28/2/17

To the Senate Community Affairs Legislation Committee inquiry into the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

Dear Ms Radcliffe and Committee Members,

I am writing on behalf of the Australasian Tuberculosis Forum (TB Forum) to express our concerns regarding regulatory barriers that currently hinder access to essential medicines and vaccines for the prevention, management and treatment of tuberculosis (TB) in Australia. We welcome the current review of Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016, particularly Review Recommendation 24 regarding the use of medications not currently in the Register. The TB Forum is a registered Health Promotion Charity comprised of a network of clinicians and public health practitioners working towards the control and elimination of TB in the Asia and Pacific regions through leadership, collaboration, advocacy and education. We wish to offer the following comments as background for the Committee with regards to the impact of existing regulation in relation to provision of care for TB.

Rates of TB in Australia are low by global standards. However, TB is the world's deadliest infectious disease and in 2015**,** 940,000 people died from TB in the Asia Pacific and there were 6.9 million new cases. Our closest neighbours and trading partners, Indonesia, Papua New Guinea, Philippines, China and India, have high burdens of disease. While the incidence of TB in Australia is low, approximately 1,300 people developed TB disease locally in 2015, with significant impact on individuals, families and health systems.

At present, several medications in routine use for the treatment of TB globally are not available as registered products in Australia. This is best exemplified by pyrazinamide, a first-line TB drug used for virtually all cases of TB. It is one of only four first line TB medications that most patients take for the first two months of TB treatment and therefore is an essential component of a TB regimen. This medication has been in widespread use since the early 1970's, is a standard part of TB treatment guidelines both in Australia and internationally, and is included on the World Health Organization's *List of Essential Medicines*. Nonetheless, pyrazinamide is not registered in Australia, and clinicians are required to apply for use for each individual patient under the *Special Access Scheme* in order to prescribe this essential and routine medication. These processes are burdensome and do not appropriately reflect the routine nature of this treatment.

Similarly, no registered Bacille-Calmette Guerin (BCG) vaccine, or alternative formulation eligible for 19A exemption of the *Therapeutic Goods Act 1989* (TGA Act), is available for use in Australia. While Australian immunisation guidelines[i] recommend BCG vaccination for children at higher risk of TB exposure, currently no product is available for use. This situation means that presently, children eligible for this important preventative intervention are not receiving it, placing them at increased risk of TB in coming years. The BCG vaccine is one of the most widely used vaccines globally, with millions of doses administered annually, yet there is currently no registered product available for use in Australia.

Finally, while individual first line TB drugs such as isoniazid and rifampicin (which are two of the four most important TB drugs used to treat drug sensitive TB, along with

pyrazinamide) are available for use in Australia, standard programmatic care in most global settings involves the use of fixed-dose combinations (FDC). FDC preparations are especially important for reducing the burden of treatment in children. While children in Papua New Guinea can access a dissolvable FDC that is palatable and easy to administer, children in Australia must take a daily combination of tablets and syrups, leading to significant difficulties with effective treatment and maintaining engagement in medical care.

We are concerned that these products, which are readily available in the poorest countries of our region, are not routinely available to treat and protect those at risk of TB in Australia. This hampers Australia's ability to effectively prevent, manage and treat TB and imposes additional burdens on patients. This is especially concerning for those at highest risk of TB, particularly Aboriginal and Torres Strait Islander children and other vulnerable or disadvantaged groups in Australia.

The solution proffered by the Therapeutic Goods Administration is for providers to obtain Authorised Prescriber Status for these unlicensed products. However, authorised prescriber status is product, site and prescriber specific. It requires a separate application for each product, including ethics committee approval and regular 6 monthly reporting, and a renewal every 2 years. This process is overly burdensome for routine, well-established treatments and is impeding the delivery of these essential and potentially life saving treatments.

The examples provided relate to well-established therapeutics in the field of TB. We would also highlight that the growing burden of multidrug resistant (MDR) TB, which is leading to rapid changes in available treatment, particularly the introduction of new drugs and formulations. Mechanisms have been established worldwide to ensure that these products are available in a timely fashion for those who need them, such as the Global Drug Facility and regional Green Light Committees. Existing regulatory systems in Australia, however, mean that TB clinicians and programs are unable to utilise these mechanisms and continue to negotiate approvals on an individual patient basis.

Members of the TB Forum are aware of the challenges arising from the existing regulatory framework relating to vaccines and therapeutics in Australia. Nonetheless, TB is an important medical and public health issue, and existing regulatory approaches are inhibiting reliable access to essential medications for TB treatment and prevention.

We urge the Committee to consider alternative approaches to ensuring that a reliable and accessible supply of TB medications and vaccines is available in Australia, including broadening provisions of the 19A exemption *Therapeutic Goods Act 1989* (TGA Act) to allow for the use of other products widely used globally.

Representatives of the TB Forum would appreciate the opportunity to meet with your staff to discuss this situation. Thank you for your attention to this matter, which is much appreciated.

Yours sincerely,

A/Prof Justin Denholm, on behalf of the Australasian Tuberculosis Forum

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[i] Australian Technical Advisory Group on Immunisation (ATAGI). *The Australian Immunisation Handbook* 10th ed (2016 update). Canberra: Australian Government Department of Health, 2016