27 October 2023

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

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

Medicines Australia thanks the Australian National Audit Office (ANAO) for the opportunity to contribute to the 2023 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 providing this response, we note that two previous audits have been conducted by the ANAO on similar topics: one in 1997,[1] and a second in 2009–2010.[2] We note that many of the recommendations from these audits have not been implemented and encourage the ANAO to consider the findings of the previous audits when conducting the current one.

The Pharmaceutical Benefits Scheme (PBS), governed by the *National Health Act 1953 (Commonwealth),* provides patient subsidies for the cost of medicines that have been recommended for funding by the Pharmaceutical Benefits Advisory Committee (PBAC) and approved by the Minister for Health and Aged Care. The PBS began as a limited scheme in 1948 to ensure that pensioners and Australians with selected conditions had access to the medicines they needed at a low cost.[3]

The purpose of the PBS has not changed – it remains a conduit to affordable medicines and related therapies for Australians. However, as the number, complexity and cost of new therapies has increased, the cost to the government of the PBS has increased. Consequently, while the purpose of the PBS remains the same, there has been a shift in the way in which the PBS is administered to focus on cost-containment and minimising the growth of PBS expenditure. While it is fiscally important to manage government expenditure for major health programs, the flat growth in investment in the forward

[1] Australian National Audit Office. The Pharmaceutical Benefits Scheme. Department of Health and Family Services 1997. Available at https://www.anao.gov.au/sites/default/files/anao_report_1997-98_12.pdf. Accessed 24 October 2023.
[2] Australian National Audit Office. Medicare Australia's Administration of the Pharmaceutical Benefits Scheme. Medicare Australia, Department of Health and Ageing, Department of Human Services. Available at https://www.anao.gov.au/sites/default/files/ANAO_Report_2009-2010_39.pdf. Accessed 24 October 2023.
[3] Australian Government Department of Health and Aged Care. About the PBS website. January 2023. Accessed 24 October 2023.

estimates[4] has placed Australians at a disadvantage compared with those in other countries in terms of access to new medicines.[5]

The requirement for new policies to manage the cost of the PBS has led to resource-intensive administrative processes that are not always efficient, coupled with capacity and capability challenges[6] in the Department of Health and Aged Care (DoHAC). Some of these policies are discussed below.

The PBS is aligned with the Australian Government's broader National Medicines Policy (NMP).[7] The NMP's vision is 'To achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment', through partnerships with a diverse range of stakeholders, including between the government and the medicines industry.

While this partnership generally works well in terms of the administration of the PBS, there are some key areas where improvements could be made to better achieve the overarching vision of the NMP and improve the relationship between the government and the medicines industry for the benefit of Australian patients and the broader health system. This submission will elaborate on these areas.

1. Governance arrangements for the PBS, including the clarity of roles and responsibilities between entities

The DoHAC oversees the Health Products Portal (HPP), launched in 2019 to provide a single, secure and easy to use place where industry can interact with government to apply, track, pay for, and manage listings for regulated and reimbursed health related products and services on the PBS, Medicare Benefits Schedule (MBS), Prostheses List (PL) and the National Immunisation Program (NIP).[8]

While the HPP is useful as a repository for PBS submissions, the platform does not allow opportunities for medicines industry representatives to easily provide feedback or raise issues of concern. Through Medicines Australia, the industry is generally able to discuss concerns related to regulatory and reimbursement processes with the Therapeutic Goods Administration (TGA) and the Office of Health Technology Assessment (OHTA).

To ensure ongoing dialogue between the medicines industry and government departments to improve PBS processes, it may be useful for Medicines Australia to establish formal networks with the section of the DoHAC that manages the HPP and key PBS contacts at Services Australia. Development of this network would help the industry understand the processes undertaken and decision making by each of the government organisations related to the PBS and discuss issues from each organisation's perspectives. Establishment of this network may also improve communication and collaboration

[4] Parliament of Australia Budget 2023-24 Review Health overview. May 2023. Accessed 24 October 2023
[5] Center for Innovative Research Science R&D Briefing 89, September 2023. Available at https://cirsci.org/wp-content/uploads/dlm_uploads/2023/09/CIRS_HTADock_RD_Briefing_89_final_v4.pdf. Accessed 24 October 2023.
[6] Australian Public Service Commission. Capability review: Department of Health and Aged Care. August 2023
[7] National Medicines Policy 2022. Available at https://www.health.gov.au/resources/publications/national-medicines-policy?language=en. Accessed 24 October 2023.
[8] Health Products Portal (HPP) – Outcomes from the Federal Budget 2021-22

between the two government organisations and improve transparency around Departmental processes relating to the administration of the PBS.

