Australian Government
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Therapeutic Goods Administration

TGA fees and charges proposal 2023-24

Consultation paper

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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* (the Act). To meet these responsibilities, the TGA recovers costs from industry in accordance with 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 2023-24 financial year. Specifically, we are seeking feedback on the potential impact of the change prior to seeking approval from the Government.

In consultation with stakeholders, fees and charges are reviewed annually. The TGA may use other consultation mechanisms, as needed, before applying significant changes to fees and charges.

Meetings with peak industry bodies were held during December 2022 to discuss the proposed changes to fees and charges set out in this paper.

1. 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 the TGA regulates therapeutic goods through:

- pre-market assessment
- post-market monitoring and enforcement of standards
- 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 medicine, biological, medical device, 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 a manufacturing licence.

The TGA also undertakes public health activities for the public good rather the direct industry benefit. These activities are discussed in detail in the TGA Cost Recovery Implementation Statement.

2. Cost recovery obligations of the TGA

In the 1997–98 Budget, Budget Paper No.2, and Part II: Revenue Measures it was stated that from 1998-99 the TGA would fully recover all costs of activities covered (at that time)under the TGA 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 Guidelines (CRG) set 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 medicines, biologicals, and medical devices.

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
- good manufacturing practice (GMP).

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. The costs of undertaking these types of activities cannot be appropriately recovered from a particular sponsor or industry group.

In the 2019-20 Mid-year Economic & Fiscal Outlook (MYEFO) as part of 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 goes towards meeting some, but not all, of the costs of fee-free services, such as registration of orphan drugs and consumer access to unapproved therapeutic goods through the Special Access Scheme, that cannot be appropriately cost recovered. This is in addition to small amounts of appropriation funding provided to partially meet the secretariat costs for medicines and chemicals scheduling regulation, and in the form of an interest equivalency payment against the special account balance from TGA reserves.

The 2020-21 Budget included approval to invest $12.0 million over four years to digitise and modernise the TGA's business systems and infrastructure. In addition, it included approval to invest $7.7 million for the implementation of a Unique Device Identification (UDI) system. These amounts are to be drawn from the cash reserves accumulated in the TGA Special Account.

The October 2022 Budget provided 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 will be 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).

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* (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 Cost Recovery Implementation Statement (CRIS) expands further on the cost recovery activities and methodology.

3. TGA funding Mechanism

The funding for the TGA falls under three broad categories. These are detailed below.

a. Fees for services

The CRG state 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.

b. Annual charges

The CRG state 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.

c. Government appropriation

In undertaking its regulatory functions, the TGA is required to provide an increasing number of services in the public good which cannot be appropriately cost recovered from industry. 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 Special Access Scheme (SAS), the Authorised Prescriber (AP) Scheme, the Orphan Drug Program and management of critical medicine shortages. Additionally, the TGA routinely undertakes a range of consumer and professional education, compliance' enforcement and litigation activities which are neither provided to therapeutic industry nor do they relate to regulated products or entities. Under the Australian Government Charging Framework (Charging Framework) these activities are not appropriate to cost recover, and the TGA receives funding of $15 million per annum from the Government to meet the costs of some of these programs. However, the total cost of the programs is over $30 million per annum.

4. TGA cash position as of 30 June 2022

As of 30 June 2022, the TGA had cash reserves of $44 million available for investment. This will reduce significantly by 30 June 2023 due to the following investments:

- Unique Device Identifier system - $3.6 million
- digital transformation project - $15.9 million
- deficit forecast for 2022-23 - $5.8 million.

The remaining $18.7 million in cash reserves is expected to be further depleted in 2023-24 to cover further digital transformation costs and public good activities. For reasons of financial sustainability, the Government is not prepared to deplete the cash reserves further than this.

The TGA also needs to retain cash reserves to cover staff entitlements ($29.6 million) and fees received in advance for product evaluations under way ($33.7 million).

