Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

6 March 2017

Via email: community.affairs.sen@aph.gov.au

Dear Sir/Madam

Re: Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

Medicines Australia welcomes the invitation to make a submission to the Committee on the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 (the Bill). The Bill will benefit Australian health consumers and the Australian health system overall. It will do this by delivering enhancements that ensure Australia's medicines regulatory system is fit-for-purpose and globally competitive whilst maintaining the existing statutory focus of the Therapeutic Goods Administration (TGA) on medicines safety, efficacy and quality. It will also align Australian medicines regulation with other comparable jurisdictions. We therefore strongly support the Bill and urge the Committee to support it also, and not delay its passage.

Medicines Australia is the peak body representing the research-based pharmaceutical industry in Australia. Our member companies are responsible for the discovery, research, development and commercialisation of up to 86% of registered prescription medicines available to Australian patients (via the Pharmaceutical Benefits Scheme, by value). We recognise that the community looks to us as providers of medicines that they can be confident in: medicines that are safe, quality and efficacious; that help patients fight illness and disease; and that are made available to patients as soon as possible to advance Australia's, as well as their own, health outcomes.

This submission does not propose to describe the Bill in detail but rather aims to detail its benefits overall.

The Bill is the result of significant consultation and has wide-ranging support and the TGA is actively consulting on the details

The Bill follows long and extensive consideration by three highly regarded Australian experts who formed the Medicines and Medical Devices Review Panel in 2014. The Panel's overall purpose was to consider whether (and where) reforms to the Australian regulatory system could benefit Australia, and Australian health consumers. It is important to note that the Review scope specifically excluded examination of Australian payment and reimbursement systems and processes, such as the Pharmaceutical Benefits Scheme.

The Review made a strong case for reform and delivered 58 recommendations following wide-ranging consultation across the entire health system, with input from Australian health consumer organisations, medical and other health professionals, carer groups and industry. Over 100 submissions were received and the Review Panel met with over 60 organisations during the consultation process.

The Review Panel's 2015 report was subsequently considered by the Australian Government for a substantial time. The Australian Government announced its acceptance of 56 of 58 of the Panel's recommendations in September 2016.

The Australian Government and the TGA are committed to ensuring they get the reforms right and the TGA has already commenced detailed consultations with the public, as well as with industry and other relevant stakeholders.

The legislative process provides further review opportunities; public consultation is under way

As noted in the motions to refer the Bill to the Senate Committee, there are additional steps (i.e. regulation-making) that will be required to support the implementation of the reforms enabled by the Bill.

The Bill provides the TGA with the ability to set out the details of new pathways in regulations, thereby creating a framework that is more sustainable and more responsive over time to medical and technological advances. Moreover, any subsequent changes to the Therapeutic Goods Regulations or the TGA's operating processes will include additional consultation opportunities to mitigate against any unintended consequences. This is a very open and transparent approach.

As stated earlier in this submission, the TGA has already begun consultations (via consultation papers and stakeholder workshops), to assist it in determining the details of the measures enabled by the Bill. Medicines Australia has actively participated in the consultations held so far, and will continue to do so.

Providing for the details of the Bill's reforms to be contained in relevant regulations and legislative instruments is consistent with legislative process across Australia and applies in many other sectors. Through this approach, the Parliament will be able to check that the detailed TGA requirements are balanced and also keep pace with new international standards, emerging technologies, innovations and advances for patients.

Implementation of the Bill will help enhance patient safety and outcomes, not reduce them

Currently, Australian patients have to wait longer to access some medicines and other treatments than patients in comparable jurisdictions, which can adversely impact health outcomes. The Bill, however, will ensure expedited pathways for certain new treatments in our health system are made available to patients, consistent with regulatory systems in the EU and the US (Review Panel Recommendation Three).

Priority Review of medicines that offer substantial benefits over existing therapies or which address high unmet clinical needs for Australian patients will reduce registration working days by almost half. In addition to more efficient Special Access Schemes for patients (Recommendations 24 and 26), this can mean a life-saving difference.

The Review Panel found that Australian patients had to wait, on average, five months longer than patients in the US or Europe for anti-cancer medicines, seven months longer for cardiovascular medicines and up to 15 months longer for nervous system medicines. Clearly, in the absence of change, Australian clinicians and their patients have more limited treatment options and far less ability to account for patient preference, than their counterparts in comparable jurisdictions. The Bill helps to address this gap.

Importantly, the expedited pathways do not replace or diminish the standard registration pathways but are additional to it. The TGA has stated that applications for standard registration will continue to be processed in a timely and efficient manner notwithstanding the introduction of expedited pathways. There will also be strict conditions imposed by the TGA before any treatment may even qualify for consideration as meriting expedited pathway registration. In fact, the TGA has indicated that expedited pathways mechanisms will be used in a minority of cases. The application for designation will ensure the pathways are only available for medicines meeting very strictly defined criteria of clinical and medical significance.[1]

The Bill also enhances patient safety by supporting stepwise learning under conditions of uncertainty. For example, sponsors will be required to collect and submit post-market safety and efficacy data (Recommendation 27). The TGA will have the authority to impose other safeguards within the more comprehensive post-market monitoring and surveillance scheme for medicines and medical devices, which was also recommended as part of the Review. These enhanced post-market monitoring mechanisms will alert health professionals and consumers that a new medicine or

[1] As per the TGA Consultation Paper, *Expedited Pathways for Prescription Medicines: Eligibility Criteria and Designation Process* (October, 2016): "The Priority Review pathway will require new and flexible business processes to facilitate faster assessment for registration, while maintaining our high standards for efficacy, safety and quality."

medical device approved under an expedited pathway is subject to intensive monitoring by the TGA.

The TGA remains the sovereign decision-maker with public health and safety at the centre

In Medicines Australia's submission to the Review Panel, over two years ago (see https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20150109-sub-medicines-australia-submission-to-medicines-review-FINAL1.pdf), we put on the record our strong support for balanced reforms to Australia's regulatory system, noting in particular that such reforms must preserve the principal role of regulation, which is *to protect public health and safety*. We believe the Bill strikes the right balance between enabling improved access for patients whilst upholding public health and safety (Recommendations One and Two of the Review).

The Bill also delivers reforms that are consistent with a viable medicines industry (one of the four pillars of Australia's National Medicines Policy 2000).

Conclusion

The Bill provides the Australian Parliament with the opportunity to enact meaningful reforms by modernising Australia's approach to medicines regulation, harnessing significant efficiency gains, reducing unnecessary red tape and delivering real savings to the benefit of government, patients and industry. It will also align Australia with world's best regulatory systems.

The prompt passage of the Bill will help Australians to have more timely access to very promising life-changing and life-saving medicines for Australian patients, which is a significant step forward. It will also position industry to continue to deliver important, innovative therapies, consistent with world's best regulatory systems.

Medicines Australia would be pleased to assist the Committee at any time, and would welcome the opportunity to elaborate further on this submission by appearing at the public hearings scheduled for Friday 17 March 2017. I may be contacted for this purpose by telephone on 02 6122 8501.

Yours faithfully

Milton Catelin
Chief Executive