The medicines industry also believes that there currently is insufficient publicly available information to enable transparent PBS processes and decision making, which in turn creates inconsistency and inequity between the two government departments and across sponsors. For example, published information on key pricing and reference pricing policies would assist sponsors to make informed decisions and undertake adequate planning, and ensure an even playing field among sponsors. Other information that would improve transparency of PBS processes includes publication of key documents that inform DoHAC decisions on matters such as risk sharing arrangements (RSAs) and link these to any relevant government or departmental KPIs.

Publication of the PBAC executive committee meeting agendas and detailed organisational charts with contact information would also improve transparency of PBS processes and allow concerns to be raised with DoHAC and Services Australia as soon as possible. Having a contact team or named person within both government organisations that sponsors can contact would also help to quickly resolve disputes related to deeds, rebates, listing queries and restrictions. The current dispute resolution process is overly protracted and there is a perception within the industry that there is a low appetite for government organisations to resolve these issues.

Another issue of concern is the significant increase in cost-recovery fees via the Cost Recovery Implementation Statement (CRIS) without adequate notice. Each pre-submission meeting, evaluation of a reimbursement application, pricing submission and so forth relating to listing a medicine on the PBS is subject to a cost-recovery fee, which helps fund the processing of these requests. Each year, a CRIS is published for consultation. The CRIS outlines planned increases in cost-recovery fees for the coming year. The most recent CRIS[9] was published in August 2023, following public consultation in June 2023. This is significantly later than usual, and the rapid implementation was insufficient for business planning purposes by sponsor companies, particularly given that some of the fee increases were in the magnitude of 14–20%.

The CRIS should articulate in a transparent manner how the increase in fees will result in an increase in resources and staffing to support timely PBS listings. There should also be adequate notice of increase in fees so that the release of the CRIS aligns with medicine sponsors' financial years with sufficient lead time to adjust operating budgets and plan business operations. For example, the TGA bilateral discussion on the likely cost recovery fees for the coming year is undertaken in the December before the CRIS. We request the same courtesy and planning for the PBS, and the CRIS should allow a minimum 6-week consultation process; further, there should be feedback following the CRIS on what was accepted/adjusted and or rejected in the consultation.

2. Engagement with stakeholders on PBS policy changes

In recent years, there have been a number of significant proposed policy changes relating to the administration of the PBS, predominantly initiated by the DoHAC. While several of these proposed changes have involved consultation with the medicines industry, some of these consultations have been insufficient to inform stakeholders about the proposed changes and thereby allow a full and comprehensive response to these consultations. Further, some changes to policy initiated by the

government and implemented by the DoHAC have not involved any consultation with relevant stakeholders.

In addition, there have been two significant reviews undertaken recently, commissioned by the DoHAC, that have resulted in reports outlining proposed changes to PBS policy that have been completed but not actioned.

This section of Medicines Australia's submission will elaborate on each of these.

Post-market review framework

Post-market reviews (PMRs) were introduced in 2015 as a means of monitoring medicines to ensure their appropriate use. The process for PMRs is outlined in a framework document. Historically, PMRs have taken between 2 and 4 years to complete.

As part of the Strategic Agreement between the Commonwealth and Medicines Australia, it was agreed that the time taken for PMRs of medicines listed on the PBS would be reduced to 12 months where possible, prompting a review of the current PMR framework.[9] The consultation period for the proposed revised framework[10] was open from 20 October 2022 until 16 December 2022. The consultation comprised a short series of highly targeted questions focussed on very specific aspects of the changes proposed to the existing framework. Stakeholders were afforded the opportunity to respond to these questions via an online form. No direct stakeholder engagement was undertaken, and no further information was provided about changes proposed to the framework that were not captured in the targeted questions or the implications of these changes, including the removal of many of the current points of contact between the DoHAC and relevant stakeholders including the medicines industry throughout the course of a PMR.

