The Pharmacy Guild of Australia

HTA POLICY AND METHODS REVIEW – CONSULTATION 2

Pharmacy Guild of Australia Response

2.1 STREAMLINING AND ALIGNING HTA PATHWAYS AND ADVISORY COMMITTEES

Overall, to what extent could the options (if implemented) address the issues that relate to them? If you would like to expand on your answer you can do so below:

- Completely address the issue(s)
- Mostly address the issue(s)
- Address some but not most of the issue(s)
- Address little or none of the issue(s)
- Don't know

Response:

While not directly impacting pharmacy operation within Australia, the Pharmacy Guild of Australia (Guild) acknowledges the often lengthy and cumbersome HTA process and supports in principle a more streamlined HTA process allowing medicines to be listed on the PBS in a timely manner. The Guild is strongly supportive of a policy environment that improves access and affordability of medicines for all patients. The Guild does not however support the proposed option to expand the role of the PBAC and does not believe the current composition of the PBAC is qualified to make decisions outside of the role the committee is currently appointed to perform, being evaluating the clinical effectiveness, safety and cost-effectiveness of a medicine recommended for listing on the PBS. The Guild also believes community pharmacy is underrepresented on PBAC in terms of members who have practical experience of pharmacy service delivery.

The Guild notes PBAC's involvement in recent policy decisions, where the advice provided by PBAC failed to recognise the impacts on the community pharmacy sector and the effective delivery of National Medicines Policy. The implementation of Increased Maximum Dispense Quantities (known in the public domain as "60-day dispensing") following a positive PBAC recommendation is the most significant example, along with the failure on the part of the PBAC to implement a Continued Dispensing program that sufficiently addresses the needs of Australians during times of emergency and disaster. The Guild is concerned about an expanding range of medicines policy decisions being made through non-transparent PBAC outcomes and resulting in sweeping impacts to primary care.

The Guild supports the important role that ATAGI plays as the experts in immunisation and the NIP and holds reservations around increased listing times coming at the cost of appropriate expert consideration. Unless the PBAC membership is expanded to reflect the proposed expanded role, then it is likely that

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recommendations provided will continue to be taken without the important context offered by individuals with direct knowledge of health care service provision.

Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP)):

The Guild is supportive of LSDP reforms that would expedite the time-to-access of these vital medicines for patients and their carers. It should however be acknowledged that this program may be increasingly delivered through a patient's local community pharmacy, particularly for patients who live in rural and remote locations who may not have easy access to a hospital. There are a number of issues with the program in its current iteration which will only be exacerbated by increased access through community pharmacy unless they are addressed.

Under current arrangements, the specialist identifies with the patient a preferred pharmacy for a patient to collect their LSDP medicine. Currently this is predominantly from hospital dispensaries as many of the LSDP medicines must be administered by injection under specialist care. The identified hospital dispensary or community pharmacy is contacted by the Department of Health and Aged Care to agree to participation and coordinate arrangements. As part of the arrangements, there is no payment provided to the pharmacy for any of the services provided by the Government, and no charge able to be raised with the patient.

To deliver the LSDP to their patients, pharmacists are required to dispense the medicine, counsel the patient, take on the risk for any damage to stock and maintain dispensing records that are audited by the Department of Health and Aged Care to assist in their ordering of LSDP medicines. Community pharmacists do all this at no charge to the patient or to the Government, with no recognition or remuneration for the work or financial risk absorbed by the pharmacy. The result being that community pharmacists are the only health professional involved in the patient journey to receiving medicines under the LSDP that is not remunerated for their time.

Not all LSDP medicines require injection and even with injectable medicines, there may be future arrangements in which a patient may be able to have the injection administered by a local health provider (e.g. community centre of general practice) with access to specialist advice if needed. In the future, the LSDP list could expand to include more non-injectable medicines and patients may have greater opportunities to have their LSDP medicine administered locally. With this there may be a greater incidence of community pharmacies dispensing LSDP medicines, but it is unacceptable that this is done without any remuneration.

