Response
2
The Department may, at its discretion, publish part or all of the information provided in your submission on the Department's website or in related documents. If information from your submission is published, the Department may identify you and/or your organisation as the author of the submission. All personal contact details will be removed prior to publishing. Please publish my submission anonymously (personal and organisational names will be removed and the submission will be marked as "Name withheld") (Note: if you select this option and your submission contains identifying information, your submission may not be published).
3
What is your name? [redacted]
7
Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice [redacted]
7.22
Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Other [please specify] - Text [redacted]
13
Please select which chapter/s you would like to provide feedback on. You may provide feedback on as many or few chapters as you wish. 1. Transparency, communication, and stakeholder involvement in HTA,2. Health technology funding and assessment pathways,5. Futureproofing Australia's systems and processes
14
Please select the topics within the chapter(s) you would like to provide feedback on. 1. Transparency, communication and stakeholder involvement in HTA 1.1. Transparency and communication of HTA pathways, processes and decisions,1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA,1.3. First Nations people involvement and consideration in HTA
15
Please select the topics within the chapter(s) you would like to provide feedback on. 2. Health technology funding and assessment pathways 2.2. Proportionate appraisal pathways
18
Please select the topics within the chapter(s) you would like to provide feedback on. 5. Futureproofing our systems and processes 5.1. Proactively addressing areas of unmet clinical need and gaps in the PBS,5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system
21
Taking all Options within this section: 1.1. Transparency, communication and stakeholder involvement in HTA into account. **Overall, to what extent could the options (if implemented) address the issues that relate to them?** Mostly address the issue(s)
23.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries Neutral
23.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Improvements to the HTA webpage including development of a dashboard Neutral
25
If you would like to expand on your answer above you can do so below -Publish plain language summaries Plain English language Guidelines; in detail, especially the economic/cost effectiveness requirements as the summaries make no sense if what was required isn't understood.
26
If you would like to expand on your answer above you can do so below -Improvements to the HTA webpage including development of a dashboard Needs an advanced search function
27
Taking all Options within this section: 1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA into account. **Overall, to what extent could the options (if implemented) address the issues that relate to them?** Address some but not most of the issue(s)
29.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework Neutral
29.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence Neutral
31
If you would like to expand on your answer above you can do so below -Develop an engagement framework The PBS covers an extensive range of medicines for many different body systems, therapeutic categories and indications. A fundamental important way to improve facilitation of engagement is to have a filtered system that enables consumers to subscribe to notifications on everything for a particular area, for example antidepressants or for a wider psychiatry interest such as pyscholeptics and psyhoanaleptics level of classifications. This stops the relevant information from getting lost among the plethora of information that covers all areas, or having to constantly keep track of the website.
32
If you would like to expand on your answer above you can do so below -Strengthen consumer evidence Consumers and clinicians are more often than not only interested in their field, and it must be acknowledged that both groups are experts in their field. The Federal Courts in Australia allow evidence from consumers in many life domains on the basis that lived experience counts as expert evidence with equivalent validity that a person with formal education. Equally, the HTA process should be segmented in this area and recognize that having consumers and clinicians in general as committee representatives is not adequate, they must be specific to the field otherwise they have no knowledge that is relevant and can't discern the real impact of decisions on the consumers it affects.
33
Taking all Options within this section: 1.3. First Nations people involvement and consideration in HTA into account. **Overall, to what extent could the options (if implemented) address the issues that relate to them?** Address some but not most of the issue(s)
35.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - First Nations peoples partnership in decision making Positive
35.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Dedicated resource for HTA submissions and education Positive
38
If you would like to expand on your answer above you can do so below -Dedicated resource for HTA submissions and education The dedicated resource must also review all medicines currently listed on the PBS that present an unacceptable high risk over any benefit. See additional information attachment, Part 2.
63
Taking all Options within this section: 2.2. Proportionate appraisal pathways into account **Overall, to what extent could the options (if implemented) address the issues that relate to them?** Don't know
65.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Case manager Very positive **If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Triaging submissions** Don't know
65.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Streamlined pathway for cost-minimisation submissions (therapies not claiming a significant improvement in health outcomes or reduction in toxicity) Don't know
65.3
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN: **Alternative option 1: Introducing an optional resolution step before HTA committee consideration** Don't know
65.4
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN: **Alternative option 2: Introducing an optional resolution step before HTA committee consideration, with additional post committee resolution** Don't know
65.5
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN: **Alternative option 3: Early Price negotiation** Don't know
65.6
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN: **Alternative option 4: Introducing an optional resolution step after HTA committee consideration but before advice is finalised** Positive
65.7
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Expanding resolution step to all relevant cost effectiveness submissions Don't know
65.8
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Development of a disease specific common model (reference case) for disease areas with high active product development Very negative
65.9

