HARM REDUCTION AUSTRALIA

Professor Andrew Wilson
Chair
Pharmaceutical Benefits Advisory Committee (PBAC)
Via email: A.wilson@sydney.edu.au pbacsecretariat@health.gov.au

cc: Jo Watson and Bel Harper consumer representatives:
Via email: pbacsecretariat@health.gov.au

Dear Professor Wilson

Request for dual s85 and s100 listing of products listed on the Pharmaceutical Benefit Scheme (PBS) for access under the Opiate Dependence Treatment (ODT) Program and support for access to the Staged Supply Program

Harm Reduction Australia (HRA) notes statements by the Minister for Health, the Hon Greg Hunt MP, that he is legally obliged to accept the recommendations and related advice of the Pharmaceutical Benefits Advisory Committee (PBAC).[i]

Accordingly, HRA is requesting the PBAC make a recommendation to the Government to dual-list buprenorphine, buprenorphine + naloxone and methadone under s85 and s100 of the PBS.

We also ask for this correspondence to be scheduled for discussion at your next meeting of the Committee.

Opiate dependency treatments (ODT) unaffordable under current listing arrangements

HRA notes that the PBAC has continued to list medicines that help patients manage opiate dependence on the PBS as s100 arrangements only, with access defined as being part of the ODT Program. We note it has done so recognising the significant financial burden the recommendation places on the most vulnerable in the community and regardless of the evolution in the treatments or that they are now increasingly accessed in community settings.

PBAC at its November 2018 meeting noted that the Economic Sub-Committee (ESC)

"…agreed that, assuming most patients transitioned to monthly dosing, there would likely be a reduction in private fees charged, and that this is a benefit for patients who currently choose not to be treated due to prohibitive private fees for existing treatments."[ii]

We are requesting the PBAC to look at the precedent it has set with other medicines on the PBS and to apply this same consistency in application to the above-medicines and improve access for patients via a dual s85 and s100 listing on the PBS.

When considering this request, we would like to highlight to the PBAC of the debilitating financial conditions it places on patients accessing these medicines by recommending them for s100 listing only under the ODT Program when recommending them for subsidy under the PBS.

This ongoing situation with the ODT Program has led to many asking a question on whether there any other treatments that the PBAC recommends allowing patients to be charged considerable out of pocket costs beyond the usual subsidy arrangements of the PBS?

PBAC has a long history of dual listing medicines to ensure timely and affordable patient access to clinically appropriate treatments

In considering the long-acting injectable (LAI) Buvidal® for subsidy on the PBS, the PBAC publicly acknowledged that 75% of patients access ODT medications listed under S100 through community pharmacy.[iii] The obvious implications of this statement are that 75% of patients are also denied access to the protections of the PBS co-payment and safety net system, and instead are charged significant out of pocket costs that can run to several thousand dollars per year.

Making these medicines dual s85 and s100 listings would introduce equality of financial treatment for patients regardless of where treatment is dispensed.

It is our understanding there are many medicines on the PBS which have a dual s85 and s100 listing, recognising that the medicine can be under the care of a specialist or general practitioner, and can be dispensed in a public hospital, private hospital, or community pharmacy setting. These include biological injectables with refrigeration requirements and ongoing specialist prescribing for the treatment of multiple musculoskeletal and gastroenterological conditions.

We would argue the medicines made available under the ODT Program would suit this same arrangement and should, for the purposes of equality of access and non-discrimination on the grounds of a disability, be subject to these same dual listing arrangements.

As outlined above, the PBAC has accepted that 75% of all medicines on the ODT Program are accessed in the community pharmacy setting so it is not clear to HRA the grounds under which it is not appropriate for listing these medicines under s85. HRA recognises that s100 provides for specific circumstances to be assigned on the basis and access point for a medicine, but we again note that the PBAC has applied these same subsidy limitations under s85 for the biological medicines we refer to above.