Pharmacists are more than willing to help their patients, particularly those with life threatening conditions. It is not acceptable to say that pharmacy participation in the program is voluntary and they can choose not to supply, as this flies in the face of National Medicines Policy and is not in the interest of patient care. Noting that an LSDP medicine could have a cost of hundreds of thousands of dollars, no consideration has been given to the potential risks to a pharmacy which is responsible for the medicine. Some of these medicines are temperature sensitive and must be stored in a refrigerator. A temperature excursion could make the medicine unusable and the pharmacy may be liable for the cost. A pharmacy may have insurance to cover normal logistics risks, but there would be significant costs to ensure insurance to cover such high-cost medicines with special storage requirements. The risk increases with increasing possibilities of power outages or dispensary losses due to natural disasters such as fires, floods or cyclones.

The Guild believes it is reasonable to expect that the Government would underwrite the cost of LSDP stock and as a minimum, pay dispensing fees in line with dispensing a PBS medicine.

Vaccine Pathway:

The Guild values the advice and expertise provided by ATAGI on the use of vaccines. The requirement for medicine sponsors to first seek ATAGI advice before applying for listing on the NIP is an important check and balance in the process to ensure vaccine effectiveness. The current application process allows for both ATAGI and PBAC advice to be properly considered and the best outcome to be achieved.

The proposed revised process indicates that PBAC will prepare a single comprehensive assessment report before receiving formal advice from ATAGI. The options paper notes that the proposed changes are 'not intended to preclude the ability for sponsors to seek early advice from ATAGI or modify/remove any functions of ATAGI'. While this may be the 'intent', it seems apparent that this is exactly what will happen under the revised process for listing a vaccine on the NIP. It is unclear to what level advice from ATAGI would impact the recommendation provided to the government on the clinical effectiveness of the vaccine through the PBAC assessment report.

Australian clinicians and the Australian public trusts ATAGI as the experts in providing evidence-based advice on immunisation policy and the NIP. The Guild questions the wisdom in reducing the function of ATAGI as it relates to vaccine listing on the NIP, regardless of whether that is the 'intent' of the options paper. The implication of the options paper is that PBAC in its current structure can perform the role of ATAGI, and the Guild holds reservations as to whether this is in fact true.

Expanding role of PBAC:

The Guild believes that any expanded role of the PBAC should be accompanied by expanded membership to address their current expertise gaps. The composition of PBAC's membership has been formed for the explicit task of evaluating the clinical effectiveness, safety and cost-effectiveness of medicines, and not necessarily to make recommendations to the Minister for Health on a broader range of health technologies.

If the role of the PBAC is to be expanded to providing HTA and related policy advice and recommendations, then it is important that its membership is expanded to ensure that the advice and recommendations made are accurate, in the interest of the Australian public, and with an understanding of the prescribing and supply pathways within the system.

The PBAC membership as it stands is unbalanced in favour of the medical profession (including specialists), and contains limited representation of other health professionals, the supply chain, or consumers. In addition, unlike the agenda for PBS listings which are published with an opportunity for public input, the PBAC consideration of policy matters such as Increased Maximum Dispense Quantities and Continued Dispensing are not transparent. The examples referenced were not included on any published agenda or opportunity provided for public submissions.

The Guild believes that the implication of policy recommendations made by PBAC, including Increased Maximum Dispense Quantities and Continued Dispensing, could have been better understood if there was a more balanced representation of other healthcare professionals. In this case, community pharmacy representatives would have the most expertise to understand the implications and actively and constructively contribute to the debate.

The PBAC membership would also benefit from community pharmacy and Community Service Obligation (CSO) wholesaler representation to give expert and informed consideration to the potential supply chain impacts that PBAC advice might have. With medicine shortages on the rise and causing access issues

for patients across Australia, the Guild is of the opinion that a better understanding of the supply chain, inclusive of wholesalers and community pharmacy, and challenges they face would enhance the advice provided to Government by the PBAC.

Consumers should also be better represented on the PBAC, particularly if the PBAC is to make HTA recommendations. While there is currently a CHF representative included as the consumer voice to PBAC, additional participation from other consumer organisations would enhance the consumer representation to better address consumer needs. Consideration could be given to including representatives from more vulnerable consumer groups that rely on health care such as representatives of older Australians and culturally and linguistically diverse people. The Guild also recommends that the needs of First Nations people should be specially recognised with First Nations health representatives included in their own right as part of the PBAC expert body.