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Decouple the requirement for the TGA Delegate's overview to support PBAC advice
Don't know

71

If you would like to expand on your answer above you can do so below -Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN

Alternative option 3: Early Price negotiation
Ensuring agreement pre-consideration on comparator is critical; it is the technicality the results in many unnecessary rejections.
Post consideration will enable an efficient, productive and consultative approach that acknowledges the interest of the consumer to arrive at a fully informed decision with all applicable avenues explored. This is much in preference to the current system where the actual need of a consumer is set aside in an adversarial process between the pharmaceutical industry and PBAC in a war on power over price, holding consumers healthcare hostage. Review of public summaries demonstrates the failure of the current system in this area and the desperate need for cooperation. If this is not adopted, the same rejections will keep occurring, cost of resubmissions will stop drugs being made available, Australia will continue to fall beneath accepted international standard of care which has already occurred for a number of diseases.
When the resolution step between consideration and advice is taken, there should be an opportunity for consumers to respond to the PBAC's reasons. Sometimes the PBAC reasons can be unexpected and entirely inconsistent with the experience of the consumer. Post consideration input recognises consumers as 'œexperts' which many are through life experience; some will also have invested extensive time researching the illness from a qualified scientific, pharmacological or medical perspective.

72

If you would like to expand on your answer above you can do so below -Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN

Alternative option 4: Introducing an optional resolution step after HTA committee consideration but before advice is finalised
Same advantage described for option 3:

This will enable an efficient, productive and consultative approach that acknowledges the interest of the consumer to arrive at a fully informed decision with all applicable avenues explored. This is much in preference to the current system where the actual need of a consumer is set aside in an adversarial process between the pharmaceutical industry and PBAC in a war on power over price, holding consumers healthcare hostage. Review of public summaries demonstrates the failure of the current system in this area and the desperate need for cooperation. If this is not adopted, the same rejections will keep occurring, cost of resubmissions will stop drugs being made available, Australia will continue to fall beneath accepted international standard of care which has already occurred for a number of diseases.
When the resolution step between consideration and advice is taken, there should be an opportunity for consumers to respond to the PBAC's reasons. Sometimes the PBAC reasons can be unexpected and entirely inconsistent with the experience of the consumer. Post consideration input recognises consumers as 'œexperts' which many are through life experience; some will also have invested extensive time researching the illness from a qualified scientific, pharmacological or medical perspective.

73

If you would like to expand on your answer above you can do so below -Expanding resolution step to all relevant cost effectiveness submissions
As disagreement on estimated usage, actual cost for clinical gain, restrictions that enable the drug to meet cost-effectiveness by limiting it to particular symptoms of a disease (or even narrower restrictions) and comparator often result in applications being summarily rejected, it is vital that a resolution step be included for this. Otherwise, it is essentially a systemic opportunity for ambushing sponsors at great and unnecessary cost to the sponsor as well as confusion and frustration of people whose lives are directly negatively impacted by cost effectiveness being a bigger issue that sinks listings when there is clinical validity.

76

If you would like to expand on your answer above you can do so below -Case manager
Facilitates open communication and productive relationship between industry and PBAC; management of expectations; guidance on what is sought in sections of the guidelines; co-operation; reduction of circumstances where there is conflict between sponsors and the PBAC - all examples of gains to be made.