To its credit, when Medicines Australia contacted the DoHAC to discuss our concerns about the limited consultation, the DoHAC was open to meeting to discuss these concerns. Representatives from the DoHAC, Medicines Australia and the medicines industry met for the first time on 28 November 2022 to discuss the consultation process. During this wide-ranging discussion, representatives from the DoHAC stated that the consultation was run in the described format on the advice of the consultation section at the DoHAC, which indicated that a short survey would be sufficient. That the team within the DoHAC responsible for public consultations felt that this limited approach with minimal stakeholder engagement was enough to elicit an appropriately informed response from relevant stakeholders on a process that has implications up to and including disinvestment in medicines is concerning.

Since this time, the DoHAC has met with Medicines Australia on three more occasions to work towards a revised process that is more inclusive and that has incorporated many of the medicines industry's suggested improvements. In parallel, the DoHAC has worked with consumer representatives to ensure that health consumers will be given the opportunity to provide input during the PMR process. The

[9] Pharmaceutical Benefits Scheme Post-market Reviews. Available at https://www.pbs.gov.au/reviews/subsidised-medicines-reviews-files/post-market-review-framework-10-2014.pdf. Accessed 24 October 2023.
[10] Consultation on the revised PBS Post-market Review (PMR) Framework. Available at https://consultations.health.gov.au/technology-assessment-access-division/revised-pbs-post-market-review-framework/. Accessed 24 October 2023.

revised PMR framework has not yet been finalised, but the latest draft shared with Medicines Australia is a significant improvement over the original proposed revised framework.

Health Technology Assessment Policy and Methods Review

Another clause of the Strategic Agreement[11] states that a review will be undertaken of Australian health technology assessment (HTA) policies and methods for evaluating new medicines and related therapies. The HTA Review is currently underway. However, despite regular meetings of the HTA Review Reference Committee, communication about the progress of the Review has been limited and is frequently delayed; for example, the most recent communiques[12] from the Reference Committee, published on 10 October 2023, provide information about what was discussed by the Reference Committee at its meetings on 14 July, 24 July and 4 August 2023. Further, several of the 'deep dives' into relevant topics, at which stakeholders could have communicated directly with the Reference Committee, that were originally intended to take place at Committee meetings have not eventuated because of time constraints.

The reasons for these delays and the reduced level of engagement with relevant stakeholders are unclear, but it appears that the Review has not been sufficiently resourced to manage the work required.

'Catch-up' price reductions

During the Strategic Agreement negotiations between the DoHAC and Medicines Australia, the medicines industry pledged savings to the PBS in the order of $1.9 billion from 'catch-up' price reductions to older medicines listed on the PBS. The expected cost savings were modelled by both parties, but the modelling prepared by the DoHAC was not shared with Medicines Australia. Consequently, it was not possible to compare methods used to model the savings. This contributed to two different interpretations of the associated legislation, with the result that the price cuts, when they were implemented by the DoHAC on 1 July 2022, were higher for some individual medicines than was expected by the medicine sponsors. This could have been avoided through greater transparency of modelling by the DoHAC.

While Medicines Australia acknowledges the need to maintain confidentiality, this lack of transparency in sharing raw data (at least in aggregated form) characterises the relationship between the DoHAC and the medicines industry in other areas. For example, through measurement of key performance indicators collected and published as part of the Stage 1 and Stage 2 Process Improvements.[13] These metrics are collected by the DoHAC and shared with Medicines Australia. However, the raw data are not shared, meaning that the figures cannot be validated. This puts the medicines industry at a disadvantage

[11] Strategic Agreement in relation to reimbursement, health technology assessment and other matters. Available at https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2021/09/Medicines-Australia-Strategic-Agreement-2022-2027.pdf. Accessed 24 October 2023.
[12] Health Technology Assessment Policy and Methods Review reference committee – Communiques. Available at https://www.health.gov.au/resources/collections/health-technology-assessment-policy-and-methods-review-reference-committee-communiques?language=en. Accessed 24 October 2023.
[13] Publication of Stage 1 and Stage 2 PBS Process Improvements metrics report for 2021-22. Available at https://www.pbs.gov.au/info/news/2023/04/publication-of-stage-1-and-stage-2-pbs-process. Accessed 24 October 2023.

because sponsors cannot fully understand the impact of the process improvements and are therefore impaired in negotiating for further reforms as needed.

