Australian Government
Department of Health
Therapeutic Goods Administration

Fees and charges proposal 2022-23

Consultation paper

Version 1.0, January 2022

TGA Health Safety Regulation

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Introduction

The Therapeutic Goods Administration (TGA) within the Department of Health is responsible for 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/performance, and quality through administering the *Therapeutic Goods Act 1989* (the Act). The TGA aims to deliver efficient, best practice regulatory outcomes through best practice, international collaboration and reform. 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 options for the TGA's proposed fees and charges for the 2022-23 financial year. Specifically, we are seeking feedback on the potential impact/s of the proposed options, prior to seeking approval from the Government for any changes.

Fees and charges are reviewed annually, in consultation with stakeholders. The TGA also uses other consultation mechanisms, as needed, for any significant changes to fees and charges.

Meetings with peak industry bodies were held during December 2021 to discuss the proposed changes to fees and charges set out in this consultation paper.

Cost recovery obligations of the TGA

As announced in the 1997-98 Budget, the TGA commenced full recovery of all costs from industry from 1998-99. Cost recovery involves Government entities charging individuals or non-government organisations some or all of the efficient costs of a specific government activity. The Australian Government Cost Recovery Guidelines (CRGs) 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, application and evaluation fees, conformity assessment fees and inspection fees, to sponsors and manufacturers of medicines, biologicals and medical devices.

The TGA also provides a number of fee-free services in the public good and undertakes a range of compliance, legal enforcement and consumer 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 and Fiscal Outlook (MYEFO) the Government announced funding of $33 million over four years for the TGA with $15 million per year ongoing from 2022-23. This funding will go towards meeting some but by no means all of the costs of fee-free services 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 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 Act provides the legal authority for the TGA to charge fees for its regulatory activities. The *Therapeutic Goods (Charges) Act 1989* provides the legal authority to levy annual charges on sponsors and manufacturers of medicines, biologicals, 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.

Review of TGA fees and charges

A consulting company, PricewaterhouseCoopers (PwC), completed their review of all TGA fees and charges in mid-2021. This included an assessment of the appropriate levels of cost recovery for services to industry plus an identification of public health/ public good and other activities that may not be appropriate to cost recover. PwC made five recommendations; the main recommendation was for the TGA to implement a consolidated workflow management system (including a time tracking system) which clearly determines the costs of chargeable and non-chargeable activities in accordance with the Australian Government Charging Framework.

The PwC review was based on staff effort data collected during the second half of 2020. However, given that during this period a significant number of TGA staff were focussed on COVID-19 related work, the data captured in the review did not represent 'business as usual'. Further data collection will be undertaken in the first half of 2022 which will be used to enhance the costing model built by PwC.

Decisions on any changes to fees and charges arising from the review will be made by Government after consultation with industry if significant changes are required for 2023-24 and beyond[1].

Annual review of fees and charges

The TGA's operations are mostly funded (approximately 96%) 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 also 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, with two exceptions:

a. in 2012-13 fees and charges were increased by 5.6% (2% higher than the indexation factor) to meet the costs of implementation of the TGA Blueprint Reforms, and

b. in 2015-16 fees and charges were increased by 2.12% (slightly lower than the indexation formula) as it was based on known direct cost increases only.

[1] *This consultation paper only focuses on changes required to the TGA fees and charges for 2022-23 and does not address any changes that may arise from the PwC review.*

