



18 April 2021

The Hon Greg Hunt MP
Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600
Via email: greg.hunt.MP@aph.gov.au

Dear Minister

Request for withdrawal of Bill setting aside protections under s135A of the *National Health Act 1953*

Better Access Australia (BAA) is writing to request the immediate withdrawal of the [National Health Amendment \(Pharmaceutical Benefits Transparency and Cost Recovery\) Bill 2021](#) (the Bill) currently before the Parliament that sets aside the protections of s135A of the *National Health Act 1953* (NHA) for submissions to the Pharmaceutical Benefits Advisory Committee (PBAC). BAA requests the proposal be fully consulted upon with all stakeholders as part of the continually delayed National Medicines Policy (NMP) review to ensure reciprocal transparency arrangements are delivered upon by the Government, your department and the relevant committees.

BAA is committed to advocating for improved access to health, disability and social services care for all Australians.

BAA is concerned about the unintended consequences of the Bill noting the Government's stated intentions as outlined in the Explanatory Memorandum and Second Reading Speech. We note media reporting on these matters including commentary by individual companies about the implications of these amendments to the timely access to medicines in Australia in an international reference pricing economy.

BAA notes the media reporting of increasing denials of Freedom of Information (FOI) requests by your department associated with health technology assessment (HTA) programs. The potentially unfettered rights the Government is bestowing upon itself with respect to the intellectual property and commercially sensitive information of applicants represents a stark contrast to this lack of transparency.

BAA is concerned that this Bill:

- ✘ Provides no caveats or exclusions on the information that can be released by the Department under the Act. This is poor regulatory practice.
- ✘ Is inconsistently applied to one sector and committee over others, with the Bill focussed on the work of the PBAC only. What are the implications for other parties who are part of the PBS supply chain, and what are the precedent-setting implications for the government's other HTA committees and processes administered or contributed to by the Australian Government Department of Health?
- ✘ Offers no reciprocity of transparency and accountability for the Government, the Department and its advisory committees.
- ✘ Provides no appeal mechanism other than the federal court noting that the actions of the PBAC (and other HTA committees) are exempted from review by the Administrative Appeals Tribunal.

Once again, the Government has determined the future of Australia's medicine access program via closed doors between the purchaser and the payer with no opportunity for those impacted (patients and taxpayers) to have a say in what is important to them in shaping the future of our medicines and emerging health technology subsidy systems.

Given the Government's commitment to the [parliamentary inquiry into approval processes for new drugs and novel medical technologies](#), this sudden move to withdraw the protection of the secrecy provisions for the pharmaceutical sector is most perplexing. Further, given the potential implications of these measures, BAA would have expected this initiative to have been a priority for exploration and consultation as part of the continually delayed NMP Review.

Withdrawing the Bill and providing for a full consultation process including a clear commitment to the Government's own transparency improvements is a must.

At a minimum BAA calls for the Government to commit to the following as part of any future discussion on legislative amendments relating to the protections of s135A:

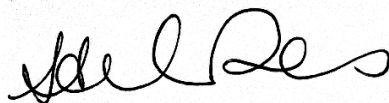
- ✓ Publication of all committee and subcommittee agendas for all HTA and funding bodies in the federal system including but not limited to the PBAC, the Medical Services Advisory Committee (MSAC), the Prosthetic List Advisory Committee (PLAC) the Australian Technical Advisory Group on Immunisation (ATAGI), the Government's Science and Industry Technical Advisory Group on COVID-19 and interdepartmental committees on screening programs.
- ✓ Expansion of the independent review mechanism for PBAC decisions to include positive recommendations and deferrals rather than just rejections.
- ✓ Expansion of the independent review mechanism of the PBAC to all HTA and new technology funding bodies.
- ✓ Introduction of consumer hearings for all HTA committee meetings based on the current model for the pharmaceutical sector in the PBAC.
- ✓ Televising of all HTA meetings.
- ✓ Introduction of clinical expert input to HTA committees on disease and technology specific areas and publication of that advice.
- ✓ Introduction of company meetings with contracted evaluators ahead of provision of reports to HTA committees.
- ✓ Abolition of the workaround process for the Life Saving Drugs Program and formal incorporation into the remit of the PBAC via amendments to the NHA noting the applicability of the National Immunisation Program model.

BAA supports transparency in Government decision making and trusts that you will intervene to ensure that is a genuine outcome of this current process. We look forward to the immediate withdrawal of the Bill and subsequent opportunity for all stakeholders to contribute to policy discussion as part of the commencement of the NMP review.

Yours sincerely,



David Mackay
Board Director



Helen Innes
Board Director



Felicity McNeill PSM
Board Director