

27 January 2023

The Hon. Dr Jim Chalmers MP, Treasurer

Senator the Hon. Katy Gallagher, Minister for Finance

The Hon. Mark Butler MP, Minister for Health and Aged Care

The Hon. Ed Husic MP, Minister for Industry and Science

CC: Adj. Professor John Skerritt

Dear Ministers,

Re: Securing sustainable funding for the Therapeutic Goods Administration

As representatives of the Australian life sciences industry, we are writing to urge the Government to retain and empower Australia's world-leading therapeutics regulator by addressing the outdated funding model that it is operating within. Additional budget funding is required to fund its worthy public health initiatives.

Together, we represent biotechnology, pharmaceutical, medical technology, and digital health companies, ranging from multinational organisations to local pre-revenue start-ups. We are united by our mission to build a strong and innovative life sciences ecosystem for the benefit of the health of all Australians and the strength of Australia's economy.

We welcome the Government's commitment to build on the strength of the Australian life sciences industry through ambitious initiatives such as the \$15 billion National Reconstruction Fund (NRF), the Trailblazer Universities Program to support select regional universities to boost research and development, and the establishment of an Australian Centre for Disease Control (CDC).

The recent announcements to build end-to-end mRNA manufacturing facilities in Australia further strengthens the capabilities of the life sciences ecosystem. It is also promising to see the Government's vision to "achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment" in the newly updated National Medicines Policy.

The Strategic Agreement between the Government and Medicines Australia supports this vision with the shared goal to reducing time to access for Australian patients so that they can access new health technologies as early as possible. These initiatives are a recognition of the lessons from the COVID-19 pandemic and increase Australia's preparedness for future health emergencies.

These very positive initiatives are, however, at odds with the lack of sustainable federal funding for the Therapeutic Goods Administration (TGA). The TGA is a central part of the Australian life sciences ecosystem and is considered a leading regulator worldwide. The agency has a vital role in safeguarding the health of the Australian public. Its role has evolved significantly over time to include a substantial amount of 'public health activities' beyond evaluating, assessing, and monitoring medicines and medical devices. The funding model has not evolved similarly.

The TGA is now involved in the management of medicine shortages, providing education to consumer and healthcare professionals, regulation of cannabis products, and management of nicotine vaping products. We fully support this essential public health work. The Government must do the same.

While these public health programs represent about a third of the TGA's work, only about 7% of the TGA's funding is provided through public funds. The remaining 93% of the TGA's revenue is collected through industry fees and charges. Funding for important public health measures and health emergencies

should be provided by the Government, not cross-subsidised through TGA measures such as existing cost recovery models.

The Australian Government's cost recovery guidelines are clear that industry fees and charges should accurately reflect the fee for services provided directly to a specific individual or organisation.¹ In addition, in its *Inquiry into approval processes for new drugs and novel medical technologies in Australia*, the Standing Committee on Health, Aged Care and Sport recommended that the Government "reconsider the current cost recovery funding model for the TGA".² We strongly recommend that the recent decision to fund the TGA's digital and business transformation through increases to cost recovery arrangements is reconsidered in such a review.

Compared to other comparable well-respected and effective regulatory agencies around the world, the TGA is alone in receiving such a small amount and percentage of public funding. In the United States, the Food and Drugs Administration (FDA) is 54% funded through public funds.³ The equivalent for the European Union's European Medicines Agency (EMA) is 13%,⁴ and 16.6% for the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA).⁵

The Federal Budget in May 2023 is the ideal opportunity to create a viable funding model for the TGA. Sustainable public funding for the TGA, commensurate with other similar national regulatory agencies, is in Australia's national interest. By providing appropriate funding for the TGA in the Federal Budget, and reviewing the agency's funding model in the medium-term, the Government has an opportunity to strengthen its position as a globally leading regulator, stay up to date with the increasing pace of innovation, and respond quickly to future health emergencies. It would also send a clear message to the public that independent public health care is a strong commitment of this Government, alongside strengthening Medicare and modernising Health Technology Assessment (HTA).

If such public funding is not secured, it has the potential to diminish the Government's otherwise ambitious life sciences initiatives, weaken the life sciences ecosystem, and most concerningly, undermine the health of all Australians.

As representatives from across the life sciences industry, we urge the Government to avoid this scenario by using the upcoming Federal Budget to provide sustainable and timely funding for the TGA. We are happy to work with the Government in any consultative process to ensure a suitable funding model to retain and empower Australia's world-leading therapeutics regulator.

Yours sincerely,

Elizabeth de Somer, CEO, Medicines Australia

Lorraine Chiroiu, CEO, AusBiotech

Ian Burgess, CEO, Medical Technology
Association of Australia

Jeff Malone, CEO, BioMelbourne Network

Bronwyn Le Grice, CEO & Managing Director,
ANDHealth

Erin Evans, CEO, Life Sciences Queensland

Gary Cox, Chairperson, Life Sciences WA

¹ <https://www.finance.gov.au/publications/resource-management-guides/australian-government-cost-recovery-guidelines-rmg-304>

² Recommendation 14, The New Frontier - Delivering better health for all Australians, November 2021

³ 54%, or \$3.3 billion: <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>

⁴ 13%, or €54.27 million: <https://www.ema.europa.eu/en/about-us/how-we-work/governance-documents/funding>

⁵ 16.6%, or £30 million:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1093177/MHRA_Annual_Report_and_Accounts_2021-22.pdf



About Medicines Australia

Medicines Australia leads the research-based medicines industry of Australia. Our members discover, develop and manufacture prescription pharmaceutical products, biotherapeutic products and vaccines that bring health, social and economic benefits to Australia. Our members invest in Australian medical research and take local discoveries and developments to the world.

About AusBiotech

AusBiotech is Australia's biotechnology organisation, working on behalf of 3,000 members for more than 35 years to promote the global growth of Australian biotechnology. AusBiotech covers the life sciences, including therapeutics, medical technology (devices and diagnostics), and agricultural biotechnology sectors, as well as the pipeline of development from early research to market.

About the Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

About ANDHealth

ANDHealth is Australia's leading provider of accelerator, incubator and commercialisation programs for digital health technology companies. Since 2017, ANDHealth has worked with over 400 digital health companies across Australia.

About Life Sciences Queensland

Life Sciences Queensland Limited (LSQ) is a Queensland Peak Body who offers opportunities for industry stakeholders to come together and cooperate to grow their businesses and help create a dynamic, internationally competitive and sustainable life sciences industry in Queensland, Australia.

About BioMelbourne Network

BioMelbourne Network is the peak body in the Victorian healthtech industry, driving engagement and growth in research, innovation, commercialisation and manufacturing through local and international networks. Since 2001, we are actively fostering and growing an innovative, globally competitive sector and transforming our Network as well as the broader Victorian ecosystem.

About Life Sciences WA

Established in 2021, Life Sciences WA is a collaboration of representatives from Government, Universities, Research Institutions, Industry Bodies and Corporates who have come together to form one united body and connect the industry. Our members represent all areas of the diverse life sciences ecosystem including pharmaceutical, biotechnology, medical technology, aquaculture, agricultural technology, research, intellectual property law and business consulting.