5. Annual review of fees and charges

The TGA's operations are mostly funded (approximately 92%) 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. For many years the Government has approved an increase to the TGA fees and charges based on an indexation factor combining the wage price index (WPI) and the consumer price index (CPI) on a 50:50 basis.

This year CPI has reached over 7%, but there are a number of other costs that will impact the TGA fees and charges in the coming year(s). As noted above, as part of the October 2022 budget, which provided $23.7 million investment in the TGA business transformation and UDI systems, the Government decision requires that this investment be cost recovered from industry over five years. Additionally, there are certain increases to medical device fees.

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

6. Components of fees and charges in 2023-24

Known standard increases to the TGA expenses in 2023-24 are estimated to be approximately $10.2 million. The two major recoverable components are outlined below. While not impacting on changes to fees and charges, it is also important to note the resourcing pressure on the TGA resulting from mandated and non-cost recovered activities following 2017 legislative and regulatory changes (outlined in 3(c) above):

a. 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 $4.1 million for the 2023-24 financial year mainly related to the 3% pay rise for non-senior executive staff that will take effect from March 2023 (as per the Department's Enterprise Agreement). This will also include leave provision increase and staff pay increments due in August 2023 (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 Enterprise Agreement).

b. Increase in corporate costs

The corporate and other costs, including depreciation, are estimated to increase by $6.1 million in 2023-24 mainly due to inflation-based increase to corporate charge back ($2.2 million) and the yearly increase apportioned for depreciation/amortisation ($3.5 million) on digital transformation projects.

c. Significant increase in mandated and non-cost recovered activities following 2017 legislative and regulatory changes

While a government appropriation of $15 million per annum is provided, the cost of public good activities and other regulatory functions where cost recovery is not appropriate has seen a significant increase to well over $30 million in recent years. In 2017-18, the Act was amended to mandate reporting of medicine shortages to the TGA by the sponsor (supplier) of the reportable medicine. This Act amendment also provided increased compliance and enforcement powers to the TGA to meet community and parliamentary expectations that there would be greater action taken by the TGA against illegal, misleading and unsafe products. The increasing costs in the following areas is putting pressure on TGA resources and impacting its service delivery to the

regulated industry. A decision by the Government would be required for an appropriate funding mechanism for these activities:

- management of medicine shortages, including obtaining unregistered products from overseas to fill supply gaps, and healthcare professional / health system information and communication activities
- raising awareness of medicines and medical device issues affecting patient health through consumer and health care professional education
- compliance, legal and enforcement costs for companies and individuals dealing outside the regulatory system and dealing with unregulated entities and products
- providing industry assistance through SME Assist to researchers and other small businesses who are new to the regulatory requirements and don't have staff or access to expertise who are familiar with TGA's regulatory framework
- cost of providing support to developers of new and emerging technologies, such as software medical devices, 3D printed devices, cell/tissue and gene therapies
- managing nicotine vaping products regulatory changes, including compliance and enforcement since the change in the legislation in October 2021.

7. Indexation factor for 2023-24

The indexation factor for 2023-24, based on the previously used formulae of the average (composite indexation) of the CPI and the WPI, is 5.2%:

- 50% of cost price index Sep 2021 to Sep 2022: 7.3%: 3.65%
- 50% of wage price index Sep 2021 to Sep 2022: 3.1%: 1.55%

8. Proposed changes to fees and charges 2023-24

The proposed changes to the fees and charges are made up of four components: a. Indexation of fees and charges; b. digital transformation annual charges; c. laboratory modernisation fit out annual charges; and d. proposed changes to some medical device fees. Not all changes relate to all areas of industry.

a. Indexation of fees and charges

Fees and charges would increase by the calculated indexation factor of 5.2%. The proposed indexation increase is not only consistent with the long-established practice but also provides opportunities for efficiency gains through business process improvements as the level of known cost increases is somewhat higher. This is also consistent with the Government's policy for cost recovered activities. As the 5.2% will not cover all known standard cost increases (salary and corporate costs) in 2023-24, the TGA will need to find savings and efficiencies elsewhere.

