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| TGA fees and charges proposal 2025-26 |
| Consultation paper |
| Version 1, January 2025 |

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## Acknowledgement of Country

The Therapeutic Goods Administration (TGA) proudly acknowledges the Traditional Owners and Custodians of Country throughout Australia and pay respect to those who have preserved and cared for the lands on which we live, work, and benefit from each day. We recognise the inherent strengths and knowledge Aboriginal and Torres Strait Islander peoples provide to the health and aged care system and thank them for their existing and ongoing contributions to the wider community. We extend this gratitude to all health and aged care workers who contribute to improving health and wellbeing outcomes with, and for, First Nations peoples and communities. We also recognise and respect Aboriginal and Torres Strait Islander peoples’ continuing connections and relationships to the lands, waters, culture, and community, and pay respect to all Elders past and present.

## Introduction

The TGA within the Department of Health and Aged Care (the department) is responsible for regulating the supply, import, export, manufacturing, and advertising of therapeutic goods. The TGA protects the health and safety of the community by regulating therapeutic goods for safety, effectiveness and quality through administering the [*Therapeutic Goods Act 1989*](https://www.legislation.gov.au/Details/C2017C00226) (the Act). To meet these responsibilities, the TGA recovers costs from industry in accordance with the [Australian Government Charging Framework](https://www.finance.gov.au/government/managing-commonwealth-resources/implementing-charging-framework-rmg-302/what-australian-government-charging-framework) (Charging Framework).

The purpose of this consultation is to provide industry and other interested stakeholders with the opportunity to comment on the TGA’s proposed fees and charges for the 2025-26 financial year. Specifically, we are seeking feedback on the potential impact of the changes prior to seeking approval from the Government.

Fees and charges are reviewed annually in consultation with stakeholders. The TGA uses other consultation mechanisms as needed when significant changes to fees and charges are required.

Meetings with peak industry bodies were held in November 2024 to discuss the proposed changes set out in this paper.

### Description of TGA Activities

To achieve the outcome of protecting the health and safety of the Australian community, the TGA approves and regulates products based on an assessment of risks against benefits. The community expects therapeutic goods in the marketplace to be safe, of high quality and of a standard at least equal to that of those supplied in comparable countries.

The TGA regulates therapeutic goods through:

* pre-market assessment
* post-market monitoring, compliance, and enforcement of standards, and
* licensing of Australian manufacturers, and verification of overseas manufacturers' compliance with the same standards as their Australian counterparts.

Therapeutic goods are divided broadly into 3 classes - medicines, medical devices, and biologicals. Medicines must be entered as either 'registered' or 'listed' medicines in the Australian Register of Therapeutic Goods (ARTG). Medical devices and biologicals must be 'included' in the ARTG. All therapeutic goods must be on the ARTG before they may be supplied in or exported from Australia, unless exempt.

If an issue is discovered with a therapeutic good or the manufacturer of a therapeutic good, the TGA may take regulatory actions including, but not limited to, continued monitoring, withdrawing the product from the market, or revoking or cancelling the manufacturing licence.

The TGA also undertakes activities that are funded through appropriation, rather than by the recovery of cost through fees and charges. These activities are discussed in detail in the [TGA Cost Recovery Implementation Statement (CRIS).](https://www.tga.gov.au/resources/publication/publications/cost-recovery-implementation-statement-2024-2025)

### Cost recovery obligations of the TGA

In the [1997–98 Budget, Budget Paper No.2, and Part II: Revenue Measures](https://archive.budget.gov.au/1997-98/index.htm) it was stated that, from 1998-99, the TGA would fully recover all costs of activities covered under the Act from industry. Cost recovery involves government entities charging individuals or industry organisations some or all efficient costs of a specific government activity. The Charging Framework sets out the overarching framework within which government entities design, implement and review cost recovery activities. Accordingly, the TGA generally operates on a full cost recovery basis for the funding of relevant activities. This includes the application of annual charges, evaluation fees, conformity assessment fees and inspection fees to sponsors and manufacturers of therapeutic goods.