Continuing cost pressures

a. Significant increase in Special Access Scheme (SAS) applications

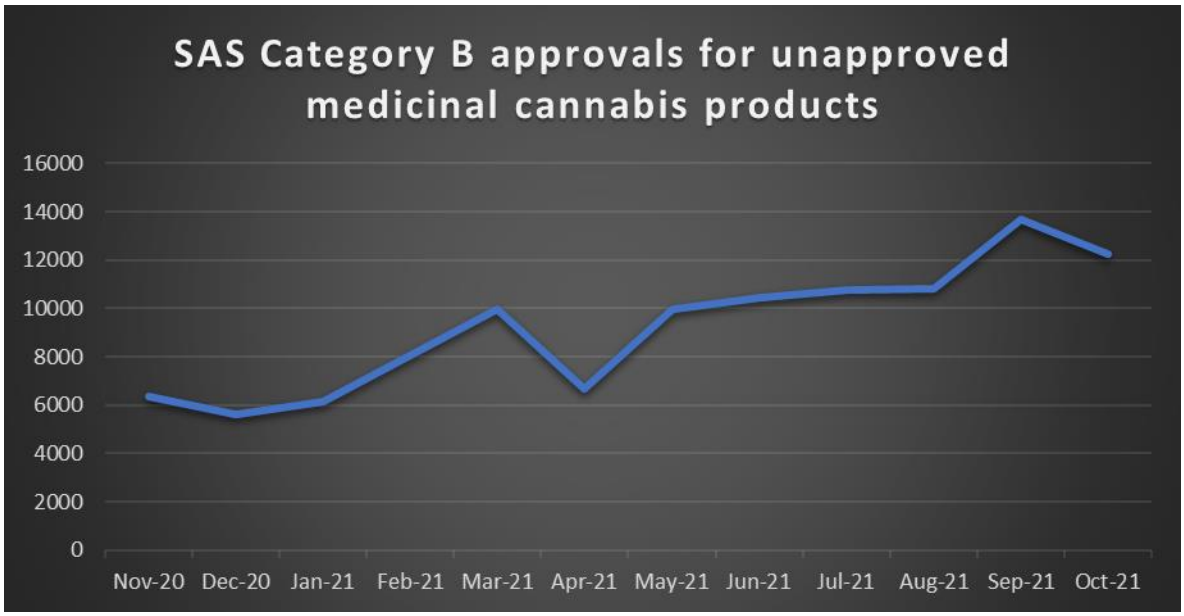
In undertaking its regulatory functions, the TGA is being required to provide an increasing number of services in the public good which cannot be appropriately cost recovered from industry. These services include, but are not limited to, providing timely access to unapproved medicines (including medicinal cannabis, cell and tissue therapies and medical devices) to patients under the Special Access Scheme (SAS), the Authorised Prescriber (AP) Scheme and the Orphan Drug Program. These services are now partly covered by appropriation funding, however the demand for them is continuing to significantly increase.

In 2016 the *Narcotic Drugs Act 1967* was amended to establish a regulatory framework for the cultivation, production and manufacture of cannabis for medicinal purposes. This has resulted in a huge increase in patient demand for medicinal cannabis products. These products are overwhelmingly provided through the SAS, which by law requires a medical doctor or pharmacist to review each application.

In 2020-21, there were 45,394 SAS category A notifications; 112,301 SAS Category B applications; 29,602 SAS Category C applications; and 5,087 AP applications. The annual cost of these fee free services is estimated to be $4.2 million or around $22 per application/ notification.

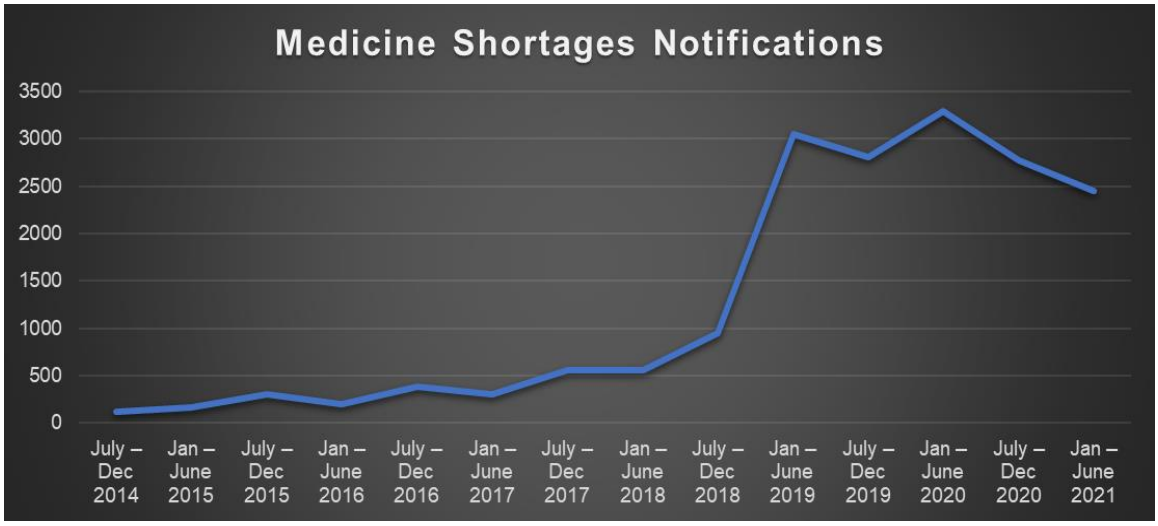
During the period November 2020 to 31 October 2021, the TGA approved over 180,000 SAS Category B applications for unapproved medicinal cannabis products. Additionally, the number of AP applications has already increased and is expected to increase further following the 1 October 2021 changes in relation to nicotine vaping products.