Should this be accepted by the Government, additional revenue of $9.5 million would be generated, assuming constant volumes of ARTG products and products exempt from annual charges under the Annual Compliance Exemption (ACE) 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 5.2% increase from 1 July 2023. For example, a company which paid $10,000 in fees this financial year would be required to pay $520 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.

b. Digital transformation costs

The October 2022 Budget provided 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 will be 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 recovery, other than for the UDI system, will be 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 components of the digital transformation being recovered as a result of the Government decision are:

i. Cost recovery of final phase of digital/business transformation - $14.7 million

An investment of $14.7 million will enhance TGA's business systems, including establishing a "single product portal". This investment will address requests by medicine and medical device product sponsors to establish a "tell us once" business system. Industry product sponsors will have a single account to do business with the TGA and with other areas of the Department. This will deliver reductions in regulatory burden and costs for businesses, and potentially support faster access to products by patients. Sponsors will be able to manage and control their own information, including tracking their applications through the review process and responding to requests for information in a timelier manner sponsors will be able to use contemporary methods of providing medical device data to the TGA, including through machine-to-machine interfaces. This will create efficiency improvements through automating and modernising manual processes. For industry it will provide a clear and consistent interaction with Government for the regulation and reimbursement of their products.

Cost recovery of this investment will require an annual increase of 3.57% to all annual charges, commencing from 2023-24 for six financial years. As cost recovery will commence from 1 January 2024, for the first financial year (2023-24) this increase will only be 50% (1.78%), with a full annual increase of 3.57% for the next four financial year. The sixth financial year will also only require a 1.78% increase.

ii. Cost recovery of investment in Adverse Event Management System - $2.2 million

The $2.2 million further investment in the Adverse Event Management System (AEMS) over the next two financial years will improve the management of medicine and biological safety. The investment will make it easier for health professionals to report adverse events and streamline how relevant data is shared with industry and jurisdictions.

The TGA is creating a self-serve portal for medicine and biologicals sponsors to access adverse event data relevant to their products from TGA systems. Sponsors will have greater, easier, and faster access to the adverse event data needed to fulfill their pharmacovigilance responsibilities. TGA receives about 130 manual requests from industry per month for this data. The investment will remove this manual step. Sponsors will be able to use their existing TGA credentials to find and extract non-public de-identified case data for uploading into their own pharmacovigilance systems. The investment will also reduce barriers to report medicine and biological adverse events for health professionals directly from the systems doctors use in general practice.

For this component, an annual increase 0.92% is required to medicines and biologicals annual charges. Like the other annual charge increase, 50% of the increase will be required in 2023-23 which equates to 0.46%.

iii. Cost recovery of further investment in the UDI system and device specific digitisation - $6.4 million

The 2020 Budget provided investment of $7.7 million for initial development of a UDI system. The initial investment only covered development of a UDI system for implanted medical devices and establishment of a UDI database with linkages to enable data provision to the database. However, to have a single supply chain and safety management system and following stakeholder feedback, the UDI platform will be expanded with a further $2.5 million investment over 2022-23 and 2023-24 to also include all medium and high-risk devices, not just those that are implanted in patients. In addition, $3.9 million will be invested in further device specific digitisation.

The UDI system will allow faster and more accurate identification of devices included in a recall and help prevent recalled or expired products from being used. The use of UDI will also enable accurate details about the device to be recorded within digital health records or patient implant cards. The UDI system will allow faster identification and correcting of problem devices and support better linking of device data across siloed systems including the UDI system, the ARTG, recalls and adverse events

The $2.5 million additional investment in the UDI system will be recovered from the medical device industry through an increase of 1.97% to annual charges for medical devices Class II and above, commencing from 2024-25, as cost recovery for this is mandated to commence from 1 July 2024.

The $3.9 million investment in device specific digitisation will allow electronic access to patient information leaflets, streamlined notification and change request processing for industry, and identification of software devices. The funding will be recovered from medical device industry through an increase of 2.46 % (annually) to annual charges of all classes of medical devices, including IVD medical devices. However, for 2023-24 this increase will only be 50% (1.23%), with full increase to commence from 2024-25.