Change to general schedule co-payment

In 2022, the then Labor opposition led by Anthony Albanese announced its intention to reduce the PBS general co-payment[14] (the maximum amount paid by a patient when a script is dispensed to them) from $42.50 to $30 per script as of 1 January 2023 if it were elected. Once in government, the Minister for Health and Aged Care stated that the co-payment reduction would be fully funded by the government, both in conversations with medicines sponsors and at his Australian Institute of Policy and Science budget breakfast speech in October 2022. However, this policy had an impact on medicines with risk-sharing arrangements involving annual expenditure caps that had been calculated prior to the co-payment being decreased. Reducing the co-payment effectively increased the proportion of the cost to government paid by medicine sponsors, meaning that the shortfall was funded by the industry and not by the government as originally intended. This lack of consultation on a change in policy therefore came with an associated cost to the medicines industry with no notice and limited time for the industry to adequately prepare.

Change to maximum dispensed quantity

As was the case for the change to the general copayment, a new policy to increase the maximum dispensed quantity to allow clinicians to prescribe two packs (two months' worth) of a select range of medicines at one time was announced in late 2022 without consultation with all affected stakeholders. Dating back to 2018 when the PBAC recommended that this occur for specific medicines, the recommendation was effectively dormant until this year. When complete, this policy will apply to over 300 medicines. The policy was applied to the first tranche of these medicines on 1 September 2023, with another two tranches to come by September 2024.

From the perspective of the medicines industry, the key concerns about this policy were (a) the lack of consultation with the industry about the medicines included and the timing of the policy implementation and (b) the possibility of supply issues for those medicines included in the policy, particularly the first tranche. Coming as it did only two months after the implementation of new stockholding guidelines on 1 July 2023, which require medicines sponsors to hold either 4 or 6 months' worth of stock of certain medicines in the country to prevent shortages, sponsors were concerned that stockpiling of medicines subject to increased maximum quantities could result in inadvertent breaches of the stockholding requirements. Of the 2900 individual brands of pharmaceutical items included in the stockholding requirements, 1306 (45%) were also given an increased maximum quantity. Medicines Australia worked with the industry and the DoHAC to try to prevent disruptions to supply of medicines resulting from the dual implementation of these two policies.

The implementation of the increased maximum quantity policy was a resource-intensive exercise for the DoHAC, requiring significant administrative changes to the Schedule of Pharmaceutical Benefits in the form of newly-created PBS item codes; consultation with stakeholders after the policy was announced

[14] PBS general co-payment reduction – What pharmacists need to know. Available at https://www.pbs.gov.au/info/news/2022/12/pbs-general-co-payment-reduction-what-pharmacists-need-to-know. Accessed 24 October 2023.

to ensure smooth implementation; and the development of resources[15] to assist people's understanding of the new policy. This diverted DoHAC resources away from other activities, resulting in delays. For example, DoHAC staff communicated to Medicines Australia that delays in the PMR framework review (described above) were due in part to DoHAC staff being redirected to the implementation of the increased maximum quantity policy. Further, a small number of sponsor companies also reported that new medicines that had been given a positive recommendation by the PBAC took longer than normal to progress towards listing, which was also attributed to resources being diverted to the implementation of this policy.

Surrogate outcomes report and recommendations

The PBAC, in association with the DoHAC and academic evaluation groups, sometimes conduct analyses relating to medicines usage, patterns in PBAC deliberations and other topics of relevance. Much of the time, these analyses are not made public until after the fact. One example of these is the recently published analysis of the use of surrogate outcomes[16] in PBAC decision-making, which was commissioned by the PBAC and the outcomes of which have significant implications for PBS policy related to the valuation of oncology medicines. This work was not visible to the medicines industry or other stakeholders until after the report was published, and no opportunity was provided for public or targeted consultation during its development.