A breakdown of the number of SAS Category B approvals by month for the previous 12 months is also provided below:



b. Increase in mandated and non-cost recovered activities following 2017 legislative and regulatory changes

There has been a significant increase in a number of reporting, compliance, legal and enforcement activities as a result of amendments to the Act in 2017, and in response to changed Government requirements and community expectations of the role of the TGA as the regulator of therapeutic goods. These include the mandatory reporting of (and action by the TGA on) medicine shortages and changes to compliance and enforcement powers in relation to entities operating illegally and outside of the regulatory system.



The Medicine Shortages Information Initiative was launched in May 2014 with voluntary reporting of prescription medicine shortages. Following consultation in 2017-18, mandatory reporting to the TGA of shortages or discontinuations of all prescription medicines and some over the counter medicines commenced from 1 January 2019, resulting in a 400% increase in the number of reported notifications compared to 2018. As such, the workload required to manage medicine shortages has increased significantly, from a monthly average of 20 in July-December 2014 to 410 in January-October 2021.

The total costs of all such fee free services, where direct cost recovery is not appropriate, is estimated to reach $28 million in 2022-23, an increase of nearly $14 million since 2018-19:

Cost of fee free services and new mandatory and legislated activities	2018-19 Actual $m	2019-20 Actual $m	2020-21 Actual $m	2021-22 Forecast $m	2022-23 Estimate $m
Orphan Drugs	3.30	3.99	4.90	5.10	6.30
Special Access Scheme (SAS)- Non-Medicinal Cannabis	3.00	2.89	2.56	2.91	3.20
SAS Medicinal Cannabis		1.27	1.78	2.01	2.21
Medicines Shortages	1.00	1.00	2.31	2.32	2.32
Compliance, enforcement, and litigation	6.67	11.60	11.22	12.33	11.27
SME Assist	0.68	0.68	0.68	0.69	0.69
Emerging Technologies		0.60	1.23	1.53	1.99
Total	**14.65**	**22.03**	**24.68**	**26.89**	**27.98**
Direct Government funding		3.20	6.60	8.00	15.00
Remaining to be absorbed within fees and charges	**14.65**	**18.83**	**18.08**	**18.89**	**12.98**

c. Corporate costs

The Department provides the TGA with a range of central corporate services, such as information technology, property (including lease payments), human resource and financial management. The costs of these services are paid through a corporate charge back arrangement. In addition, a small number of corporate/administrative functions are undertaken within the TGA and funded through fees and charges.

Corporate Expense	2018-19 Actual $m	2019-20 Actual $m	2020-21 Actual $m	2021-22 Forecast $m (excluding relocation costs)	2022-23 Estimate $m (excluding relocation costs)
Corporate expenses for IT, HR and Property	36.04	41.66	41.66	41.66	42.38
Residual corporate expenses such as parliamentary, legal and admin support	4.79	2.75	2.98	4.88	5.36
Total	**40.83**	**44.41**	**44.64**	**46.54**	**47.75**

d. Additional Cost of Relocation

After 30 years at Symonston, the TGA will be relocating to new and more modern facilities. The new site (at Fairbairn in Canberra) will include two purpose-built new buildings – an office building and a dedicated laboratory building. The move into the new premises will take place in early to mid-2022, prior to the expiration of the Symonston lease.