The table below summarises the increase to annual charges in 2023-24.

Increase to annual charges in 2023-24	Digital Transformation	AEMS	Devices Digitisation	Total Increase
Medicines and biologicals	1.78%	0.46%		2.24%
Medical devices and IVDs	1.78%		1.23%	3.01%
Other annual charges i.e., manufacturing licences, OTGs	1.78%			1.78%

The table below summarises the increase to annual charges in 2024-25.

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	1.78%		1.23%	1.97%	4.98%
Other medical devices	1.78%		1.23%		3.01%
Other annual charges i.e., manufacturing licences, OTGs	1.78%				1.78%

The table below summarises cost recovery revenue from increased annual charges for the six financial years.

Cost recovery over six financial years	2023-24 $m	2024-25 $m	2025-26 $m	2026-27 $m	2027-28 $m	2028-29 $m	Total $m
Digital Transformation	1.470	2.941	2.941	2.941	2.941	1.470	14.703
AEMS	.217	.433	.433	.433	.433	.217	2.166
Device specification digitisation	.390	.779	.779	.799	.799	.390	3.895
UDI system		.503	.503	.503	.503	.503	2.514
Total	2.076	4.656	4.656	4.656	4.656	2.579	23.278

c. Laboratory modernisation fit out costs

Last year the TGA relocated to purpose-built facilities in Fairbairn (ACT). The new laboratory building has a flexible and modern design that allows for reconfiguration and efficiency in the laboratory spaces which facilitates more efficient workflows for testing. It also has enhanced security for test samples improving the handling and tracking of products that come to the TGA for analysis. The new modern workspaces allow staff across scientific disciplines to work together more effectively which is critical for solving complex post-market problems or work on highly complex products.

While the relocation of the TGA to the new office building was 'cost neutral' for the TGA, an additional investment was required for the laboratory fit out. For this investment the Department is required to make an additional payment of $4.85 million annually to the landlord for the initial lease term of 15 years. The Department has agreed to charge back only 70% of this amount to the TGA (aligning with the approximate proportion of laboratory activity related to industry product testing with remaining 30% to be absorbed by the Department (although with some increase to TGA corporate charge back from the Department)

To implement the Department's decision to cost recover the 70% component (or $3.4 million annually) from industry an increase of 4.12% will be required to all annual charges.

d. Proposed changes to some medical device fees

Demand for medical devices has seen an unprecedented number of new sponsors and new applications over the past two years, as well as the need to deliver activities that are not necessarily covered by direct fees. Many new entrants to the medical devices industry, have limited knowledge of regulation, quality management, and certification processes. Efforts have focused on supporting those manufacturers (including significant investment in domestic manufacturing capability) and sponsors seeking regulatory approval for devices used in the response to the COVID-19 pandemic. In parallel, the TGA has continued to progress reforms as outlined in *An Action Plan for Medical Devices*, including alignment with the significant changes occurring in Europe, which requires recertification of devices in most instances and the flow on implications for existing Australian market approvals. Important reforms, extensive education sessions and clarifications to how emerging technologies are regulated in Australia such as personalised medical devices (including 3D printed devices) and software medical devices have been critical activities where the TGA is unable to charge fees. We also reviewed our business-as-usual evaluation and post market activities and identified a number of processes and activities that could change to streamline processes and deliver efficiencies – but also activities that had not been reviewed for many years where the fees charged were not commensurate with the effort needed.

The workload in relation to medical devices pre-market activity continues to be significant. The TGA processed 7,624 medical device (including IVD), disinfectant and variation applications in

2021-22. A recent review of the average time taken to carry out regulatory activities found discrepancies between costs and fees for:

- disinfectant evaluations
- certain new and variation application
- application audits
- conformity assessment certification activities

i. Reduction of Fees

The Therapeutic Goods (Medical Devices) Regulations 2002, prescribe circumstances where assessment fees for medical devices may be reduced, including in the interests of public health (Regulation 9.6) and when the TGA has information that allows the assessment to be abridged (Regulation 9.7).