The TGA’s cost recovery arrangements cover the following industry sectors:

* prescription medicines
* over the counter medicines
* complementary medicines
* medical devices, including in vitro diagnostic (IVD) devices and software as a medical device (SaMD)
* blood, blood components and biologicals, and
* good manufacturing practice (GMP).

The TGA also provides several fee-free services for 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 and cannot be cost-recovered. While the TGA also receives some time-limited funding, such as for health emergency or pandemic measures, approximately 78% of its 2024-2025 funding will be generated through fees and charges set under the cost recovery arrangements.

In the [2019-20 Mid-year Economic & Fiscal Outlook (MYEFO)](https://www.health.gov.au/sites/default/files/documents/2020/02/health-portfolio-budget-statements-2019-20-health-portfolio-additional-estimates-statements-2019-20_0.pdf), as part of the ongoing measure, *Improving Access to Medicines Item 7*, the Government announced funding of $33 million over 4 years for the TGA, with $15 million per year ongoing from 2022-23. This funding is used to deliver fee-free services, such as registration of orphan drugs and consumer access to unapproved therapeutic goods through the Special Access Scheme (SAS).

In the [2023-24 Budget](https://archive.budget.gov.au/2023-24/index.htm) the Government provided $61 million over 4 years to deliver a range of other public good activities, such as:

* enhancing compliance and enforcement for products and companies operating outside the regulatory system
* managing medicine and medical device shortages
* providing educational and communication activities for consumers and healthcare professionals, and
* continuing assistance to small and medium enterprises in the sector, particularly those developing emerging technologies.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Department** | **2023-24****$’m** | **2024-25****$’m** | **2025-26****$’m** | **2026-27****$’m** | **Total****$’m** |
| Health and Aged Care | 14.979 | 15.214 | 15.332 | 15.467 | 60.992 |
| **Total** | **14.979** | **15.214** | **15.332** | **15.467** | **60.992** |

In the 2023-24 MYEFO Budget, the Government provided $55 million over 2 years to the department for the Measure - Enhanced Regulatory Model for Vaping Products, of which $23 million was allocated to the TGA in 2024-25 for vaping activities. In the 2024-25 MYEFO Budget, the Government provided $150.4 million to the department for Vaping Regulatory Reform Package, including $92.6 million over 2 years from 2025–26 to the TGA to extend their regulatory, compliance and enforcement activities on all vaping products, including for staffing costs and uplifting TGA’s IT and digital infrastructure.

Some Australian Government funding is also provided to meet the secretariat costs for medicines and chemicals scheduling regulation, and in lieu of interest earned by the Government on the special account balance.

**Legal authority to charge**

The Act provides a legal authority for the TGA to charge for its activities within the scope of the Act. The [*Therapeutic Goods (Charges) Act 1989*](https://www.legislation.gov.au/Details/C2018C00066) (the Charges Act) provides a legal authority to levy annual charges, a type of tax, on sponsors and manufacturers of medicines and medical devices. Applicable fees and charges are prescribed in the subordinate regulations made under these Acts.

The fees and charges are deposited into the TGA Special Account, established under section 45 of the Act. Any unspent funds at the end of a financial year remain in a reserve for the TGA for future spending for regulatory purposes only, such as business improvement, IT systems enhancement and regulatory reforms.

The TGA’s current CRIS expands further on the cost recovery activities and methodology.

### TGA funding Mechanism

The funding for the TGA falls under 3 broad categories:

1. **Fees for services**

The Charging Framework states that cost recovery fees are charged when a good, service or regulation is provided directly to a specific individual or organisation. Fees are used mainly to recover the cost of the pre-market services performed by the TGA. Fees are designed to reflect as closely as possible the underlying cost of service.

