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| TGA fees and charges proposal 2024-25 |
| Consultation paper |
| Version 1, January 2024 |

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## Introduction

The Therapeutic Goods Administration (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 cost recovery arrangements.

The purpose of this consultation is to provide industry and other interested stakeholders with an opportunity to comment on the TGA’s proposed fees and charges for the 2024-25 financial year. Specifically, we are seeking feedback on the potential impact of the changes prior to seeking approval from the Government.

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

Meetings with peak industry bodies were held during late November and early December 2023 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 comparable countries.

To achieve this outcome, the TGA approves and regulates products based on an assessment of risks against benefits. The TGA regulates therapeutic goods through:

* Pre-market assessment
* Post-market monitoring and enforcement of standards; and
* Licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

Therapeutic goods are divided broadly into three 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 before they may be supplied in or exported from Australia, unless exempt.

If a problem 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, and revoking or cancelling the manufacturing licence.

The TGA also undertakes public health activities for the public good rather than direct industry benefit., these activities are funded by the Australian Government and are discussed in detail in the [TGA Cost Recovery Implementation Statement (CRIS).](https://www.tga.gov.au/resources/publication/publications/cost-recovery-implementation-statement-2023-2024)

### 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 [Australian Government Cost Recovery Policy](https://www.finance.gov.au/government/managing-commonwealth-resources/implementing-charging-framework-rmg-302/australian-government-cost-recovery-policy) (CRP) sets out the overarching framework under which Government entities design, implement and review cost recovered activities. Accordingly, the TGA generally operates on a full cost recovery basis. 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 (OTC) medicines;
* Complementary medicines;
* Medical devices, including in vitro diagnostic (IVD) devices;
* 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 from time to time the TGA also receives time limited funding (such as for health emergency or pandemic measures), the vast majority (around 85%) of funding is 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 an ongoing measure, Improving Access to Medicines, Item 7, the Government announced funding of $33.0 million over four years for the TGA with $15 million per year ongoing from 2022-23. This funding will be 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://budget.gov.au/content/bp2/download/bp2_2023-24.pdf) the Government provided $61 million over four years to deliver a range of other public good activities, such as:

* 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
* Continued 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** |

Additionally, small amounts of Australian Government (appropriation) funding is 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.

1. **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 set up 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 three broad categories. These are detailed below.

1. **Fees for services**

The CRP 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 to mainly 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, issue of manufacturing clearances, certification, and licences, and GMP inspections. Numbers, timeframes for these services are available in the [TGA Annual Performance Report](https://www.tga.gov.au/resources/publication/publications/therapeutic-goods-administration-performance-report-2022-23).

1. **Annual charges**

The CRP states that charges are imposed when a good, service or regulation is provided to a group of individuals or organisations (e.g. 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 is different from general taxation that 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, the Authorised Prescriber (AP) Scheme, the Orphan Drug Program and management of critical medicine and medical device shortages. Additionally, the TGA routinely undertakes 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 [Australian Government Charging Framework](https://www.finance.gov.au/sites/default/files/2019-11/RMG-302%20Australian%20Government%20Charging%20Framework_1.pdf) (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 2023

As of 30 June 2023, the TGA had cash reserves of $8.2 million available for investment. The cash reserves have significantly 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; and
* Further investment of $23.3 million to complete digital and business transformation and full implementation of the UDI system, as per the October 2022 Budget decision.

The current cash reserves are less than 5% of TGA’s budget. It is important to note, the TGA also needs to retain cash to cover staff entitlements ($31 million) and fees received in advance for product evaluations under way ($25 million).

This balance will be partially replenished through the increased charges (from this year) through to 2028-29. It will raise $23.3 million over the next six financial years.

### Annual review of fees and charges

The TGA’s operations are mostly funded through the fees and charges it collects for its regulatory activities. Every year, the TGA undertakes a review of its fees and charges to ensure they are set at the appropriate level and cost recovery for each therapeutic industry sector is appropriate. Necessary adjustments to fees and charges are made, after seeking Government approval, by considering known cost increases including any annual wage and other cost movements. The increase to the TGA fees and charges is based on an indexation factor combining 50% of the Wage Price Index (WPI) and 50% of the Consumer Price Index (CPI) to form a new indexation factor for increase in TGA fees and charges.