131

Taking all Options within this section: 5.1. Proactively addressing areas of unmet clinical need and gaps in the PBS into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?
Address some but not most of the issue(s)

132

If you would like to expand on your answer above you can do so below:
"Unmet needs" must be defined and a rating must be allocated. It will be seen differently according to the aetiology and difficulty of treating a disease and the familiarity/understanding of the members of any committee/team making decisions.
Prioritisation is likely to be biased and inequitable simply due to lack of specialist knowledge.
There needs to be exceptional transparency on how prioritisation is decided as well as a public list of medicines being considered and the queue in order of priority of the others that will be evaluated.

133.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Development of a priority list
Positive

133.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Identifying therapies to meet priority list (horizon scanning)
Very positive

133.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early assessment and prioritisation of potentially promising therapies
Very positive

133.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Proactive submission invitation and incentivisation
Don't know

133.5

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early PICO scoping
Don't know

135

Attachment to HTA Review Options
Consultation Response

[redacted]

[redacted]

Evidence-based structural and applied changes - summary

The systemic failures that must be addressed in this attachment which utilises a specific disease as a real-world example (inherently demonstrating the value of real-world evidence) to provide researched evidence of the issues. These are accompanied by rectification recommendations; the changes discussed are needed to achieve health outcomes expected of Australia and by Australians.

Bipolar disorder is the field of specialty of the author of this survey response and will be used as the example that demonstrates extensive issues that affect people who have a disease that relies on old and repurposed medicine with current research also investigating drugs that will be repurposed. The survey structure did not allow for the full context of the series of interlocked foundational changes required. The identified deficiencies that affect people with BD are highly likely affecting people with other diseases too.

Stigma against bipolar disorder is rife in Australia among the public, government agencies and healthcare professionals alike.[1] *It is respectfully requested that if you are not convinced about bipolar disorder being an illness deserving of equity in healthcare that you allow yourself to be challenged by the facts presented here-in. Bipolar disorder is not self-inflicted nor are the majority of people diagnosed irresponsible in their healthcare – mental and physical healthcare is widely inaccessible due to stigma. Bipolar disorder is a hereditary endogenous neuropsychiatric disease requiring specialist medical treatment.*[2]

Core necessary changes to facilitate access to medicines consistent with humane healthcare:

- Unmitigated removal of mandated sponsor initiation of submissions requesting listing or change to subsidised indications for off-patent medicines; The PBAC must be wholly independent with full discretionary control of public access to medicines – authority to initiate changes to medicines, additions of medicines for any purpose. The PBAC must have the authority to compel sponsors to provide any information that will facilitate improved access.
- Change the regulatory structure that is preventing access to the minimum standard essential medicines set by the World Health Organisation; extend the changes to ensure Australians can gain access to healthcare consistent with the National Medicines Policy
- Untether PBS restrictions from TGA approved indications for off-patent medicines
- Introduce a new dedicated pathway for approval of repurposed medicines:

