



AusBiotech submission in response to the
TGA fees and charges proposal 2023-24
consultation paper

To: Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia
TGA FeesAndCharges@health.gov.au

16 March 2023

From: AusBiotech Ltd
ABN 87 006 509 726
Level 33, 477 Collins Street
Melbourne VIC 3000
Telephone: + 0428 056 173
Website: www.ausbiotech.org

Introduction

AusBiotech welcomes the opportunity to submit a response to the Therapeutic Goods Administration's (TGA) consultation paper on the *TGA fees and charges proposal 2023-24*.

AusBiotech is the Australian representative body for one of Australia's most innovative industries with a well-connected network of over 3,000 members in the life sciences industry, which includes biotherapeutics, medical technology (devices and diagnostics), and agricultural biotechnology sectors.

Australia has a substantial life sciences and biotechnology sector, which is consistently ranked as one of the top countries for biotechnology innovation globally when adjusted for population. Industry employs almost 100,000 Australians and consists of more than 1,425 biotechnology companies. Around 80 per cent of these industry companies are classified as small to medium enterprises (SMEs) and are working to commercialise their research, with an important number developing new and novel technologies.

This response has been developed together with the AusBiotech's AusMedtech Regulatory Affairs Advisory Group, which provides guidance and advice on operational and policy-related regulatory matters. The submission represents AusBiotech members actively engaged in delivering social and economic benefits to Australia through the commercialisation of biotechnologies and medical technologies.

By providing appropriate funding for the TGA in the short-term, 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.

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.

AusBiotech urges the Government to avoid this scenario by providing sustainable and timely funding for the TGA.

Key recommendations

AusBiotech remains supportive of fees and charges increasing by the calculated indexation factor; for 2023-2024 this will be at an increase of 5.2%. This position is in line with previous increases, offers an approach where fees are commensurate with the opportunities for efficiency gains, and is consistent with the Government's policy for cost recovered activities.

AusBiotech strongly urges the Government to retain and empower Australia's world-leading therapeutics regulator by addressing the outdated funding model that it is operating within.

Industry is fully supportive of the essential public health work being undertaken by the TGA, however, industry is already investing in these important activities itself and therefore it is unreasonable for it to pay for them again by increasing the TGA fees and charges by up to 12.33%. Additional Federal funding is required to fund its worthy public health initiatives.

Sustainable funding for the TGA is integral to Australia's world-class health future

It is 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, however, this vision is at odds with the lack of sustainable federal funding for the TGA.

If Australia wants to maintain its status as an internationally competitive regulator, it needs an agency that is empowered to contribute to the Australian economy and to the life sciences sector.

The TGA is a central part of the Australian life sciences ecosystem, is considered a leading regulator worldwide, and has a vital role in safeguarding the health of the Australian public. Its activities have evolved significantly over time to include a substantial amount of 'public health activities' beyond evaluating, assessing, and monitoring medicines and medical technologies and the funding model has not evolved similarly. This is problematic, with the Administration now in a financially unsustainable position.

The TGA is now involved in the management of medicine shortages; providing education to consumer and healthcare professionals; compliance, legal and enforcement costs for companies and individuals dealing outside the regulatory system (i.e. unapproved therapeutic goods); and the management of nicotine vaping products.

This is noted in the consultation paper: "The TGA also provides several fee-free services in the public good and undertakes a range of compliance, legal enforcement and consumer and health professional awareness activities **which do not directly relate to any product or industry group.**" While the 2019-2020 MYEFO allocated \$15 million per year ongoing from 2022-23, this only contributes to, and by no means covers, all of the costs of these services which is in excess of \$30 million per annum.

Industry is fully supportive of this essential public health work, however, it is already investing in these important activities itself and therefore it is unreasonable for it to pay for them again through their fees and charges.

While these public health programmes represent about a third of the TGA's work, only about eight per cent of the TGA's funding is provided through public funds. The remaining 92 per cent 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 the existing cost recovery models.

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 per cent funded through public funds.¹ The equivalent for the European Union's European Medicines Agency is 13 per cent,² and 16.6 per cent for the United Kingdom's Medicines and Healthcare products Regulatory Agency.³

Sustainable public funding for the TGA, commensurate with other similar national regulatory agencies, is in Australia's national interest.

¹ 54%, or \$3.3 billion: <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>

² 13%, or €54.27 million: <https://www.ema.europa.eu/en/about-us/how-we-work/governance-documents/funding>

³ 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

Should the current proposal be accepted where fees and charges are increased by up to 12.33%, it proffers a challenging regulatory burden on companies across the entire development pipeline.

Pre-revenue start-ups and SMEs companies, which make up around 80% of the Australian life sciences industry, will face restrictive budgetary burdens.

Often these start-ups are developed from hospitals or universities and have limited funding for innovative therapies for unmet needs.

Small biotechs face costs to obtain a GMP manufacturing licence, gain product regulatory approval, and maintain the product on the ARTG, in addition to any clinical trial costs (i.e. CTA), and cumulative financial increases proposed for regulatory approvals for development and manufacturing, risks seeing home-grown IP taken off-shore, or not developed at all. With the increase in fees and charges applying to medium and large pharmaceutical companies it offers an unnecessary and disproportionate hurdle to the Australia's SME biotechnology industry.