The TGA applies fees for entering new products in the ARTG or making any variations to them, issuing manufacturing clearances, certification, and licences, and undertaking GMP inspections. Numbers and timeframes for these services are available in the [TGA Annual Performance Reports.](https://www.tga.gov.au/resources/publication/publications/performance-reports)

1. **Annual charges**

The Charging Framework states that charges are imposed when a good, service or regulation is provided to a group of individuals or organisations, such as an industry sector. An annual charge is a type of levy or tax. Revenue from charges is ‘earmarked’ to fund activities provided for the purpose for which charges have been levied. This differs from general taxation, which can be spent as the government deems appropriate.

1. **Government funding**

In undertaking its regulatory functions, the TGA is required to provide an increasing number of fee-free services in the public good. These services include, but are not limited to:

* providing timely access to unapproved medicines- including medicinal cannabis, cell and tissue therapies and medical devices- to patients under the SAS and the Authorised Prescriber (AP) Scheme
* the Orphan Drug Program
* management of critical medicine and medical device shortages, and
* a range of consumer and professional education, compliance enforcement and litigation activities which are neither provided to the therapeutic goods industry nor do they relate to regulated products or entities.

Under the Charging Framework, these activities are not appropriate to cost-recover, and the TGA receives funding from the government to assist in the delivery of these activities.

### TGA cash position as of 30 June 2024

As of 30 June 2024, the TGA had cash and cash equivalents of $78 million, which is needed to cover the liabilities and provisions of the TGA. These include $39.8 million cash to cover staff entitlements, and $31.6 million in fees received in advance for product evaluations under way. The cash reserves have reduced in the last few year years, mainly due to draw down of cash for the following investments:

* investment of $19.7 million in the TGA’s digital transformation program and the Unique Device Identification (UDI) system, as per the 2020-21 Budget decision
* investment of $23.3 million for digital and business transformation and full implementation of the UDI system, as per the October 2022 Budget decision, and
* further capital investment of $5.9 million in TGA business systems and other assets in 2023-24.

To replenish the TGA’s cash reserves, Government mandated cost recovery of $23.3 million from industry over 6 financial years, commencing 1 January 2023. TGA charges were adjusted in 2023-24 and 2024-25 for cost recovery of this amount.

### Annual review of fees and charges

Each year, the TGA reviews its fees and charges to ensure they are set at appropriate levels and that cost recovery for each therapeutic industry sector is adequate. Necessary adjustments are made, with government approval, by considering known cost increases, including annual wage and other cost movements. The increase in TGA fees and charges is based on an indexation formula that combines 50% of the Wage Price Index (WPI) and 50% of the Consumer Price Index (CPI). This forms a new indexation factor for the increase in TGA fees and charges.

After unprecedented rises in the CPI to over 7% (September 2021 to September 2022), and 5.4% (September 2022 to September 2023) in the last 2 years, CPI has now reduced to 2.8%.

Additionally, minor changes are proposed to a small number of the medical device design examinations fees.

The required indexation changes and the medical device examination fee changes are discussed in detail below.

### Cost pressures in 2025-26

Known increases to the TGA expenses in 2025-26 are estimated to be approximately $10.74 million. There are 2 major cost pressures outside our control:

1. **Anticipated increase in salary and related costs**

The single largest component of the TGA costs is salary and other staff-related costs. Employee costs are estimated to increase by $8.79 million in the 2025-26 financial year, mainly related to the 3.8% pay increase that will take effect from March 2025 as per the Department’s Enterprise Agreement (EA). This will also include a leave provision increase and staff pay increments due in July 2025. All non-SES staff with at least 3 months of service and a satisfactory performance rating are eligible for an increment in line with the Department’s EA.

1. **Increase in corporate costs**

Corporate costs are estimated to increase by $1.95 million, due to inflation-based increase to charge-back payment to the Department.

### Indexation factor for 2025-26

The indexation factor for 2025-26, based on the established composite indexation formula of the average of the CPI and the WPI, is 3.2%:

* 50% of cost price index Sep 2023 to Sep 2024 of 2.8% - 1.4%; and
* 50% of wage price index Sep 2023 to Sep 2024 of 3.6% - 1.8%

The proposed indexation factor for 2025-26 of 3.2% is significantly lower than 5.2% in 2023-24 and 4.7% in 2024-25.