    - substantially adjusted evidence requirements: scope to accept medicine by validation of evidence used by experts in formulating clinical practice guidelines recommended use of the medicine
    - remove use of expert panel that provides advice on current practice that the new medicine will replace as clinical guidelines recommending improved practice should be supported by the PBAC for better health outcomes
    - cost-minimisation must be evaluated using economic cost to government of provision of healthcare [excluding secondary economic impact in other domains] Use of individual treatment comparators should be eliminated
    - discretion to ensure alternatives can be added to accommodate differences in tolerability and efficacy variation for individuals
- Enable consumer- and/or clinician-initiated submissions for repurposed off-patent medicines that are listed on the PBS for other indications. Submissions should be required to be accompanied by sufficient researched scientific evidence of both clinical efficacy and health system economic impact to facilitate an adequate preliminary assessment; the PBAC would decide to request or decline a review to be undertaken a qualified team for a full submission for consideration of listing change
- Require Australian clinical practice guidelines be referenced in all PBAC determinations (new technology and repurposed medicines)
- Indications for all medicines recommended for use in the RANZCP clinical practice guidelines for bipolar disorder that are listed for other indications be extended for unrestricted use in bipolar spectrum disorders
- Enact a system to identify diseases that have complex polypharmacy needs and low quantity of research. Allow greater discretion in listing additional options despite having clinically equivalent alternatives and the proposed addition having a marginally higher cost (reasonable adjustment per sections 24 and 29 and ratified UN rights and conventions)
- Recommendation should be made to the minister to introduce amendments to the Therapeutic Goods Act to facilitate necessary changes that are consistent with the medicine needs of Australia today that were not foreseen in 1989
- A taskforce should be employed to review medicines currently on the schedule that are likely to have specific negative or positive effects for First Nations peoples, particularly issues of toxicity profile and make recommendations for specific changes; A similar analysis should be done for every new technology submission, both new and repurposed. [TGA PIs do not contain up to date information on risks/compromised safety in use of medicines.]
- The PBAC should utilise resources in colleges overseeing medical specialists and practice, Accredited members of colleges are inherently engaged in horizon scanning in seeking and researching repurposed medicines and new technologies in order to provide best care for their patients. The involvement of sponsors in horizon scanning should be decreased to eliminate

conflict-of-interest bias in information. Similarly, clinician conflicts of ineterst should be declared and taken into account.

1. Unmet clinical need and unrecognised inequity

People with complex diseases or small populations have repurposed medicines as a singular pathway for improved medical care. Research that establishes the validity of use of a medicine is not designed for the purpose of regulatory submissions and falls short of PBAC guidelines. A submission is also required by sponsors who will not do so as it is not in their commercial interest. Where repurposed medicines have been submitted, the PBAC has set precedents where drugs were rejected on technicalities despite when the drugs having an indication that no other drug on the PBS had for symptoms that are universally considered difficult to alleviate. The system did not allow real world common-sense that could be reasonably expected by Australians. Those drugs more than a decade ago are now first-line treatments recommended by the Royal Australian and New Zealand College of Psychiatrists (RANZCP) and remain unsubsidised.

The listing decision tree where the PBAC does not have authority to decide whether a medicine is reconsidered at a later date if indicated by clinical necessity; the current system requires initiation by the sponsor. This should be a matter of health policy determined by the PBAC, not the commercial interests of a company for whom the health needs of Australians are rendered irrelevant.

The position of the PBAC is understandable in requiring sponsor initiation for new technologies as they hold the relevant clinical information. However, that reason is not valid for off-patent repurposed medicines as the research is undertaken by research groups independent of the sponsor. Requirement of sponsor initiation denies Australians equitable.

Important facts about a hidden population:

2.9% of Australia's population live with a bipolar spectrum disorder

BD has a **risk of suicide 10-30 times higher** than the general population[3]

15-20% of people with BD end their own life[4]

BD accounts for approximately **10% of Australia's annual deaths by suicide**[5].

39.5 years old: Average age of suicide related to BD[6]

Despite these horrifying statistics, bipolar disorder is never discussed in the context of suicide prevention as a high-risk or targeted group.

Yet here-in lies a critical unmet clinical need in the PBS:

Many extensive peer reviewed studies and literature reviews have demonstrated BD-related suicide can be reduced by more than 60% by stabilisation with effective pharmaceutical treatment[7].

In 2012/13 the federal government spent $3.3bn on mental health and suicide prevention. In 2022/23 the amount spent had increased to $6.8bn. The number of people who died by suicide in 2012/13 was 2580 and *increased by 25.9%* over the ten years to 2022/23 despite increased spending on prevention programs. The 25.9% increase in the rate of suicide far outstrips population the growth rate of 14.4% of for the same period.

Despite the catastrophic statistics of BD-related suicide as well as the extensive community and government focus on suicide prevention accompanied by substantial funding, BD is never listed as a priority population for suicide prevention. Yet it is the only closely-associated elevated risk factor that can be treated by evidence-based medicine and prevent deaths. Bipolar-related suicide has a neurological cause not requiring resolution of environmental factors and therefore can be treated with exceptionally high effectiveness; *only if medicines that can adequately stabilise the disease and manage acute episodes are made available.*

Current accessibility of medicines for bipolar disorder through the PBS is woefully inadequate and leaves most people either seriously undertreated or untreated altogether.