After an unprecedented rise of the CPI to over 7% last year (September 2021 to September 2022), it has reduced to 5.4% this year which results into a lower proposed indexation for 2024-25. In addition to the indexation-based increase, the TGA annual charge will need to factor in the remaining 50% increase for cost recovery of digital transformation, and for commencement of the UDI cost recovery from 1 July 2024. As detailed in last year’s consultation paper [Public Consultation - TGA Fees and Charges proposal 2023-24](https://consultations.tga.gov.au/regulatory-practice-section/public-consultation-tga-fees-and-charges-proposal/), the Government’s October 2022 Budget decision required cost recovery of $23.7 million investment in the TGA business transformation and the UDI system from industry over five years (six financial years).

Additionally, there are a small number of other changes proposed to medicine and medical device fees and charges which are not significant in nature.

The required changes to TGA annual charges and the annual indexation increase to all fees and charges are discussed in detail below.

### Cost pressures in 2024-25

Known increases to the TGA expenses in 2024-25 are estimated to be approximately $14.3 million. The two major cost pressures, outside our control, are outlined below:

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

The single largest component of the TGA costs is salary, contractors and other staff related costs. Employee costs are estimated to increase by $7.0 million for the 2024-25 financial year mainly related to the 4% pay increase for non-senior executive staff that will take effect from March 2024 (as per the Department’s Enterprise Agreement (EA)). This will also include a leave provision increase, and staff pay increments due in July 2024 (all 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**

The corporate and other costs, including depreciation, are estimated to increase by $7.3 million in 2024-25 mainly due to the yearly increase apportioned for depreciation/amortisation ($6.1 million) on TGA’s business and IT software systems and the inflation-based increase to corporate charge back ($1.2million) payable to the Department.

### Indexation factor for 2024-25

The indexation factor for 2024-25, based on the previously used formulae of the average (composite indexation) of the CPI and the WPI, is 4.7%:

* 50% of cost price index Sep 2022 to Sep 2023 of 5.4% - 2.7%; and
* 50% of wage price index Sep 2022 to Sep 2023 of 4.0% - 2.0%

### Proposed changes to fees and charges 2024-25

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. Not all changes relate to all areas of industry.

1. **Indexation of fees and charges**

Fees and charges would increase by the calculated indexation factor of 4.7%. The proposed indexation increase is consistent with the long-established practice and also provides opportunities for efficiency gains through business process improvements as the level of known cost increases will require a higher increase (around 7%). This aligns with the Government’s policy for cost recovered activities. As the 4.7% will not cover all known cost increases (salary and corporate costs) in 2024-25, the TGA will need to find efficiencies and savings in discretionary costs.

Should this be accepted by the Government, additional revenue of $10.6 million would be generated, assuming constant volumes of ARTG products and products exempt from annual charges under the Annual Compliance Exemption scheme. However, it is possible that some sponsors may consolidate their listings on the ARTG reducing income from TGA annual charges.

The financial impact on sponsors of this proposal, if implemented, will be a 4.7% increase from 1 July 2024. For example, a company which paid $10,000 in fees this financial year would be required to pay $470 more next financial year. It is important to note that this is only the impact of the indexation component of the increase. The other required additional annual charge increases are discussed in the following paragraphs.

1. **Mandated increase to annual charges to cost recover investment in the TGA’s Digital transformation and business systems enhancements**

The October 2022 Budget provided approval to drawn down from TGA reserves, funding of $23.3 million over the two financial years, 2022-23 and 2023-24, to complete digital and business transformation and full implementation of the UDI system to expand its scope to include medium and high-risk devices. While this money has been drawn from the TGA Special Account cash reserves, the Budget decision requires this amount to be cost recovered from industry over five years commencing from 1 January 2024 (six financial years), except for the cost recovery of the UDI system which will commence from 1 July 2024.

In the 2023-24 financial year the increase to annual charges (other than for the UDI system) was pro-rated for the 6-month period (50% of a full year attribution). A full year attribution of cost recovery, including for the UDI system, will commence in 2024-25.

