



AusBiotech submission in response to the *TGA fees and charges proposal 2024-25*

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

23 February 2024

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

Introduction

AusBiotech welcomes the opportunity to submit a response to the Therapeutic Goods Administration's (TGA)'s consultation paper on the *TGA fees and charges proposal 2024-25*.

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), food technology 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.

The consultation outlines that the proposed changes to the fees and charges are made up of three components: a) indexation of fees and charges; b) digital transformation and UDI cost recovery; and c) a small number of other changes to medicine and medical device fees and charges.

Key recommendations

1. AusBiotech is supportive of the proposed fee increase of 4.7%, as outlined in 8.a) *indexation of fees and charges*; 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.
2. AusBiotech strongly recommends that the decision to fund the TGA's digital transformation through increases to cost recovery arrangements is reconsidered.
3. AusBiotech recommends the development and publication of metrics to demonstrate the value that the publicly-funded public good activities announced in the 2023-2024 Federal Budget are delivering to Australians and Australia. These metrics will support attaining sustainable public funding for the TGA that commensurate with other similar national regulatory agencies, and that is in Australia's national interest.

a. Indexation of fees and charges

AusBiotech is supportive of the proposed fee increase of 4.7%, as outlined in 8.a) *indexation of fees and charges*; 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

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

b. Modernising TGA's infrastructure: 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, 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

AusBiotech is yet to learn of any other government body, even those undertaking cost recoverable activities, that puts the costs of infrastructure updates onto its stakeholders.

AusBiotech strongly recommends that the decision to fund the TGA's digital transformation through increases to cost recovery arrangements is reconsidered.

Other considerations

AusBiotech welcomes the Government's additional funding for four years of public good activities in the 2023-2024 Federal Budget. As an internationally competitive regulator, Australia needs an agency that is empowered to contribute to the Australian economy and to the life sciences sector.

Industry is fully supportive of the essential public health work being undertaken by the TGA, with industry also investing in these important activities itself.

Funding for important public health measures and health emergencies should be provided by the Government, and AusBiotech recommends the development and publication of metrics to demonstrate the value that these publicly-funded public good activities are delivering to Australians and Australia.

These metrics will support attaining sustainable public funding for the TGA that commensurate with other similar national regulatory agencies, and that is in Australia's national interest.

¹ <https://www.finance.gov.au/publications/resource-management-guides/australian-government-cost-recovery-guidelines-rmg304>