The portion of the costs of relocation and building fit out required to be funded by the TGA is budgeted at $13.7m of which $8.7m will be spent in 2021-22. The breakdown of this budgeted expenditure is as follows:

- shortfall in lease incentive - $2.35m in 2021-22
- videoconference facilities - $3.1m in 2021-22, further $2.5m in out years
- laboratory IT network and other costs - $1.2m (including air filters, waste removal, laboratories transport, installation, and calibration services)
- costs for make good at Symonston (repair and maintenance of Symonston building) - ($3.1m over 3 years), and
- other costs $2.6m.

e. Other cost pressures

Since the start of the COVID -19 pandemic, requirements and expectations of the TGA, as a regulator, have substantially increased. There has been a significant increase in consumer education and communications, sponsor support, and compliance and enforcement activities. While fees and charges partially cover the costs of approving and regulating COVID-19 treatments and vaccines, a rolling review of data is very expensive and there has been a remarkable increase in post market efforts in respect of these products.

Recent changes in relation to nicotine vaping products is anticipated to result in a major increase in workload due to compliance requirements and laboratory testing of these products. This will put upward pressure on TGA's expenses as there are no approved nicotine vaping products on the ARTG.

Additionally, in the coming years, the TGA will also experience cost pressures due to the continuing reforms in medical devices, additional maintenance and depreciation of recent IT investments (including UDI) and fit- out and equipment costs of the new building.

TGA cash position as at 30 June 2021

As at 30 June 2021, the TGA had cash reserves of $34.2m available for investment. This will reduce significantly by 30 June 2022 after the following investments:

- Unique Device Identifier system - $5.6m
- Digital Transformation project - $11.4m
- Deficit forecast for 2021-22 - $7.5m

The remaining $9.8m in cash reserves is expected to be depleted in 2022-23 to cover relocation, digital transformation costs and other costs as outlined above.

In addition to the $34.2m available for investment, the TGA needs to retain cash reserves to cover staff entitlements ($28.9m) and fees received in advance for product evaluations underway ($34m).

Known cost increases in 2022-23

Known increases to the TGA expenses in 2022-23 are estimated to be approximately $7.8 million. The major items are outlined below:

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 $4.6 million for the 2022-23 year mainly related to an increased number of contractors (including contract service costs), 2% staff pay rise to take effect March 2022 (as per the Department's Enterprise Agreement), leave provision increase as a result of the 2% pay rise and staff pay increments due August 2022 (all staff with at least 3 months of service and a satisfactory performance rating are eligible for an increment in line with the Enterprise Agreement).

b. Increase in corporate costs

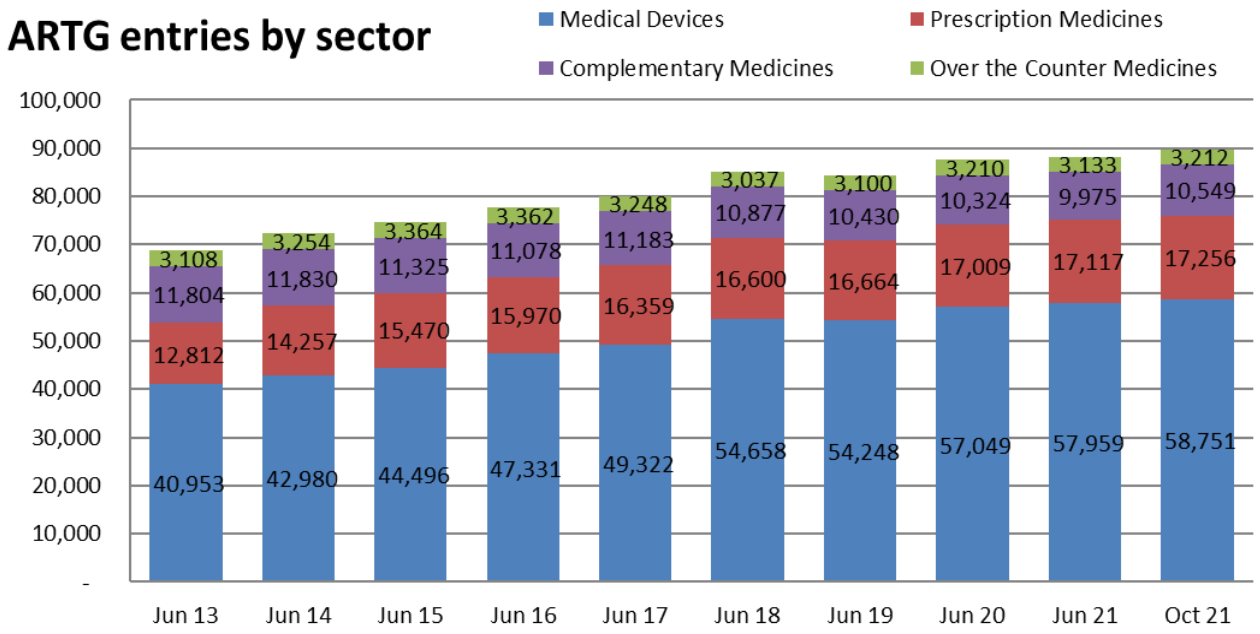
The corporate cost including depreciation is estimated to increase by $2.4 million mainly due to the relocation costs to Fairbairn and the yearly increase apportioned for depreciation/amortisation on digital transformation projects.

