

20 March 2023

Via the TGA Consultation Portal

Dear Therapeutic Goods Administration,

Re: Public Consultation – Fees and charges proposal 2023-2024

Medicines Australia has consulted with our members regarding the proposed increases to the TGA's fees and charges for 2023-2024. We note the agreed formula for increases to the fees and charges is calculated on the average of the wage price index (WPI) and the consumer price index (CPI) at the September quarter. For 2023-24, an increase in line with the indexation formula would be 5.2% for fees and charges.

However, as communicated in the bilateral meeting with the TGA in December 2022, we are deeply concerned about the proposed increase in charges, which is well beyond inflation and appears inconsistent with the Australian Government's Cost Recovery Guidelines (CRG).

Therefore, Medicines Australia formally submits:

- **not to oppose** the inflation-based increase of 5.2% to fees and charges.
- **opposes** the increase to charges between 11.1% - 12.33% to fund the TGA's digital transformation and the lease charge for its upgraded laboratory.

Medicines Australia does not oppose the agreed approach of increasing fees and charges in line with inflation and consistent with the agreed formula, provided it drives the continuous improvement of services. However, we have long maintained that utilising industry fees and charges to cross subsidise other functions or fund non-industry related services is inappropriate and inconsistent with the CRG.

Furthermore, Medicines Australia emphasises that there was inadequate consultation for the proposed changes. Medicines Australia also disagrees that the industry should be required to pay for the TGA's necessary, and long-overdue, digital transformation and the lease charge for its upgrade to its laboratories. The decision to cost recover the digital transformation initiative was forewarned in the October 2022 Federal Budget, without prior consultation. The decision to cost recover the laboratory upgrade was not forewarned in the Budget.

As a result, while industry expected increases to TGA fees and charges in line with inflation, it is now being presented with substantial changes beyond inflation. These changes are being proposed at short notice, and without regard to the impact on the sector. Medicines Australia has signed successive strategic agreements with the Federal government to provide (*inter alia*) a mutual goal of policy predictability and business certainty. Many companies' set their budgets for the calendar year well in advance of these announcements which will have a significant and unexpected impact on their business operations.

In addition, the combined life sciences sector has written to the Government seeking sustainable funding for the TGA to continue to deliver measures in the public interest, without diverting industry fees and charges to cross-subsidise these important public health functions.

Securing sustainable funding for the Therapeutic Goods Administration

The proposed increase to the TGA's fees and charges highlights the broader issue of the TGA's lack of a sustainable funding model. This issue was identified by the Standing Committee on Health, Aged Care and Sport in its report *The New Frontier - Delivering better health for all Australians*, in which the Committee recommended that the Government should reconsider the current cost recovery

funding model used by the TGA.¹ In January 2023, Medicines Australia and a consortium of other industry peak bodies wrote to the Treasurer, the Minister for Finance, the Minister for Health and Aged Care, and the Minister for Industry and Science to highlight the TGA's lack of a sustainable funding model and urged the Government to use the Federal Budget in May 2023 to create a viable funding model for the TGA.² In addition to this, Medicines Australia strongly recommends a broader public consultation and discussion about the TGA's funding model.

The TGA has a vital role in safeguarding the health of the Australian public, however, its cost recovery funding model does not reflect the scope of the agency's responsibilities. These responsibilities have expanded over time to include a substantial amount of 'public health activities', which include the management of medicine shortages, providing education to consumer and healthcare professionals, regulation of cannabis products, and management of nicotine vaping products. While we are supportive of this work, these activities should be publicly funded, not cross-subsidised from industry cost-recovery / fee for service. We note that in the consultation paper the TGA itself recognises that these activities "cannot be appropriately cost recovered from industry".³ Yet, the lack of sustainable public funding means that the TGA must continue the unreasonable practise of using industry fees and charges to fund these activities.

In addition, while these public health programs represent about a third of the TGA's work, only about 8% of the TGA's funding is provided through public funds. The remaining 92% of the TGA's revenue is collected through industry fees and charges. 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.⁴ The equivalent for the European Union's European Medicines Agency (EMA) is 13%,⁵ and 16.6% for the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA).⁶

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). Medicines Australia contends that the proposed substantial increase to charges is premature until adequate consideration is given to TGA's funding model.

The proposed increase to TGA charges appears inconsistent with the Cost Recovery Guidelines

Medicines Australia believes maintaining the TGA as an efficient and capable regulator is vital for public health and the life sciences ecosystem. As such, we were supportive of modernising the TGA's infrastructure, such as the digital transformation and the laboratory upgrade. However, we oppose the notion of using industry charges to fund these initiatives as they appear inconsistent with the CRG.

¹ Recommendation 14, The New Frontier - Delivering better health for all Australians, November 2021

² 'Securing sustainable funding for the Therapeutic Goods Administration': https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/01/Budget_Life_sciences_industry_TGA_funding_27Jan23.pdf

³ TGA fees and charges proposal 2023-24 Consultation Paper, Section 8.3

⁴ 54%, or \$3.3 billion: <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>

⁵ 13%, or €54.27 million: <https://www.ema.europa.eu/en/about-us/how-we-work/governance-documents/funding>

⁶ 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

The CRG specify that there needs to be clarity on how cost recovery might affect:⁷

- The policy outcomes for the activity
- Other government policies and legislation (e.g. policies relating to access to essential community services).

The consultation paper does not adequately explain the policy outcomes that the digital transformation initiative will bring to industry. While the cost recovery of the initiative was forewarned in the October 2022 Federal Budget, this decision was taken without consultation. Details are needed about what aspects of the initiative will improve services to the innovative pharmaceutical industry specifically.

In addition, CRG states that that a government entity must measure and assess its performance in achieving government policy outcomes, which includes assessing whether desired outputs and outcomes have been attained.⁸ It is therefore essential to develop a comprehensive analysis and reporting framework to enable industry to assess the benefits of the digital transformation initiative and its cost effectiveness to industry.

Utilising cost recovery to pay for the TGA's upgraded laboratory as part of its relocation costs also appears inconsistent with the CRG. It remains unclear how this initiative can be justified through a performance review, as stipulated in the CRG. In addition, although the consultation paper indicates that the TGA's relocation was 'cost-neutral', it is unclear how this can be the case given that \$3.4 million is set to be recovered annually for a period of 15 years. It is not appropriate to cost recover the laboratory upgrade without clearly explaining how it aligns with the CRG and the reasons for the additional cost after the relocation had been described as cost-neutral.

Summary

Medicines Australia supports the work of the TGA and its vital role to public health. Currently, the TGA does not have a sustainable funding model. The Federal Budget in May 2023 is the ideal opportunity to create a viable funding model for the TGA, followed by a review of the agency's funding model in the medium term.

Medicines Australia does not oppose increasing TGA fees and charges in line with inflation. However, we oppose the proposed increase to charges to cost recover the costs of the digital transformation and laboratory upgrade, as there is insufficient evidence to demonstrate how this aligns with the CRG.

To discuss any information in relation to this submission, please contact Eric Johnsson, Senior Manager, Policy on eric.johnsson@medicinesaustralia.com.au.

Yours sincerely,



Elizabeth de Somer

CEO, Medicines Australia

⁷ Australian Government Cost Recovery Guidelines (RMG 304): <https://www.finance.gov.au/publications/resource-management-guides/australian-government-cost-recovery-guidelines-rmg-304#-part-i-australian-government-cost-recovery-policy->

⁸ Ibid.