The TGA granted 278 conformity assessment certificates to manufacturers of medical devices in 2021-22. The cost of reducing fees for those applications in the 2021-22 financial year was $3.5 million in revenue foregone.

ii. Efficiencies

Work continues to be undertaken to move human resources to areas of high demand and to make efficiencies to save on resources, including the adoption of online solutions to:

- apply for and track applications relating to a consent to supply devices that are non-compliant with the Essential Principles
- notify ARTG entries subject to reclassification and for lapsed certification
- publish guidance and supporting data checklists to assist sponsors with the documentation to meet regulatory requirements

A range of efficiencies have also been achieved, such as application assessment and conformity assessment processes and using the Medical Device Single Audit Program in lieu of TGA audits for over 100 manufacturers.

The Government also agreed that a number of fees could be reduced for a range of reforms such as changes to raw materials, reclassifications, consent to supply applications, European certification changes.

iii. Medical Device Reforms

There are reforms that are not directly funded but are necessary to improve the regulatory system and safety for patients. Progression of the reforms has continued and involves significant external and internal engagement. Preparation for and supporting changes to medical devices with European certification for devices supplied to Australia will continue to be a priority.

During 2021 the rules that exempt manufacturers from reporting adverse events in some circumstances were reviewed with the intention of further consultation with stakeholders on any proposed changes. Work on the design of a new medical device sponsor vigilance program (aimed at educating sponsors about compliance with legislative adverse event reporting requirements) commenced. A pilot program is scheduled to commence in 2023.

iv. Implications of not increasing fees and charges to cover costs

To address under recovery for our activities relating to medical devices, changes are required to a number of fees in particular cost of evaluation of Class 3 IVDs which include COVID-19 rapid antigen tests have seen significant under recovery. Without increasing certain medical device fees, the deficit for medical device activities will significantly increase in 2023-24 and will likely

continue because of rising costs and anticipated increased activities (eg: the end of transition periods).

One option to address the current under recovery, the TGA would need to reduce its medical device staffing. This would cause delays in completing applications, assessments, onsite audits, and post-market safety reviews and hinder the implementation of beneficial regulatory reforms. Several support activities would also cease, such as the provision of guidance, updates to the website, international activities, and updates to current IT systems.

v. Proposed changes to fees and estimated change in revenue

To address under recovery of medical device fees, it is proposed make changes to several fees to align with the costs of undertaking associated work. It is also proposed to reduce a few fees because of reduced cost of undertaking that work.

The below table lists the current fee and the proposed new fee structure.

Description	Current fee $	Proposed Fee $	Projected volume (based on 2021-22)	Estimated Impact on revenue $
Conformity Assessment Certificate Application	1,077	1,416	181	61,359
Device Class 1 Sterile – Application for Inclusion	1,098	575	2,610	(1,365,030)
Device Class 1 Measuring – Application for Inclusion	1,098	575	34	(17,782)
Variation to ARTG inclusion entry if entry is incomplete or incorrect				
IVD Class 3	482	1,750	59	74,812
IVD other classes	482	1,000	118	61,124
Other Medical Devices	482	1,000	735	380,730
Application Audit Assessment – Level 2				
Medical Device Class III and AIMD	7,582	16,000	237	1,995,066
Other Medical Devices (non IVDs)	7,582	4,000	5	(17,910)
Application Audit Assessment fee for Class 3 IVDs	7,387	22,387	163	2,445,000
Listed Disinfectant – application fee	482	2,200	109	187,262
Listed Disinfectant – variation fee	482	1,400	317	291,006
Expected additional revenue				**4,095,637**

Note: Proposed fees are subject to further approved indexation increase in 2023-24

The TGA is also proposing to remove the safety evaluation fees for disinfectants with a new ingredient as it is simpler to continue to recover costs through the application and variation fees.

vi. Other potential future fee changes for medical devices

After the repeal[1] of Regulation 4.1 and amendment of Regulation 5.3 in 2021, and extension of the EU IVD Regulation transition timelines we have been receiving Class 4 IVD ARTG inclusion applications supported by EU IVD certification. These applications require an audit and the significant assessment effort undertaken is not specifically recovered as there is currently no provision for a fee for this service. It is anticipated that the fee for Class 4 IVDs will be same as the proposed fee for Class III non-IVD devices, as the assessment effort is similar.