Efficient Funding of Chemotherapy review

In Australia, weight-based chemotherapy medicines sometimes require the use of partial vials to make up the correct dose for the individual patient. To determine the number of vials that will be needed to make up the correct dose, the combination of vials that will achieve the closest to the desired dose is used. This is referred to as the 'efficient funding of chemotherapy' (EFC).

Recently, a significant review of the EFC system was commissioned by the DoHAC and undertaken by the Centre for Health Economics Research and Evaluation (CHERE) at the University of Technology Sydney. The final report[17] of the review was published on 14 September 2023, and makes several recommendations for reforming the EFC system that the medicines industry would like implemented. Disappointingly, despite CHERE consulting with the medicines industry and other stakeholders during the review, the final report was largely unchanged from an interim report shared with stakeholders early in 2023.

When Medicines Australia contacted the DoHAC about the next steps in the EFC reform process, we were advised that 'The Department of Health and Aged Care does not currently have plans to proceed with any of the recommendations set out in the EFC Review Final Report 2023', but that if this changed

[15] Cheaper Medicines. Available at https://www.health.gov.au/cheaper-medicines. Accessed 24 October 2023.
[16] A review of cancer related surrogate outcomes used for PBAC decision making. The Cancer Surrogate Report for the PBAC, July 2023. Available at https://www.pbs.gov.au/reviews/review-of-cancer-related-surrogate-outcomes-used-for-pbac/Cancer-Surrogates-Report.PDF. Accessed 24 October 2023.
[17] Review of the Efficient Funding of Chemotherapy (EFC) Funding Arrangements Final Report, January 2023. Available at https://www.pbs.gov.au/reviews/efc-review-files/Efficient-Funding-of-Chemotherapy-Review-Final-Report-with-Addendum.PDF. Accessed October 2023.

the DoHAC would undertake further stakeholder consultation. It is disappointing that the DoHAC has no plans to take this review further at this time.

Transparency of pricing and other policies

While not strictly related to engagement on change of policy, it is also worth noting that pricing and other policies employed by the DoHAC are not always transparent. While some policies and processes are clearly defined and documented, others are applied in what appears to be an ad hoc way and can be counterintuitive; sometimes medicines sponsors (and the medicines industry as a whole) are not aware of these policies until they are implemented in specific circumstances.

One example of this relates to an administrative price reduction policy that the DoHAC recently applied to a new product with two presentations of the same pharmaceutical item. A single submission requested PBS listing for the two presentations; these were both recommended for listing on the PBS at the same PBAC meeting, and subsequently proceeded towards PBS listing on the same day. At this point, the sponsor was advised that listing both presentations on the same day would result in a 25% price reduction. To date, Medicines Australia has not been able to identify a document outlining this policy, or determine any reason for this apparently arbitrary rule.

Similarly, the policy around reference pricing is not clear or transparent. Frequently, new medicines are valued with reference to the price of medicines that are already on the PBS. While this is widely known within the medicines industry, no clearly elucidated policy outlining the way in which reference pricing is applied that is readily accessible to the medicines industry or other stakeholders.

Clearly written policies that are readily available to medicines sponsors and other stakeholders would be helpful for clarity, planning purposes and certainty.

3. Communication with stakeholders on processes and requirements for the delivery of PBS services and payments

There are several areas where communication between the medicines industry and the DoHAC and Services Australia could be improved. These are discussed in this section.

Communication with the DoHAC via the Health Products Portal (HPP)

Communication between the DoHAC and the medicines industry, historically, took several forms, predominantly telephone calls and emails. Pre-pandemic, the DoHAC (and more specifically the sections of the DoHAC responsible for health technology assessment, pricing and PBS listings) had dedicated public phone numbers, and staff members were known to the industry. This streamlined communications, made transparent who was responsible for particular tasks, and generally made interactions straightforward and relatively fast.