Limited revenue growth

Revenue from services increases annually in line with an increase in the volume of regulatory activities for which a cost recovery fee is charged. Similarly, growth in the number of products in the ARTG, subject to the annual charges exemption (ACE), also generates additional revenue. In addition, revenue increases due to annual price increases.

A 4% increase in entries was noticed for 2019-20, bringing the total number of ARTG entries to 87,592. However, 90% of this was due to COVID-19 related medical device entries. In 2020-21 there was a 1% increase in total ARTG entries, mostly from Class IIa medical devices, bringing the total number of ARTG entries to 88,184. Of the 88,184 active products in the ARTG at 20 June 2021, only 68,419 were invoiced for the 2021-22 annual charges with the balance of products exempt under the ACE scheme.

The TGA does not anticipate a significant increase in ARTG entries in 2022-23. The chart below shows the numbers of ARTG entries by industry sector.



Indexation factor for 2022-23

The indexation factor for 2022-23, based on the previously used formulae of the average (composite indexation) of the CPI and the WPI, is 2.60%:

a. 50% of cost price index Sep 2020 to Sep 2021: 3.00%: 1.5%
b. 50% of wage price index Sep 2020 to Sep 2021: 2.20%: 1.1%

Proposed changes to fees and charges for 2022-23

a. Annual change to fees and charges

A number of options were considered before arriving at the preferred option for 2022-23. These options are discussed below.

Option 1 – No increase in fees and charges

In this option, without any increase to fees and charges for 2022-23, the TGA may run into a deficit of up to $7.8 million. This approach is unlikely to be consistent with the Government's Government Charging Framework. In order to minimise the impact of a potential budget deficit, the TGA would need to reduce its staffing significantly. This in turn would result in the TGA being unable to perform its regulatory duties in a timely manner; for example, there would likely be delays in completing applications for new medicines and medical devices within the agreed timeframe, or in the implementation of its regulatory reforms program and oversight of product safety.

Option 2 - Percentage increase in line with known increase in costs

If the TGA were to increase its revenue to fully recover the anticipated increase in known costs, an increase in fees and charges of 3.26% would be required. The other indirect cost pressures would need to be met through internal efficiencies and business process improvements. While the 3.26% increase is likely to be consistent with the Cost Recovery Guidelines, a fee increase that is inconsistent with the long-established indexation practice may compromise certainty for sponsors and manufacturers.

Option 3 - Increase all fees and charges by indexation factor (proposed)

Under this option, all fees and charges would increase by 2.6%, subject to rounding. The indexation only increase is not only consistent with the long-established practice but also provides opportunities for efficiency gains through business process improvements. This is also consistent with the Government's policy for cost recovered activities.

In applying the indexation factor, fees and charges would be rounded to the nearest $10 for items less than $10,000 and to the nearest $100 for items $10,000 and above.

Should the proposed option be accepted by Government, additional revenue of $4.6 million would be generated, assuming constant volumes of ARTG products and products exempt from annual charges under the ACE scheme. The financial impact on sponsors of this proposal, if implemented, will be a 2.6% increase from 1 July 2022. For example, a company which paid $10,000 in annual charges this financial year would be required to pay $260 more next financial year. Any fee or charge below $190 will not change due to the rounding policy.

b. Fees for clinical trial variation applications

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) and Clinical Trial Approval (CTA) 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 or CTA is required in relation to the use of the therapeutic goods is the responsibility of the trial sponsor. Consultation with a Human Research Ethics Committee that will approve the trial protocol may assist in the decision.