The Essential Medicines List (EML)[8] published by the WHO is considered the international minimum standard for a national formulary. Comparison of the EML with the medicines subsidised by the PBS illustrates a cavernous gap in equity for Australians with BD.

Medicine	EML	PBS BD Type I	PBS BD Type II
Carbamazepine	Yes	Yes	Yes
Lithium	Yes	Yes	Yes
Quetiapine	Yes	Yes authority required and limited in scope of use	No
Aripiprazole	Yes	No	No
Olanzapine	Yes	Yes authority required and limited in scope of use	No
Paliperidone	Yes	No	No
Risperidone	Yes	Yes authority required and limited in scope of use	No
Haloperidol	Yes	Yes	Yes
Chlorpromazine	Yes	Yes	Yes
Sodium Valproate	Yes	Yes	Yes
Fluoxetine	Yes	No	No
Fluvoxamine	Yes	No	No

Medicine	EML	PBS BD Type I	PBS BD Type II
Citalopram	Yes	No	No
Paroxetine	Yes	No	No
Sertraline	Yes	No	No
Amitriptyline	Yes	Yes	Yes
Asenapine	No	Yes authority required and limited in scope of use	No
Ziprasidone	No	Yes authority required and limited in scope of use	No
Periciazine Not in RANZCP clinical guidelines	No	Yes	Yes
Flupentixol Not in RANZCP clinical guidelines	No	Yes	Yes
Fluphenazine Not ARTG listed	*Yes*		

The accessibility of affordable essential medicines for BD in Australia does not exceed the minimum international standard, nor does it even meet it. Australia is home to some of the most esteemed international specialists in bipolar disorder who are at the leading edge of research and evidence-based best practice. Yet Australians are the people who cannot benefit from the medical expertise we have.

The Office of the Attorney General has published a guidance sheet on the Right to Health, Article 12 of the UN International Covenant on Economic, Social and Cultural Rights (ICESCR). In the guidance provided it states, "*Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity*." "The Committee has stated that the notion of 'the highest attainable standard of health' takes into account both the conditions of the individual and the country's available resources... In this regard, *developed countries such as Australia will be held to higher standards than developing countries*."[9]

> ***There is no dignity in involuntary detention in mental health facilities because treatment in community is not accessible; there is no dignity in being subjected to forced injections of medication; there is no dignity in being stigmatised; there is no dignity in being marginalised.***

There are a considerable number of additional medicines recommended for use in the treatment of BD in the the clinical guidelines published by the RANZCP. These include lamotrigine, brexpiprazole, cariprazine, lurasidone, pramipexole, methylphenidate, modafinil and all antidepressants used in the treatment of MDD as well as expanded indications than those permitted by the PBAC on PBS listed medicines. Some of the non-subsidised medicines are considered first-line treatments by the RANZCP.

Expanding the range of subsidised medicines for BD is an identified core need which is emphasised by the WHO Expert Committee for essential medicines selection: "not all treatments are equally effective and tolerable. Further, treatments might not be equally effective in different phases of disease (acute manic/hypomanic/depressive episodes, or long-term prevention of recurrences), and might differ in

terms of certainty of the evidence supporting them. Further, some people with bipolar disorder do not respond to standard treatments, and there is a need for more effective treatments for treatment-resistant bipolar disorder."[10]

Australian regulatory advancement, that has positioned Australia as world leaders in medicine regulation of efficacy, safety and quality of new healthcare technologies, has simultaneously enforced the progressive requirement of substandard care for populations what have no prospect of new technology. 33 years to the month since implementation, the regulatory system is now systemically preventing access to essential medicines for diseases where drug discovery and changes in clinical practice follow a different path to those with continual development of new technology.

Tethering the PBS to TGA approved indications prevents all Australian psychiatrists from following the approved clinical guidelines published by the RANZCP when treating people with BD in the community.

