBS listing need to be used in combination with other oncology treatment, providing patients with incremental improvements in overall survival and other patient-relevant outcomes. The use of combination oncology regimens is expected to continue to increase over time as additional targeted treatments are developed, and as the clinical evidence matures. In these cases, it can be difficult for sponsors to achieve recognition of the value of the innovative treatment by the PBAC and its sub-committees.

In some circumstances, because the value of the combination is consumed by the value of the existing backbone treatment (the medicine already on the PBS), it is difficult for a sponsor to make a submission or for a recommended combination to proceed to PBS listing because there is little or no additional value for the innovative medicine. The HTA system in Australia is not set up for this situation. This results in two issues:

- Sponsors may not be able to launch the product because the additional price for the new medicine means that it is not commercially viable to do so and may require delays until the backbone treatment moves into the F2 formulary.
- If the combination of medicines has more than one sponsor, competition law makes it challenging for sponsors to negotiate value attribution between the components of the combination. The United Kingdom's Competition and Market Authority recently made a prioritisation statement that "clarifies the circumstances under which it will not prioritise enforcement action against drug firms when they implement a specific 'negotiation framework'

to make more combination therapies available on the NHS." Similar steps in Australia would be beneficial for patient access to combination regimens.

The system should be amended to allow greater value recognition of the newer component of the combination to ensure that bringing these combinations to market is viable; and to allow communication between sponsors of the component medicines to discuss pricing in a compliant way, and facilitate PBS listing of these combination medicines.

Risk-sharing arrangements

Risk-sharing arrangements (RSAs) have been in place since 2006. They aim to manage residual uncertainties in HTA submissions, including uncertainty relating to cost-effectiveness, patient numbers, uptake rates, and overall cost to the Commonwealth. RSAs have become increasingly common since their inception. A survey of Medicines Australia member companies undertaken in 2023 found that around 70% of medicines are now under a RSA as a condition of their PBS listings.

During evaluation of reimbursement submissions and the subsequent pricing negotiations, the PBAC and the Department negotiate with sponsors over the assumptions in the budget impact modelling. The experience of sponsor companies is often that the assumptions accepted by the PBAC are on the lower end of the range of possible inputs, which can result in the need for multiple submissions, delays in PBS listings, and has resulted in around one-third of companies not proceeding with a PBS listing for at least one medicine. Further, in the majority of cases a rebate of 75% to 100% is applied for expenditure over the RSA caps, meaning that the balance of risk is borne by the sponsor.

As a cost-containment measure, therefore, RSAs are highly effective. However, RSAs should not solely be a cost-containment measure; they should reflect shared risk and RSAs should have subsidisation caps which reflect as far as possible the most reasonable, credible and accurate estimates of likely utilisation presented by the Sponsor and agreed by the PBAC. This would limit financial uncertainty to both sponsors and the Commonwealth and enable reimbursement, as far as possible, to appropriately cover the population deemed cost-effective by the PBAC and facilitate listing of new medicines.

To this end, reviewing the terms of a RSA should be undertaken as more information becomes available that would address the original uncertainty. While this is theoretically possible, in practice this rarely leads to removal of the RSA or an increase in the RSA caps despite evidence justifying the increase. Similarly, RSAs are rarely terminated at the end of the five-year term of the Deed encapsulating the RSA, instead rolling on to subsequent years with RSA caps in place. It is often incumbent on sponsors to request the removal of the RSA at this point, and the experience of sponsor companies is that the DoHAC may take time to respond to these requests, necessitating several follow-up communications by the sponsor. Without timely responses, member companies can often not meet reporting requirements, impacting business operations. There is no clear process or timelines for requesting changes to or cessation of a RSA, but responses from the DoHAC should come within a reasonable and defined timeframe.

Further, when sponsors do request cessation of an RSA, there have been instances where the DoHAC has asked sponsors to accept a price reduction on the medicine that is subject to the RSA, or even another medicine belonging to the same sponsor, with no justification. Removal of an RSA should not be incumbent on a price reduction or other changes that do not relate directly to the terms of the RSA.

Special pricing arrangements

As discussed, SPAs are an important feature of the Australian HTA system, and are integral to the listing of many medicines currently on the PBS. Without SPAs, it would not be possible for these medicines to

proceed to PBS listing because of the impact on the price of these medicines in countries that price-reference to Australia. Therefore, maintaining SPAs is key to ensuring access to medicines for Australian patients.

Recently, some sponsor companies have been asked to reduce the gap between published and effective medicine prices, at a time when they are being pushed to lower their prices in key markets such as the US. Maintaining published prices is important for the ongoing sustainability of the pharmaceutical industry globally due to reference pricing of medicines in other countries to Australian medicine prices (international reference pricing).

Lowest-cost comparator policy

As discussed, the DoHAC and the PBAC interprets Section 101(3b) of the National Health Act to mean that the PBAC is legally bound to price benchmark new medicines to the lowest-cost comparator. This devalues innovative treatments. Further, it links F1 and F2 through price-benchmarking of new F1 medicines to older F2 medicines, diluting the original intention of the two distinct formularies. Comparator price erosion coupled with inability to demonstrate superiority or incremental value creates disincentives for companies to commercialise new entrants to the PBS. It is Medicines Australia's contention that Section 101(3b) of the Act does not dictate that the lowest-cost comparator must be applied in every case.