For larger companies, the scale of their product portfolio will result in greater aggregate application costs and therefore force them to reconsider their full portfolios and rationalise the technologies that they bring to Australia. This reduction in offering may be seen through the iteration of technology improvement offered, or in the smaller-volume products intended for special groups, thereby directly impacting Australian patients' access to leading technologies.

In addition to budgets, application timelines are of similar importance to industry, therefore, should the TGA not receive funding from Government and consequently need to reduce human capital/extend timelines, then companies have indicated that this will heavily impact their decisions on when (if at all) to register cutting-edge innovative technologies in Australia.

Case study: public good activities offer Australians special access to innovative technologies

The AusBiotech-led Regenerative Medicine Consortium Project's Global Pipeline Tracker report recently revealed that the globe is anticipating a pipeline of new and novel regenerative medicine treatments, and that Australia may share in access to some. While there are currently six RM therapies already approved in Australia⁴, the new data shows a rich pipeline with 140 therapies in late-stage development globally in multiple therapeutic areas, and up to nine may reach Australian patients in the next five years.

This is just *one* example in *one* access Scheme/Program that is included in the \$15 million Government appropriation funding, and is demonstrative of the continued pressure the TGA faces as it undertakes its regulatory functions. An appropriate funding model to not only continue these activities but to also enable the significantly increasing demand is essential for Australia and Australians.

Indexation of fees and charges

AusBiotech remains supportive of fees and charges increasing by the calculated indexation factor; for 2023-2024 this will be at an increase of 5.2%. This position is in line with previous increases, offers an approach where fees are commensurate with the opportunities for efficiency gains, and is consistent with the Government's policy for cost recovered activities.

Should the TGA retain this approach, the thriving Australian biotechnology sector will not face excessive regulatory burden through fee increases, and therefore it is expected that industry will

⁴ [Australia's Regenerative Medicine Clinical Trials Database](#), August 2021

continue to develop, manufacture, supply, and export innovative therapeutic goods on its current trajectory.

Modernising TGA's infrastructure: Digital transformation costs & Laboratory fit out costs

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.⁵ 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".⁶

AusBiotech is yet to learn of any other government body, even those undertaking cost recoverable activities, that puts the costs of infrastructure updates – in both an online/business systems as well as physical facilities sense - onto its stakeholders.

AusBiotech strongly recommends 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.

Digital transformation costs

The consultation paper explains that to cover the long-overdue TGA's digital update, costs will be recovered from industry over five years, commencing from 1 January 2024. Industry is very supportive of the modern operating system that the digital update offers, and has also been involved in the UDI system consultations for many years. However, it was surprised and disappointed to learn about the funding arrangement through the 2022 Budget announcement as the funding, and therefore the broader and compounding impacts of the decision-making, had not been indicated throughout the consultation processes.

Laboratory fit out costs

A world-class regulator needs world-class facilities, however, in the face of an additional increase of 4.12% to all annual charges in addition to standard calculated indexation factor outlined above, industry seeks to understand why the additional payment of \$4.85 million annually for the initial lease term of 15 years (\$72.75 million in total) was enacted.

Other considerations

Industry is supportive of maintaining regulation that is commensurate with risk, and has identified an opportunity for the TGA to assess application of its risk against benefit analysis for relatively benign low-risk classification devices, including Class 1 devices, that are registered and marketed elsewhere in the world in countries that would be considered comparable to Australia. This would maintain a high standard of safety while reducing resourcing burden on both regulator and industry.

As a consequence of the additional resources and time currently faced, as well as the significant increase in fees and charges proposed, there is a risk that Australia's biotechnology industry, including home-grown companies, will de-prioritise or forgo registration in Australia because of the (already) high cost involved in navigating the disproportionately burdensome regulatory processes in this country.

⁵ <https://www.finance.gov.au/publications/resource-management-guides/australian-government-cost-recovery-guidelines-rmg304>

⁶ Recommendation 14, *The New Frontier - Delivering better health for all Australians*, November 2021

For example, products that have been through successful conformity assessment in Europe (a comparable world-class regulator) as Class 2a medical devices, based on their classification in line with the Australian regulations, have also been included in non-mandatory application audits by the TGA, after the product owner/company pursues inclusion of its products in the Australian Register of Therapeutic Goods.

In some cases, these application audits have gone on for periods of years, with multiple rounds of questions. Ultimately, some of these low-risk classification products are included in the ARTG, after significant time and expense by industry and, presumably, the TGA. This example demonstrates an uncharged non-mandatory activity where it would be beneficial for the TGA to review and provide guidance on how it uses risk against benefit analyses to decide how it applies its valuable resources. In addition, the impact of these additional audits delay the time a product can be marketed in Australia, and is disproportionate to the low risk that the product may have.

The adoption of the European regulatory changes also offers an opportunity to streamline red tape whilst still maintaining high safety requirements.

For example, the TGA's need to audit applications for medical devices where European conformity assessment has already been completed under the new, more stringent regulations should now be superfluous.

Industry believes there is an opportunity to streamline, reduce duplication, and presumably decrease the cost for both industry and the TGA for low-risk medical device product processes.