### Proposed changes to fees and charges 2025-26

The proposed changes to the fees and charges for the upcoming financial year 2025-26 are discussed below.

1. **Indexation of fees and charges**

It is proposed to apply the 3.2% indexation factor to all fees and charges in 2025-26. However, in applying the indexation factor to annual charges, additional increases included in 2023-24 and 2024-25 for cost recovery of the TGA’s digital transformation program and UDI will be excluded from the base. As a result of this, effective indexation increase to annual charges will be lower than the indexation factor.

The table below summarises the proposed indexation increase to TGA fees and charges for FY 2025-26:

|  |  |
| --- | --- |
| Proposed Indexation increase to Fees and Annual charges in 2025-26 | Indexed Base Increase |
| All TGA Fees | 3.20% |
| Charges | Medicines and Biologicals Annual Charges | 3.06% |
| Medical Devices Class II and above | 2.96% |
| Other Medical Devices and IVD annual charges | 3.02% |
| Other annual charges i.e., manufacturing licences and Other therapeutic goods (OTG) | 3.09% |

It is important to note that the proposed indexation increase will not cover all known mandatory cost increases, such as salary and corporate costs for the 2025-26 financial year. A fee increase of 5.2% would be required to cover all additional costs. This means, to avoid incurring losses or reducing its current staffing level, the TGA must identify savings and efficiencies to manage these additional costs.

Should the Government accept this proposal, it is expected to generate additional revenue of approximately $6.40 million. An example of the financial impact on sponsors, if the above indexation proposal is implemented from 1 July 2025, is:

* A company that paid $10,000 in annual charges this financial year would be required to pay an additional up to $306 next financial year, depending on the class of goods, and assuming the same number of entries on the ARTG.
1. **Changes to certain medical device fees**

In 2021, the TGA’s Medical Device & Product Quality Division (MDPQD) engaged external experts to complete a broad review of the fees and charges structure for medical device regulatory activities (the Review). The Review found that several medical device premarket fees were not sufficiently recovered to cover the costs associated with providing those services.

During 2021 to 2024, the TGA also undertook several public consultations on proposed regulatory reforms. As a result, the Government approved changes to specific medical device fees to better align fees charged to regulatory effort, specifically in relation to those reform activities.

The fees for conformity assessments were not changed at that time, as further analysis was required to better understand the variability in costs, identify process improvements and account for policy changes, such as those relating to acceptance of comparable overseas regulator certificates.

The TGA has now undertaken, with significant input from sponsors, a detailed analysis of both the application audit and the conformity assessment processes. We have committed to implementing shorter target assessment time frames, streamlined processes, and improved transparency. Implementation of the streamlined processes are underway, and the associated fees have been reviewed to identify adjustments required to reflect these new processes and the efficiencies realised.

The external Review and our subsequent more detailed analysis have identified that there remains under-recovery in conformity assessment work, mainly due to the TGA’s fee reduction policy, while there is a small over-recovery where full fees are charged for conformity assessment applications. The following 2 proposals aim to recover the costs of the medical device product assessment services we provide by aligning the associated fees with those costs, as well as improving the transparency of the fees and ensuring consistent fee reduction practices.

**Proposal One: Reduce the design examination scheduled fees from 1 July 2025**

Based on an analysis of data, including consideration of the recent process improvements implemented, we propose to reduce design examination scheduled fees:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of assessment | Fee Schedule | Current fee | Proposed fee (pre-indexation) | Fee change | Proposed 2025-26 fee (post-indexation) |
| Initial design examination (non-IVD) | Item 1.9(b) | $65,850 | $59,924 | - $5,926 | $61,842 |
| Initial design examination (IVD) | Item 1.9A(b) | $71,650 | $65,202 | - $6,448 | $67,288 |
| Design examination of a change (non-IVD) | Item 1.10(b) | $39,746 | $36,169 | - $3,577 | $37,326 |
| Design examination of a change (IVD) | Item 1.10A(b) | $42,990 | $39,121 | - $3,869 | $40,373 |

**Proposal Two: Implement a revised fee reduction policy, taking into consideration the number of devices in each application**

To address under recovery and ensure fees charged are commensurate with work effort, it is proposed to implement a revised fee reduction policy. Under the revised policy, it is proposed that fee reductions could be applied on the basis of the number of devices included in an application.