The RANZCP is responsible for accrediting psychiatrists. The guideline for treating BD have been rigorously researched by a specialist committee and has international recognition as best-practice having been subjected to published peer-review by a group the most experienced and highly regarded international specialists in BD. Yet the exceptional and committed pro-bono work of our specialists who undertook the task of the guideline update, has been rendered null and void in Australia while it advances the care in other countries without this restrictive framework.

This is untenable, requires urgent rectification and made future-proof. Australia should be seeking to implement evidence-based best practice but by tethering indications and subjecting repurposed medicines to the same process as new technology, treatment is simply not available. The drugs needed are not those that cost the PBS hundreds of millions of dollars for small populations. They are not medicines that prevent loss of eyesight in the elderly. They prevent premature death for hundreds of Australians each year – who are typically younger than 45 years old.

The population of people with BD are much more likely to have minimal financial means. Medicines that are not subsidised are not an option, particularly as they are used long-term. Using current PBS approved medicines, a person with BDII experiencing severe hypomania the choice of two *first generation antipsychotics*. These are exceptionally strong medicines with warnings on use and attract higher levels of severe adverse events. They are also more intolerable than atypical antipsychotics.

Disparity between medicines on the EML and those accessible with PBS subsidy is the result of failure to use, or appropriately weight clinical guidelines written by the most experienced experts in Australia. Utilisation of guidelines should be foundational as they define responsible Australian medical practice, and a product of extensive review of published research. They also provide the most up-to-date safety information.

The necessity to remove BDI and BDII distinction for PBS listings to be consistent with the RANZCP Mood Disorders Clinical Practice Guidelines 2020 and the World Health Organisation to facilitate exceptionally improved clinical care. The guideline states: *"Both DSM-5 and ICD-11 divide bipolar disorders into bipolar I and bipolar II. However, the MDcpg2020 no longer makes this distinction because partitioning bipolar disorder in this manner is arbitrary and does not meaningfully inform management."*

The World Health Organisation concurs as the EML uses the term *"medicines for bipolar disorders"*. The TGA currently categorise according to BDI or BD II on the basis that clinical trials are not conducted specifically for BDII and therefore there is not sufficient technical evidence for registration of indication. In accepted and standard Australian and international clinical practice, the same medicines are used for both forms of the disease. The response and effectiveness for medicines for the two forms of disease are sufficiently similar. The issue of inequity even between marginally differing presentations of the same disease is significant.

While it is essential to comply with the National Health Act, the applicability of other legislation and rights of Australians should also be considered in decisions on structural changes that will deliver equity:

- Disability Discrimination Act 1992
  Sections 24 and 29A11
- UN International Covenant on Economic, Social and Cultural Rights (ICESCR)[12]
  Article 12 (1) – Right to Health
- UN Convention on the Rights of Persons with Disabilities (CRPD)[13]
  Articles 1 - Purpose, 10 - Right to Life and 25(a) and (b) - Health
- Disability Discrimination Act 1992
- UN Principles for the protection of persons with mental illness and the improvement of mental health care[14]
  Principle 1, paragraph 1; Principle 8, paragraph 1
- Australian Charter of Healthcare Rights[15]
  Guiding principle 2
- National Medicines Policy (NMP)[16]
  Vision, Aims, Fundamental Principle of equity and access, Pillar 1 (inequity), Pillars 2–3 (Commonwealth as a partner), Governance.
- National Mental Health and Suicide Prevention Agreement[17]
  Paragraph 36(b).
- Australia's Disability Strategy 2021-2031[18]

Regarding the range of medicines listed, there are substantial inequities in the number of choices listed for different diseases. For more "straight-forward" diseases that require one main type of medication eg depression requires antidepressants, schizophrenia is treated with antipsychotics, there are an extensive number of options currently available as subsidised prescriptions for each of those. In a 2023 public summary recommending tofacitinib for use in ankylosing spondylitis, the PBAC observed that "eight treatments were currently PBS listed for AS," and proceeded to state they had "considered the *clinical need for additional therapies was low*; however, the PBAC considered an additional oral therapy option may be *beneficial for some patients*."[19] [emphasis mine]

For BD, however, there are four states of disease that require different types and combinations of medication. There are currently severe limitations and lack of subsidised options.