We note the PBAC Guidelines explain that the assignment of a medicine to s100 or s85 is not about patient safety or patient access but instead focuses on the distribution arrangements.[iv] We acknowledge that making a medicine an s100 listing makes it cheaper for government to dispense than an s85 medicine because of the differing applications of the wholesaler margins, administration, and handling infrastructure (AHI) fee, and the dispensing fee.

We do not consider these are grounds to continue with an exclusive s100 listing which then allows for the charging of uncapped private fees for dispensing of these medicines. An s85 listing would see an end to this practice.

PBAC should increase access to these treatments

HRA notes the PBAC's interest in improving access to these treatments, particularly the opportunity of LAI prescribing and administration in the GP-setting.[v]

HRA also notes that at the time of considering Buvidal® in November 2018, the PBAC questioned the capacity of the s85 listing to be used to improve community access to these treatments through GPs due to the possibility the medicine would never be in the hands of the pharmacist to claim the dispensing.[vi]

HRA also notes that Prolia® provides an established precedent for an injectable medicine to be placed in s85 and administered in the GP setting and would ask the PBAC to consider the same listing approach for the new LAI treatments.

HRA further notes the administration of the s100 botulinum toxin program operates with the injectables often being directly delivered to the treating specialist and billed and dispensed through a local community pharmacy.

These examples demonstrate that the PBAC and the Department have previously applied several solutions to improve patient access to treatments and we ask the PBAC to consider the application of these prior precedents to the ODT Program.

Further, through its independent consideration of the safety and appropriateness of the treatment setting for medicines, PBAC has improved access and health outcomes for hepatitis C, HIV, hepatitis B and schizophrenia patients.[vii] [viii] [ix] The PBAC appears to be increasingly giving consideration to the need for s85 listings versus s100 listings to improve access to treatment.

Accordingly, we ask that the PBAC use that same independent clinical judgement to support improved health outcomes for patients accessing PBS-subsidised opioid dependency treatments by recommending dual s85 and s100 listing of the medicines.

PBAC and its role in ensuring safe supply and access

Setting aside cost, we respect and welcome the PBAC's previous concerns about ensuring safe use of these medicines.

We note the listings of the LAIs on the ODT Program reflected the follow-up risk assessment by the Therapeutic Goods Administration (TGA) as part of their ARTG registration which have been successfully concluded and the PBS restriction adjusted accordingly. That confidence in the safety of these medicines should support broader GP prescribing and administration access under s85.

We appreciate that an increasing proportion of opioid dependence in Australia today stems from medically prescribed opioids and that the PBAC and TGA over many years have worked hard to balance the need for access to pain management medicines with the need to appropriately manage any potential harms. HRA supports programs such as the community pharmacy staged supply programs with their specific policy intent of improving health outcomes by reducing the risks associated with medicines of high potential for dependence or risk of misuse or harm.[x] Unfortunately the design of this program specifically precludes access to anyone accessing a medicine under the ODT Program.

Finding a solution for <u>all</u> ODT Program medicines

HRA understands that the most significant barrier presented to the PBAC for retaining these medicines on the s100 ODT Program only, is the frequent dispensing of methadone and the potential costs of this to either the PBS safety net arrangements or the staged supply program.

However, during the COVID-19 pandemic management, multiple states and territories demonstrated the capacity of the system to be responsive by providing increased access to take-home dosing for methadone to minimise the risk of COVID-19 to these patients and the community in general. While the issue of expanded access to take-home doses is not our primary focus here, we raise it to make the point that the system clearly has the capacity to identify a problem and solve it to achieve the best health outcome for the patients and the community.

Methadone is dispensed as a daily dose and we understand it is delivered to pharmacy in a large bottle and measured out by the pharmacist to provide the daily dispensed dose. We have further been advised by the Department that this "bulk purchasing" arrangement is what makes changes to this program difficult.

HRA notes that no such challenge exists with the efficient funding of chemotherapy (EFC) program, where weight-based dosing and dispensing relies on combinations of multiple vials to achieve the treatment administered to the cancer patient at regular intervals.

We therefore believe that the PBAC can apply its expert clinical knowledge to the long-understood use of this treatment to allow a regular script for methadone to be established. This would provide for an appropriate co-payment by the consumer which in turn could count towards their PBS safety net.