[1] https://www.legislation.gov.au/Details/F2021L01032

The TGA will review the discounting (abridgement) guidelines in 2023-24 to ensure there is more consistency and any reduction of fees is commensurate with work effort and appropriate. The current application of these guidelines contributes to average fees charged that are less than the cost of carrying out the work for the conformity assessment certification activities. The full scheduled fees for conformity assessment certification activities are not always charged and significantly reduce the level of income received for this activity.

A more in-depth review and proposed changes to fees and charges were initially discussed with medical device industry through the RegTech industry forum and were also foreshadowed at the bilateral meetings with peak industry bodies in December 2022.

9. Summary of proposed changes to fees and charges in 2023-24

To summarise, in 2023-24:

- all fees and charges are proposed to increase by an inflation-based indexation of 5.2% – capped at the previously used indexation formula (refer section 8(a))
- mandatory increase to annual charges for cost recovery for final phase of digital and business transformation – 50% of the required increase – 1.78% to 3.01% (refer 8(b))
- increase to annual charges for additional chargeback for Fairbairn TGA building/laboratory – 4.12% (refer section 8(c))
- changes to certain medical device fees as discussed above. (refer section 8(d))

	Inflation Based Increase (preferred option)	Cost Recovery – Digital Transformation and Others	TGA Building Lease Charge Back (50%)	Total Increase
All TGA fees	5.2%			5.2%
Medicines and biologicals annual charges	5.2%	2.24%	4.12%	11.56%
Medical devices and IVDs annual charges*	5.2%	3.01%	4.12%	12.33%
Other annual charges i.e., manufacturing licences, OTGs	5.2%	1.78%	4.12%	11.1%

*For some medical devise and IVD sponsors additional cost impacts may occur as a result of proposed changes in section 8(d).

10. Stakeholder Engagement

a. Consultation on 2023-24 fees and charges proposals

The following industry representative groups were consulted on the proposed changes to fees and charges in December 2022:

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
13. MTP Connect

While most peak bodies were supportive to annual indexation increase which is based on an established formula, concerns were raised in respect of additional annual charge increases to cost recover $23.7 million investment in TGA's digital and business systems given that the money was drawn from the TGA Special Account cash reserve paid by industry in the past. However, it was explained that this decision was a decision of government that had already been made.

There was also significant opposition to an increase in charges to cover a loan made to the Department to support the move of the TGA laboratory to the Fairbairn site. Industry emphasised that this impact on industry charges had not been raised with them prior to the Department's decision to move to the new site.

To obtain broader feedback from industry, the TGA encourages all stakeholders to provide their comments on the proposed 2023-24 fees and charges (preferably through their relevant peak body). The feedback will inform the final proposal to Government for consideration and decision.

b. Impact analysis

The proposed 5.2% 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.

Additionally, in the Budget October 2022 the Government agreed to raise $23.7m over six years from cost recovery from 2023-24 from changes to the cost recovery arrangements for the TGA. This will be done by proposed increases to annul charges discussed in this paper.

The other changes discussed in this paper are not likely to change the regulatory burden on stakeholders. Therefore, the TGA is not proposing to do any further impact analysis to inform the 2023-24 changes to fees and charges.

11. Next steps

Through this consultation paper, the TGA is inviting submissions through consultation hub to the 2023-24 fees and charges.

The TGA will consider the feedback before seeking approval of fees and charges for 2023-24 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 2023. This will allow sufficient notice to affected businesses about changes to fees and charges effective from 1 July 2023.

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

Version History

Version	Description of change	Author	Effective date
V1.0		Cost Recovery Management Section	20/02/2023

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