For diseases that have significant polypharmacy regimens and therefore a need for a much greater range of subsidised medications, there needs to be a process where clinical complexity and degree of risk for untreated patients are considered and given a significant weighting.

2. Prescribing of medicines that have increased rick and toxicity implications for First Nations peoples

Lithium is “the gold standard” in proven prevention of suicide. It is also a 70+ year old drug commonly used as a cost-comparator for newer drugs (or was the comparator used in approving drugs cost-minimised to lithium that are comparators for more recent submissions). However, the population who are full effective responders is lower than 30%[20]; its tolerability is poor with a third of people discontinuing on the basis of adverse effects[21] and it has high short- and long-term toxicity with approximately 67-90% of people who use it experiencing at least one toxicity episode. [22]

The most common consequences of lithium toxicity is nephrogenic diabetes insipidus which occurs in up to 85% of those who use lithium[23]. This form of diabetes is known to be hard to treat.[24] The prevalence of chronic kidney disease is reported to be 10-35%. Some cases of chronic toxicity result in end-stage renal disease. Other implications of lithium toxicity are thyroid dysfunction, polyuria, hypercalcemia and hyperparathyroidism.[25] The economic costs of lithium toxicity are significant, needing other PBS medicines to treat the person when another drug could achieve the same result without the toxicity implications of lithium.

The significance of the above detail of the implications of considering lithium as the benchmark for the listing of all other medicines is that for people who are Indigenous, lithium is must be considered contraindicated. Kidney Health Australia state “regardless of whether their locality is urban, regional or rural. Compared with the general population, they [First Nations peoples] are five times more likely to develop kidney disease and four times more likely to die from kidney disease.”[26] Additionally, the rates of kidney failure are 20 times higher than for non-Indigenous Australians[27] and dialysis is the greatest cause of hospitalisation for Indigenous Australians at 46%[28].

The demonstrated contraindication of lithium for First Nations peoples further highlights the issues of the 1991 change in regulatory requirements. The TGA approved ARTG PI does not state that lithium is contraindicated for use in Australia’s Indigenous population. Lithium was a grandfathered product which required documentation to be submitted but with little oversight in order to facilitate a fast transition to the new system. Since then, there have been some updates however the PI is not consistent with current published data. The most recent update for LithiCarb was a safety update but the PI states that nephrogenic diabetes insipidus is “rare” with no mention of any special populations.

The risk in using lithium for First Nations peoples cannot be overlooked and must be addressed in the issue of medicine access equity for Indigenous Australians. This serves to demonstrate that the TGA must also address the specific medical implications of therapeutic goods for the Indigenous population. This will further inform the PBAC when considering applications for listing medicines and ensuring there

are adequate alternatives for those that present any elevated risk; including items such as lithium that are currently listed and require sufficiently safe alternatives.

Amidst a disadvantaged cohort defined sue to disease, Indigenous people who live with BD disease are further disproportionally disadvantaged by lack of subsidised medicines. Consumers who are Indigenous suffer not just from the disease but even further elevated levels of co-morbid illnesses than non-Indigenous people with BD.

Through lack of treatment and therefore escalation of disease symptoms, there is a much higher incidence of encounters with the justice system, involuntary detention in mental health facilities, substandard treatment forced under community treatment orders, compounded stigma, denial of sufficient funds to live by Human Services and being rendered homeless through negative encounters with government public housing agencies. These are further "gaps" that can be and must be addressed.

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[1] Groot, C, Rehm, I, Andrews, C, Hobern, B, Morgan, R, Green, H, Sweeney, L, and Blanchard, M (2020). Report on Findings from the Our Turn to Speak Survey: Understanding the impact of stigma and discrimination on people living with complex mental health issues. Anne Deveson Research Centre, SANE Australia. Melbourne.

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