The PBAC Guidelines define the relevant comparator as the '*the therapy that prescribers would most replace in practice*', and Clause 6.6. of the Strategic Agreement between the Commonwealth and Medicines Australia states that '*the PBAC can determine, including after taking into account matters put to it, whether a particular therapy is an alternative therapy, regardless of whether it is the lowest cost comparator*'. However, in practice the lowest-cost comparator policy is often applied even in circumstances where the comparator nominated by the PBAC is not the most clinically relevant.

When considering incremental innovation and patient benefit, there is a need to better define and evaluate terms for superiority and how a clinically relevant improvement is determined, to avoid delays in access. This could be informed by HTA Review recommendations where relevant.

Non-transparent pricing policies

Medicines Australia has recently been made aware of several instances in which sponsors have been asked to accept as policy the application of price reductions that are not documented anywhere. These examples do not fall within the statutory price reductions, which are well-defined by legislation and supporting explanatory memoranda and are applied consistently.

The first of these is the application of an administrative price reduction upon listing a new medicine with two presentations (for example, a tablet and a liquid formation) on the same day. Following a positive PBAC recommendation, companies have been told that listing two such presentations on the same day would trigger a 25% administrative price reduction. This policy is not documented anywhere and is not known to the industry at large.

One sponsor affected by this policy opted to list one presentation first and follow with a PBS listing for the other presentation later. During this process, the sponsor has been asked to provide real-world evidence or trial data to demonstrate that the second presentation provides an objective patient benefit. Given the listing of the second presentation is cost-neutral to the Commonwealth, this request for extra evidence is not aligned with the intention of the new presentation provisions of the National Health Act 1953.

The second example of a non-transparent pricing policy relates to the application of indication-specific pricing to the price of a new PBS entrant cost-minimised to another medicine, and relates to the lowest-cost comparator policy described above. The comparator medicine was a medicine on F2, without indication-specific pricing by special pricing arrangement since moving into F2, and with associated statutory price reductions applied over time. It was not clear to the sponsor of the new medicine that it would be cost-minimised to the lowest indication-specific price of the F2 comparator product until after receiving a positive recommendation by the PBAC and pricing negotiations were well underway. This policy does not appear to be documented anywhere. The indication-specific price (which incorporated all statutory price reductions) of the F2 medicine was entirely theoretical and not reflective of the amount the Commonwealth actually pays for the F2 medicine.

Subsequent to this, a different comparator had a price reduction applied, making it the new lowest-cost comparator, and the sponsor was advised that they would be cost-minimised to this new comparator.

Because of the need for confidentiality around pricing discussions, it is legally not possible for sponsor companies to discuss these sorts of non-transparent policies, making it necessary for sponsors to take it on faith that these policies are being applied consistently. The application of price-reduction policies that are not transparent to sponsor companies makes business planning and forecasting challenging, and has the potential to delay or even prevent PBS listing of new medicines. Clearly this has implications for patient access to new medicines. Policies aimed at reducing medicine prices in an effort to contain the cost of the PBS should be transparent, and developed in consultation with the industry and other stakeholders.

Manage pharmacy remuneration for dispensing PBS medicines (e.g., approval of suppliers, fee setting)

Efficient Funding of Chemotherapy Programme

In 2014, the Efficient Funding of Chemotherapy (EFC) Programme introduced algorithms that based reimbursement on the most efficient combination of vials to deliver a prescribed dose of chemotherapy, with the objective of minimising wastage and reducing cost to patient and the Commonwealth. Real world practice, particularly with respect to third-party commercial compounders is characterised by 'batch compounding' whereby multiple doses of the same chemotherapy regime for multiple patients are prepared on the same day, such that any wastage left over from the preparation of one dose is used to make up the dose for the next patient, a process referred to as 'vial sharing'. As a result, the total number of vials used to produce the required number of doses is less than what is calculated via the EFC algorithm. Facilities that can batch produce can also take full advantage of the 'overage' (the additional volume included in each vial of EFC medicines to ensure that the full dose can be extracted), to further reduce the number of vials required to produce a given number of doses, which is not currently accounted for under the funding of EFC medicines.

Vial sharing, as it is currently practiced, does not provide savings to the Commonwealth because reimbursement is based on an estimation of the most efficient combination of vials required to deliver a specific dose, assuming that any remaining drug is wasted. In practice, any residual drug is used to prepare the next dose for the next patients. Therefore, the total number of vials actually used to produce a given number of doses is less than the number of vials calculated and reimbursed via the EFC algorithm. Consequently, Commonwealth expenditure on the EFC Program is higher than is necessary. This is discussed in more detail in Medicines Australia's response to the EFC Review in 2021.

Since this time, the final report of the review has been released. The report recommends several changes to the programme, which are supported by Medicines Australia. However, progress towards implementation of these recommendations has been slow; advice from the DoHAC at the end of 2023 indicated that there is no plan to implement these recommendations in the immediate future.