In recent years, the DoHAC has introduced the HPP. While initially used primarily for submitting reimbursement applications and associated documents electronically, its use has now expanded to include almost all correspondence between the industry and the DoHAC. The HPP itself is at times difficult to navigate and can ‘crash’ when overloaded with large documents, as happens three times a

year at PBAC submission cut-off times. Further, there is a disconnect between linked documents that are entered into the HPP at separate times – each new document is given a new tracking number, despite being related to existing documents shared via the HPP, meaning that traceability is difficult.

Although the industry understands and supports the use of the HPP as a central repository of correspondence, improvements are needed to address the lack of transparency, the time taken to respond to correspondence, the lack of individual accountability and responsibility and the impersonal, anonymous nature of the interaction.

Communication with the DoHAC via email

In parallel, the transparency of staffing at the DoHAC has decreased; an organisational chart[18] for the Technology Assessment and Access Division (TAAD) shows individual personnel down to the level of Assistant Secretary, but it is not clear who or how many people are employed within each section. Any correspondence not sent via the HPP must be emailed to the DoHAC using generic email addresses (such as PBAC@health.gov.au; PBSpricing@health.gov.au), and responses do not typically have a full name or the email address of the individual who has responded included within them. Often, a generic auto-reply email response is provided in the first instance.

One such generic response, from the Pricing Section at the DoHAC, states (in part), '*For all other enquiries, we will endeavour to reply to you as soon as possible. Please note that during periods of high workload it may take longer to respond to you'.* Responses beyond this are unpredictable. Medicines sponsors report that there are times when no response is provided and at other times, the response can be immediate. The PBS Pricing email address is the only avenue via which sponsors can raise important pricing related queries; there is no Pricing Section telephone number. As for the HPP, there is currently no visibility on how the queries are progressing. It is incumbent upon the sponsor to follow up on emails for which they have received no response.

Sponsors also report similar experiences relating to requests for brand price premium increases and termination of Deeds of Agreement. For instance, one sponsor reports requesting an increase to a brand price premium in June 2023. After the sponsor sent a follow-up email on 21 August, they were asked to complete a deed poll to support the request, which they completed and returned to the DoHAC within 24 hours on 25 August. After two further follow-up emails in early and mid-September, the sponsor received a generic response on 19 September 2023 simply stating that the Delegate would consider their request and notify them of the outcome closer to the effective date of 1 October 2023.

A sponsor company also reports a lack of response relating to a request that a RSA Deed of Agreement term expired after the standard 5-year period. The sponsor has emailed the Pricing Section at the DoHAC three times requesting that the Deed be terminated, along with supporting justification. At the time of writing, there had been no response in over two months. Without any action being taken, Deeds continue, with Year 5 PBS spending caps carrying forward to subsequent years. There is a risk of the Year 5 caps being breached in Years 6 or 7, so there is a financial penalty to the sponsor if no action is taken by the Pricing Section, as well as significant uncertainty for the sponsor.

[18] Department of Health and Aged Care Organisational Chart. Available at https://www.health.gov.au/about-us/who-we-are/organisational-chart. Accessed 23 October 2023.

Consequent to this, it is extremely difficult to know whether correspondence has been received or actioned, how long it takes for DoHAC personnel to access correspondence, and who is following up on the communication. The lack of transparency can hamper communications and on occasion interferes with timely responses at time-critical junctures.

Risk-share arrangement invoicing

In general, digital transformations within the DoHAC are slow, unpredictable and lack transparency. One such example is the recent upgrades to the invoicing system for risk-sharing arrangement (RSAs) invoices. These should be issued annually, after the accumulation of a full year's expenditure. However, upgrades to the Department's invoicing system have been going on for over two years now with no proactive communication from the DoHAC on when this will be resolved. This has required medicines sponsors to stockpile money for rebates with no insight into when or how much they'll need to pay, creating significant business uncertainty. Further, the delays are likely to have impacted the rebates accrued by the DoHAC, which were lower than expected as per the DoHAC's Annual Report 2022–2023.[19]

Sponsors were advised of the delay in an email from the DoHAC on 11 August 2022. Since then, Medicines Australia contacted the DoHAC on behalf of the medicines industry four times between 13 March 2023 and 22 September 2023. In each case, we have been advised that the system upgrades are not yet complete. In the most recent correspondence on 26 September 2023, the DoHAC indicated that they were working on an interim solution that would allow some invoices to be issued in the coming weeks. This has yet to transpire.