We propose to undertake more targeted consultation with impacted sponsors on the options to change the fee reduction policy. To ensure transparency and engagement of sponsors, a consultation process will occur to discuss the proposal for how the TGA applies fee reductions in a consistent way for design examinations. Updating our fee reduction policy and guidance does not require regulation changes. It is proposed that targeted consultation on the options to change the fee reduction policy occurs early in 2025, with a possible commencement date in 2025.

### Summary of proposed changes to fees and charges in 2025-26

To summarise, in 2025-26:

* all fees and charges are proposed to increase by an inflation-based indexation – capped at the amount as calculated in accordance with the previously agreed indexation formula (refer section 8(a)); and
* changes are proposed to certain medical device fees as discussed above (refer section 8(b)).

### Stakeholder Engagement

1. **Consultation on 2025-26 fees and charges proposals**

The following industry representative groups were consulted during the TGA and Industry representative bilateral meetings on the proposed changes to fees and charges in late November 2024:

1. Medicines Australia

2. Generic and Biosimilar Medicines Association

3. AusBiotech

4. Medical Technology Association of Australia

5. Pathology Technology Australia

6. Australian Dental Industry Association

7. Consumer Healthcare Products Australia

8. Complementary Medicines Australia

9. Accord Australasia

10. Optical Distributors & Manufacturers Association of Australia

11. Assistive Technology Suppliers Australasia

12. Australian Medical Manufacturers and Distributors Association

13. MTP Connect

The presentations delivered at the bilateral meetings were subsequently circulated to all thirteen groups for their information and consideration.

Consistent with feedback from previous years, industry peak bodies were generally supportive of the annual indexation increase, which is based on an established formula. No concerns were raised regarding the proposed medical device fee changes.

To obtain broader feedback from the industry, the TGA encourages all stakeholders to provide their comments on the proposed 2025-26 fees and charges, preferably through their relevant peak body. This feedback will be instrumental in shaping the final proposal that will be submitted to the Government for consideration and decision.

1. **Regulatory Impact analysis**

The proposed 3.2% increase to all TGA fees and charges is within the parameters of the agreed carve-out between the Department and the Office of Impact Analysis.

The proposed indexation-only increase and small number of changes to medical device fees discussed in this paper are not likely to change the regulatory burden on stakeholders. Therefore, the TGA is not proposing to develop a regulatory proposal, including a Regulation Impact Statement, to inform the annual changes to fees and charges.

### Next steps

Through this consultation paper, the TGA is inviting submissions through the [consultation hub](https://consultations.tga.gov.au/login_form?came_from=https://consultations.tga.gov.au/regulatory-practice-section) for the 2025-26 fees and charges.

The TGA will consider any feedback before seeking approval of the proposed fees and charges for 2025-26 from the Minister for Health and Aged Care. Subject to Ministerial approval, it is expected that the amendment regulation to give effect to the new fees and charges will be submitted for consideration by the Federal Executive Council in May/June 2025[[1]](#footnote-1). This will allow sufficient notice to affected businesses/ sponsors about changes to fees and charges effective from 1 July 2025.

The TGA CRIS will be published on the TGA website before the revised fees and charges take effect. The TGA fees and charges on the website will also be updated.

Any questions relating to submissions should be emailed to TGAFeesAndCharges@health.gov.au

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|  |

1. *This timeframe may be impacted by the next federal elections.* [↑](#footnote-ref-1)