The changes foreshadowed for 2024-25 in last year’s consultation paper are summarised in the table below. Please note that the figures below have been updated and revised on page 11.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Proposed increase to annual charges in 2024-25 | Digital Transformation | AEMS | Devices Digitisation | UDI System | Total Increase |
| Medicines and biologicals | 1.78% | 0.46% |  |  | **2.24%** |
| Medical devices Class II and above, including implantable devices | 1.78% |  | 1.23% | 1.97% | **4.98%** |
| Medical devices Class I, Im and Is and all classes of IVD devices | 1.78% |  | 1.23% |  | **3.01%** |
| Other annual charges i.e., manufacturing licences, Other Therapeutic Goods | 1.78% |  |  |  | **1.78%** |

1. **Other fees and charges changes**

**Medical Devices**

1. ***Application audit assessment fee for Class 3 and 4 IVDs***

In the 2023-24 financial year several medical device fees were revised – resulting in some increasing and some decreasing. Class 3 and 4 IVD application audit assessments had significant under recovery mainly during the COVID time and to address the under recovery, the fee for Class 3 and 4 IVD application audit assessment was increased from $7,387 to $22,387.

This fee was based on the estimated cost of undertaking application audit assessment of these classes of IVDs, including the cost of laboratory testing. A recent review of these applications and associated activities found that not all Class 3 and 4 IVD application audit assessments required laboratory testing.

To align the fees with the costs incurred, it is proposed that there be two application audit assessment fees for Class 3 and 4 IVDs. It is proposed to reduce the fee from $22,387 to $14,198 (subject to indexation) if no laboratory testing is required. The current fee of $22,387 (subject to indexation) still applies where laboratory testing is required.

1. ***Clinical Trial Notification fees for additional unapproved medical devices site***

Under the Act, clinical trials conducted in Australia are subject to TGA regulatory controls to ensure the safety of participants. The Clinical Trial Notification (CTN) schemes provide for the lawful importation into and/or supply in Australia of ‘unapproved’ therapeutic goods for use solely for experimental purposes in humans (i.e., clinical trials). The overall decision as to whether a CTN is required in relation to the use of the therapeutic goods is the responsibility of the trial sponsor.

Fees are currently applied to notify the TGA of an additional clinical trial site for unapproved medicines, biologicals and medical devices (including IVDs). While these are long-standing fees, the fee for notification of an additional site for medical devices was omitted from the Therapeutic Goods (Medical Device) Regulations 2002. It is proposed to correct this omission and include a clinical notification fee of $410 ($429) if the proposed indexation is approved) for each notification of an additional site for unapproved medical devices (including IVDs).

The fee is consistent with the fee for unapproved medicine or biological for notification of an additional clinical trial site.

**Medicines**

1. ***Removal of higher annual charge for certain medicines***

When annual charges were significantly lowered for most generic medicines in 2015, a higher annual charge was prescribed for prescription medicines that contain one of the named ingredients:

* Thalidomide
* Leflunomide
* Lenalidomide
* Mifepristone
* Clozapine
* Isotretinoin

The main reason for a higher annual charge for specified medicines was due to significant risk management activities associated with them. Risk minimisation programs for these medicines are now well established and requires less regulatory oversight. Therefore, it is proposed to reduce this charge from $4,876 to $3,972 (subject to indexation).

There are currently 234 entries on the ARTG that fall into this category. The reduction of the annual charge per entry will provide a total saving of approximately $211,000 to the sponsors of prescription medicines who currently have one or more products such products on the ARTG.

1. ***Consent to supply prescription medicines fees (medicinal cannabis)***

The quality standard for medicinal cannabis, Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017 was updated in December 2022 to include requirements for labelling of medicinal cannabis products and for manufacturers overseas to hold equivalent GMP authorisations as domestic manufacturers. These changes were effective from 1 July 2023.

Since the update to the requirements for imported medicinal cannabis to be manufactured at sites that hold the GMP evidence specified in section 13(3) of TGO 93, the TGA has received 6 section 14/14A application for consent to supply medicinal cannabis products that do not meet TGO 93.