IT infrastructure

While it is commendable that the DoHAC is upgrading some of its systems, there are several others within both the DoHAC and Services Australia that could also benefit from an upgrade to ensure ongoing relevance and to improve efficiency.

For example, legacy Health Professional Online Services (HPOS) software at Services Australia is not integrated with the Online PBS Authorities system. This results in clinicians needing to re-supply baseline scores when switching a patient to a product with a Written Authority.

Further, there is frequently a backlog in PBS claims data, resulting in months-long delays. Although it is possible at times to get these data earlier from Services Australia, the data supplied is an earlier set that has not been checked for accuracy.

Finally, misclassification of PBS claims under incorrect item codes is an ongoing issue, as can be observed in several DUSC reviews, Public Summary Documents and publications.[20] The Schedule of

[19] Department of Health and Aged Care Annual Report 2022–23. Available at https://www.health.gov.au/sites/default/files/2023-10/department-of-health-and-aged-care-annual-report-2022-23_0.pdf. Accessed 24 October 2023.

[20] DUSC reviews: Novel oral anticoagulants for non-atrial fibrillation indications: utilisation analysis, October, 2014; Novel Oral Anticoagulants: Predicted vs Actual Analysis, September 2016; PBAC Consideration of the Report of the Drug Utilisations Sub-Committee, November 2018; Bevacizumab for epithelial ovarian, fallopian tube, or primary

Pharmaceutical Benefits (the database underpinning the PBS) is cumbersome and complex. The Schedule feeds into prescribing software used by clinicians to prescribe drugs to patients and dispensing software used by pharmacists, resulting in an interface that can make it difficult to identify the correct item code under which to prescribe or dispense a specific medicine for a patient, particularly for medicines with multiple indications and complex restrictions involving initiating and continuing codes. This issue has implications for the correct calculation of SPA and RSA rebates.

4. Handling of stakeholder complaints about PBS administration

There is no formal process for making complaints relating to the administration of the PBS. As outlined above, the majority of communication between the DoHAC and the medicines industry takes place via the Health Products Portal, which can be an inefficient and opaque means of communication, or via generic email addresses. Due to the lack of transparency about DoHAC personnel it can be difficult for medicines sponsors to know who to contact to make a complaint and, as outlined above, the process of requesting information about services relating to the administration of the PBS such as RSA invoicing can be protracted and slow to resolve. A clear and transparent approach to making complaints, including a clear escalation process and timelines for each step, would be valuable.

5. Processes for monitoring, review and evaluation of the administration of PBS services and payments

Although some metrics are in place for the monitoring of time from PBAC submission to PBS listing for medicines, Medicines Australia is not aware of any publicly available monitoring process or metrics of any kind for benchmarking of the administration of the PBS, either within the DoHAC or Services Australia.

Medicines Australia would welcome the introduction of transparent monitoring, review and evaluation of PBS administration. Some areas for consideration are:

- The establishment of key metrics relating to PBS administration, including but not limited to: the time taken to respond to and resolve enquiries and complaints; timeliness and frequency of invoicing for rebates; and the number and quality of consultations for policy and process reform.
- Monitoring and measuring of medicines through the supply chain, relating to aspects of the process like pharmacovigilance, and RSA and SPA administration.
- Measuring of service delivery by the DoHAC and Services Australia, particularly in the context of increasing cost-recovery fees.

peritoneal cancer: 24 month predicted versus actual analysis, September 2018; GnRH Agonists: Utilisation analysis, November 2019. Public Summary Document: Item 7.04 Denosumab, July 2019 PBAC meeting. Publications: Chien, TH et al. An Australian Real-World Study of Treatment Persistence of Ustekinumab in Crohn's Disease. Biologics: Targets and Therapy 2021:15 237–245.

Thank you for considering our submission as part of this audit. Should you have any questions, please contact me at heather.wrightman@medicinesaustralia.com.au.

Regards,

Heather Wrightman
Senior Manager of Access and Funding,
Medicines Australia