Medicines Australia contends that these recommendations should be implemented as soon as is practicable, with the goal of generating savings to the Commonwealth that can be reinvested into PBS listing of new medicines.

Distribution fees

Medicines listed under Section 100 of the National Health Act have traditionally been delivered in hospitals, which do not use wholesalers in the supply chain. Recently, some Section 100 medicines have moved into being administered in community settings, with wholesalers being included in the supply chain. However, the remuneration fees for Section 100 medicines supplied into community pharmacies do not include a wholesaler markup despite wholesalers distributing the medicines. The result of this is that either:

- wholesalers distribute at a loss because no markup is applied
- wholesalers add their own mark up and charge the pharmacies, so the pharmacy incurs a loss
- the manufacturer may pay the wholesaler a markup because when pharmacies incur the cost through this mechanism they may choose not to stock the medicine, thus reducing access to these medicines and potentially compromising continuity of treatment.

A wholesaler markup fee should be added for Section 100 medicines dispensed via community pharmacies, as for Section 85 medicines, to prevent this issue from arising.

Manage the out-of-pocket costs of PBS medicines to patients (e.g., co-payment, PBS Safety Net)

Recently, some measures have been implemented by the Government to help reduce the cost of medicines for patients. Medicines Australia is broadly supportive of these measures because they clearly benefit people living with medical conditions. However, the way in which these measures were implemented have impacted the industry with potential negative consequences for patients.

Reduced general co-payment

On 1 January 2023, the Albanese government reduced the general co-payment to $30.00. While it was intended that the Government would fully fund the difference between the old and new co-payments, some medicines with existing RSAs were affected by this measure. Because the RSA caps were not revised following the reduction in the co-payment, the risk of breaching the RSA caps increased, ultimately costing sponsors money. This policy was not implemented in consultation with stakeholders including the pharmaceutical industry, leaving sponsors with limited time to prepare for this additional cost. Consultation and collaboration between the DoHAC and the industry could have avoided this situation.

Minimum stockholding requirements and increased maximum dispensed quantities (60-day prescribing)

In 2023, in accordance with the Strategic Agreement between the Commonwealth and Medicines Australia (and a similar Agreement between the Commonwealth and the Generic Biosimilar Medicines Association), certain medicines became subject to a minimum quantity of stock in the country. This aimed to prevent stock shortages.

Shortly after, the Government announced its intention to increase the maximum dispensed quantity of some medicines to allow prescribing of two months' supply of these medicines. Subsequently, the co-payment for these medicines would be reduced to one co-payment every two months, rather one co-

payment per month. Some medicines subject to minimum stockholding requirements were also nominated for 60-day dispensing, which impacted sponsors' supply chains.

In March 2024, the second tranche of medicines subject to 60-day prescribing was added to the PBS. Although it has been widely known that the second tranche would be added in March 2024, sponsors were only given 2 weeks' notice that their specific medicines would be in the second tranche. This left little time for planning supply chains, communicating with clinicians and pharmacists about changes to PBS item codes, and otherwise planning for this change. Further, other stakeholders were given more notice than the medicine sponsors. More notice and consultation with the industry and other stakeholders in the supply chain is required to ensure the smooth transition of these changes.

Additional comments

Capacity and capabilities within the PBAC and DoHAC: impacts on efficiency

In recent years, the industry has noted that the time taken for Departmental staff to respond to correspondence has increased. This may indicate capacity issues at the Department, which could be addressed via an increase in staffing levels within the Technology Assessment and Access Division (TAAD). Some ideas are outlined in Medicines Australia's submission to the first round of consultation for the HTA Review, including an expanded Office of Health Technology Assessment.

Another example is the complex spreadsheet template used by sponsors to estimate the cost to the Commonwealth of listing a new medicine on the PBS. In some instances, sponsors, evaluators, PBAC sub-committees, and Department staff have reviewed the estimates only to find errors in the spreadsheet at the final step. For especially complex modelling, there is limited capacity within the DoHAC to resolve these errors. This has flow-on effects to the overall estimate of cost, which affects caps on risk-sharing arrangements among other things. Reducing the complexity of the spreadsheet and increasing capacity and capability could help to resolve these issues.

Similarly, improvements in capacity and capabilities within the PBAC and its sub-committees could help to reduce the time to access to new medicines. The number of reimbursement submissions each PBAC cycle is increasing, leading to very full agendas with little time to discuss each submission. In addition, there are some gaps in the types of specialties among members of the PBAC and its sub-committees, requiring the committees at times to rely on the expertise of one person within a specialty. While the PBAC can seek expert advice in cases where expertise in a specific field is lacking, there have been examples where the DoHAC and committee members have been reluctant to seek input from specialists who have been involved in the key clinical trial for a specific medicine, despite those specialists having specific experience in managing the condition and with the medicine under review. More clarity around the process undertaken to seek input from relevant specialists, and more representation from specific specialties on the PBAC and its sub-committees, would be beneficial.

Thank you again for the opportunity to provide input into this audit. Please contact me if you have any questions or require more information.

Your sincerely,

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