For the CTA scheme, there is a formal regulatory process undertaken whereby sponsors apply for TGA's approval to supply 'unapproved' therapeutic goods in a clinical trial. These

applications are assessed and accompanied by a relevant fee. The full list of legislative and regulatory provisions for the CTA scheme, including fee provisions, is included in the Australian Clinical Trials Handbook.

Where there are changes to approved clinical trials, the sponsor is required to inform the TGA of these variations to CTAs. Before amendments to the Act in September 2020, there was no provision in the legislation to allow for variations to CTAs. Therefore, the TGA had treated any request for changes to existing CTAs as entirely new CTA applications.

Amendments to the Act (new subsections 19(4B), 32CK(9A) and 41HB(8)) allow variations to previously approved CTAs for medicines, biologicals and medical devices respectively. These subsections require that a request to make changes to an existing CTA must be accompanied by the fees prescribed in the regulations. Currently no such fees are prescribed in the regulations.

Based on staff effort required for variation applications, it is proposed to implement the following variation application fees with effect from 1 July 2022, subject to approved indexation for 2022-23.

a) Variation to medicines CTA – 30-day evaluation: $510
b) Variation to medicines CTA – 50-day evaluation: $6,300
c) Variation to biologicals CTA: $7,670
d) Variation to medical device CTA: $5,376.

Note: The proposed fees equate to 28% of a new CTA application fee.

Stakeholder engagement

a. Consultation on 2022-23 fees and charges proposals

The following industry representative groups were consulted on the proposed changes to fees and charges in December 2021:

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[2]
11. Assistive Technology Suppliers Australasia
12. Australian Medical Device Distribution Association
13. MTP Connect.

Consistent with their feedback over the past few years, industry peak bodies were generally supportive of the TGA's preferred option of an increase to fees and charges by the indexation factor. Some industry bodies in the medical devices and complementary medicines expressed concerns about the impact of the COVID-19 pandemic on supply chain and general consumer demand, increasing pressure on business margins and at times even forcing businesses to shut down.

In order to obtain broader feedback from industry, the TGA encourages all stakeholders to provide their comments on the proposed options for the 2022-23 fees and charges (preferably through their relevant peak body). The feedback will inform the final proposal to Government for consideration and decision.

b. Feedback on stakeholder engagement and consultation process

The TGA has an established practice of stakeholder engagement specifically targeting changes to the TGA's fees and charges as detailed in the CRIS in the section 'Stakeholder consultation'. Based on feedback from industry bodies during annual bilateral meetings, the TGA has made changes to its consultation process by bringing forward bilateral meetings to provide more notice of changes to sponsors and inviting three additional therapeutic goods industry bodies to increase engagement with particular sectors of the industry.

[2] *Optical Distributors & Manufacturers Association of Australia couldn't attend this year's bilateral meeting. Therefore, the bilateral meeting presentations were provided to them for their feedback.*

As part of the implementation plan for the recommendations from the Application of Cost Recovery Principles report issued by ANAO in May 2019, the TGA introduced a targeted survey in October 2020 to gain feedback on the TGA's engagement on cost recovery matters from sponsors and industry bodies. This is in addition to the annual stakeholder survey conducted by the TGA to obtain feedback from the wider community including health professionals and consumers. The survey was distributed to a sample of around 6,000 sponsors who paid TGA fees or charges in the last two years and have provided their email address and to

the thirteen peak industry bodies who participated in the annual bilateral meetings.

A brief summary of the survey results was included in the TGA CRIS. Based on feedback from sponsors about more direct communication from the TGA, the TGA has included a news banner about the public consultation on the TGA business system (eBS) to which all current sponsors have access to. This is in addition to the news updates on the TGA website.

Regulatory impact assessment

The proposed change to the TGA fees and charges is within the parameters of the carve-out of the Office of Best Practice Regulation. The proposed indexation-only increase of 2.6%, as well as the small number of other changes 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 from stakeholders and other interested parties on the proposed changes to the 2022-23 fees and charges. The TGA will consider the feedback before seeking approval of fees and charges for 2022-23 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 2022. This will allow sufficient notice to sponsor's about changes to fees and charges effective from 1 July 2022.

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.

Version history

Version	Description of change	Author	Effective date
V1.0	Draft version – TRIM	Regulatory Pricing and Decision Review Section	25/01/2022

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