The importance of this clinical advice cannot be overstated. For too long Australian patients accessing methadone, buprenorphine, and buprenorphine-naloxone and now Buvidal® and Sublocade® have been charged uncapped out of pocket fees for accessing their medicines.

Further, they have been denied access to the community pharmacy staged supply program because a monthly or weekly supply script for subsidy has not been sufficiently contemplated.

Accordingly, we ask the PBAC to consider how the subsidy arrangements of methadone on a dual-listing s85 and s100 listing could reflect the use of the treatment in clinical practice based on a 7, 10 or 20-day script. HRA would welcome the piloting of these arrangements if necessary, noting the number of pilots currently provided for via s100 legislative arrangements registered with the Federal Register of Legislative Instruments (FRLI).

State and territory regulations should not be the basis for determining s85 or s100 listing

HRA acknowledges there are state and territory regulations that determine who can prescribe and dispense these medicines, but also note that similar arrangement apply for the opiates themselves which are freely available in s85 and s100.

HRA considers that the detailed restrictions the PBAC puts in place for a multitude of other medicines should provide ample confidence to the Committee that it can apply the same approach for these medicines.

For example, the limitation of indications for subsidy compared to a medicine's ARTG listing and the dosing frequency and continuation rules. We recognise that regulation of the medicines is separate to the funding of them and ask the PBAC to make recommendations for subsidy changes recognising the role the states and territories will continue to play in who can prescribe, dispense, and administer these medicines.

PBAC not responsible for financial inequity of the system but can make recommendations

HRA acknowledges the genesis of the ODT Program in the 1970s was to provide equality of access to these treatments across Australia noting the disparity of access that existed between different states and territories. That was at a time when treatment was almost exclusively within the hospital or outpatient treatment setting.

Modern clinical treatment recognises the importance of ongoing treatment being available in the community setting – no different to the management of other chronic diseases.

This is why over 75% of patients accessing these medicines do so through their community pharmacy (s85) setting. It is not cost shifting by jurisdictions, it is modern clinical practice.

Neither the PBAC nor the Government appear to have concerns when a patient is initiated on cardiovascular medicines in hospital but once discharged accesses those medicines under s85 through their community pharmacy. So we ask the question again, why is the PBAC recommending a different approach for patients managing the chronic disease of opioid dependence?

HRA respectfully requests that the PBAC immediately review the listing arrangements for these medicines and recommends their dual s85 and s100 listing. In doing so the PBAC will remove the basis on which the administration of the PBS provides for the financial disadvantage and discrimination against one group of patients.

We appreciate that this request may require the input of the relevant pharmaceutical companies and ask that any engagement is done so expeditiously. We would also welcome the opportunity to provide further input to ensure a timely consideration of this request and hopefully a recommendation for clinical change.

Yours sincerely

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[i] The Hon Greg Hunt MP, Speech to PharmAus 2019, 13 October 2019 https://www.greghunt.com.au/speech-medicines-australia-pharmaus-2019/

[ii] Pharmaceutical Benefits Advisory Committee (PBAC), Buvidal® Public Summary Document (PSD) November 2018, para 2.7

[iii] *Ibid* para 2.6

[iv] PBAC, PBAC Guidelines version 5, September 2016, page 20

[v] PBAC, PSD Buvidal® November 2018 PBAC Meeting, paragraph 7.2, 7,4, 7,8 and 7.10 and PSD March 2019 PBAC meeting, paragraph 4.2

[vi] PBAC, PSD Buvidal® November 2018 Meeting, paragraph 2.4

[vii] PBAC, Sovaldi® PSD March 2015, para 7.3

[viii] PharmaDispatch, *'Guild welcomes changes to HIV testing and treatment arrangements'*, 9 July 2014

[ix] PBAC, PBAC Guidelines, Section 100 – Highly Specialised Drugs Program (community access), page late updated 1 September 2019

[x] Pharmacy Programs Administrator (Australian Healthcare Associates), Community Pharmacy Program Rules – Staged Supply, July 2020, page 3