There is currently no fee prescribed for the assessment of these applications. A fee would legitimise the section 14/14A pathway consistent with the Good Clinical Practice. Based on staff effort required for assessment of these applications, it is proposed to implement the following application fees with effect from 1 July 2024:

* Application fee - $3,545 (subject to indexation).
1. ***Fees for requests made under subsection 28(3A)***

There is currently no fee prescribed in the regulations for requests made under subsection 28(3A) of the Act for varying conditions of listing and registration of medicines conditions. Based on cost estimates, it is proposed to implement the following application fees with effect from 1 July 2024:

* Prescription medicine $2,750 (subject to indexation);
* Other medicines $1,710 (subject to indexation); and
* Biologicals $1,920 (subject to indexation).

### Summary of proposed changes to fees and charges in 2024-25

To summarise, in 2024-25:

* all fees and charges are proposed to increase by an inflation-based indexation of 4.7% – capped at the previously agreed indexation formula (refer section 8(a));
* there will be increases to annual charges for cost recovery for the final phase of digital and business transformation (refer section 8(b));
* there will be an increase to Medical Devices Class II and above, (including implantables) annual charges for the UDI system (refer section 8(b)); and
* there will be changes to certain medicines and medical device fees and charges as discussed above (refer section 8(c)).

The impact of the proposed changes to 2024-25 fees and charges (other than the small number of changes discussed in para 8(c) above) are summarised in the table below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Details** | **Indexation Based Increase**  | **Digital Transformation Cost Recovery**  | **UDI Cost Recovery**  | **Total Proposed Increase**  |
| All TGA Fees | 4.70% |   |   | **4.70%** |
| Annual Charges | Medicines and Biologicals  | 4.70% | 2.01% |   | **6.71%** |
| Medical Devices Class II and above, including implantables  | 4.70% | 2.68% | 1.75% | **9.13%** |
| Medical Devices Class I, Im and Is and all classes of IVD devices  | 4.70% | 2.68% |   | **7.38%** |
| Others i.e., manufacturing licences and Other Therapeutic Goods | 4.70% | 1.60% |   | **6.30%** |

*Note: Increases required for cost recovery of digital transformation and UDI have been adjusted for indexation and other increases in 2023-24 which resulted in lower percentage increases than previously discussed.*

### Stakeholder Engagement

1. **Consultation on 2024-25 fees and charges proposals**

The following industry representative groups were consulted on the proposed changes to fees and charges in November/December 2023:

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 Device Distribution Association; and

13. MTP Connect.

Consistent with their feedback of previous years, industry peak bodies were generally supportive of the annual indexation increase which is based on an established formula. Industry maintained its concerns raised last year in respect of additional annual charge increases to cost recover $23.7 million investment in the TGA’s digital and business systems. Whilst industry acknowledges this was a decision of Government the cumulative effect, especially on smaller sponsors, and the impacts of parallel cost increases by other parts of the Government (e.g. reimbursement processes) were noted.

In order to obtain broader feedback from industry, the TGA encourages all stakeholders to provide their comments on the proposed 2024-25 fees and charges (preferably through their relevant peak body). The feedback will inform the final proposal to Government for consideration and decision.

1. **Regulatory Impact analysis**

The proposed 4.7% increase to all TGA fees and charges are within the parameters of the agreed carve-out between the Department and the Office of Impact Analysis.

Increases to annual charges for digital transformation and UDI cost recovery are in accordance with the October 2022 Budget decision in which the Government asked the Department to raise $23.7 million over five years from industry through the TGA cost recovery. The regulatory impact of this decision was captured through the 2022-23 Budget process.

The other changes discussed in this paper are not likely to change the regulatory burden on stakeholders and the TGA is proposing no further impact analysis is required.

### 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 2024-25 fees and charges.

The TGA will consider the feedback before seeking approval of the proposed fees and charges for 2024-25 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 2024. This will allow sufficient notice to affected businesses/ sponsors about changes to fees and charges effective from 1 July 2024.

The TGA Cost Recovery Implementation Statement 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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