Australian Government
Department of Health
Therapeutic Goods Administration

Fees and charges proposal 2020-21

Consultation paper

Version 1.0, January 2020

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. In order to meet these responsibilities, the TGA recovers its 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 2020-21 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 2019 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 particular 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, including $6.6 million in 2020-21 and $15 million per year ongoing from 2022-23. This funding will go towards meeting the costs of fee-free services that cannot be appropriately cost recovered; as well as (in 2020-21) substitution for lost fee revenue for complementary medicine and opioid medicine sponsors who have been required to change their ARTG information along with implementation of safety related regulatory changes for opioid medicines. In addition, some appropriation funding is provided to meet the secretariat costs for medicines and chemicals scheduling regulation, and in the form of an interest equivalency payment against the special account balance (reserves). In 2020-21, the overwhelming majority (around 95%) of TGA revenue will be generated through fees and charges set under cost recovery arrangements.

The *Therapeutic Goods Act 1989* (the Act) provides the legal authority for the TGA to charge 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.

Performance audit – TGA cost recovery

In 2018-19, the Australian National Audit Office (ANAO) conducted a cross-entity performance audit of the application of cost recovery principles in the Commonwealth. The TGA was one of three selected cost recovery services subject to this audit[1]. The objective of this audit was to assess whether the selected regulatory entities effectively applied the cost recovery principles of the Australian Government's cost recovery framework.

The audit found the TGA's cost recovery policies and methodology were largely compliant with the CRGs, although it had scope to improve the effectiveness of some of the cost recovery arrangements. The three broad TGA specific recommendations were:

1. Ensure that the TGA's CRIS is fully compliant with the CRGs and cost recovery performance at the regulatory activity level is reported annually in the CRIS.

   Action: Fully implemented - the fully compliant CRIS was published on the TGA website in June 2019 which was further updated and published in December 2019.

2. Seek a decision from Government in relation to funding for the TGA's fee-free services.

   Action: Fully implemented - in the 2019-20 MYEFO, the Government announced funding of $33 million over four years, including $15 million per year ongoing from 2022-23 to go towards meeting the costs of the fee-free services and other activities where cost recovery is not appropriate.

3. The TGA adjust fees and charges to reduce cross subsidisation across industry sectors.

   Action: Fully implemented - the TGA reviews its fees and charges regularly in consultation with industry and adjusts charges as required.

The ANAO also suggested that the TGA implement ongoing stakeholder engagement strategies for cost recovery arrangements in consultation with stakeholders and include performance measures for engagement on cost recovery in the CRIS. The TGA's consultation strategy is discussed in the latter part of this paper.

The ANAO report (*Auditor-General Report No. 38 of 2018-19*) was published in May 2019 and is available on the ANAO website.

Annual review of fees and charges

The TGA's operations are mostly funded through the fees and charges it collects for the services it provides. 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 taking into account 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

[1] *The other two entities included the Australian Maritime Safety Authority and the Department of Agriculture and Water Resources*

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:

- 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
- 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.

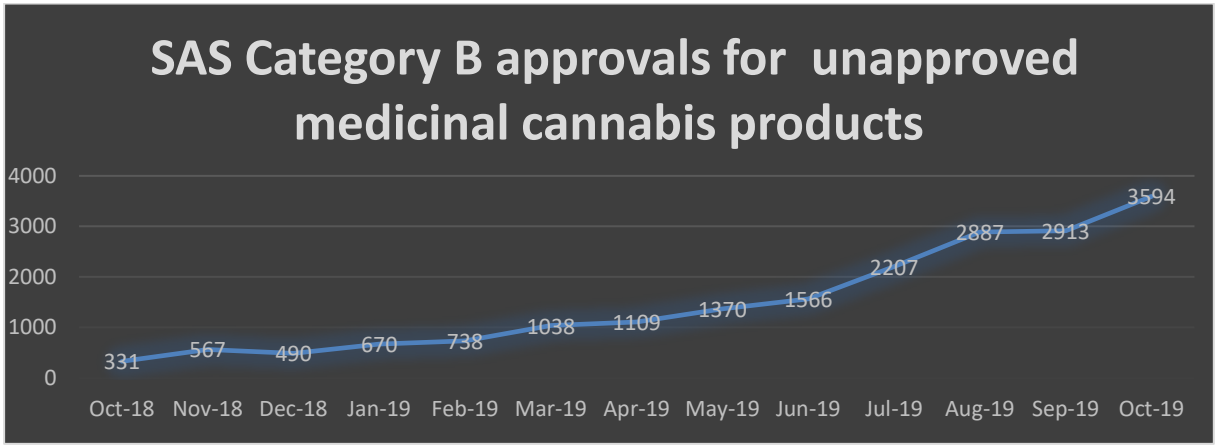
In addition to the aforementioned 2019-20 MYEFO decision, during 2020 the TGA will undertake a review of its fees and charges to ensure they remain consistent with the Government's cost recovery framework.

Continuing cost pressures

a. Significant increase in fee free services

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) and the Authorised Prescriber Scheme (AP).

Many of these specific services were either not anticipated 20 years ago or initially had very low volumes. The 2016 legislative amendments to the *Narcotic Drugs Act 1967* have resulted in a huge increase in patient demand for medicinal cannabis products, which is overwhelmingly provided through the SAS which by law requires a medical doctor or pharmacist to review each application.

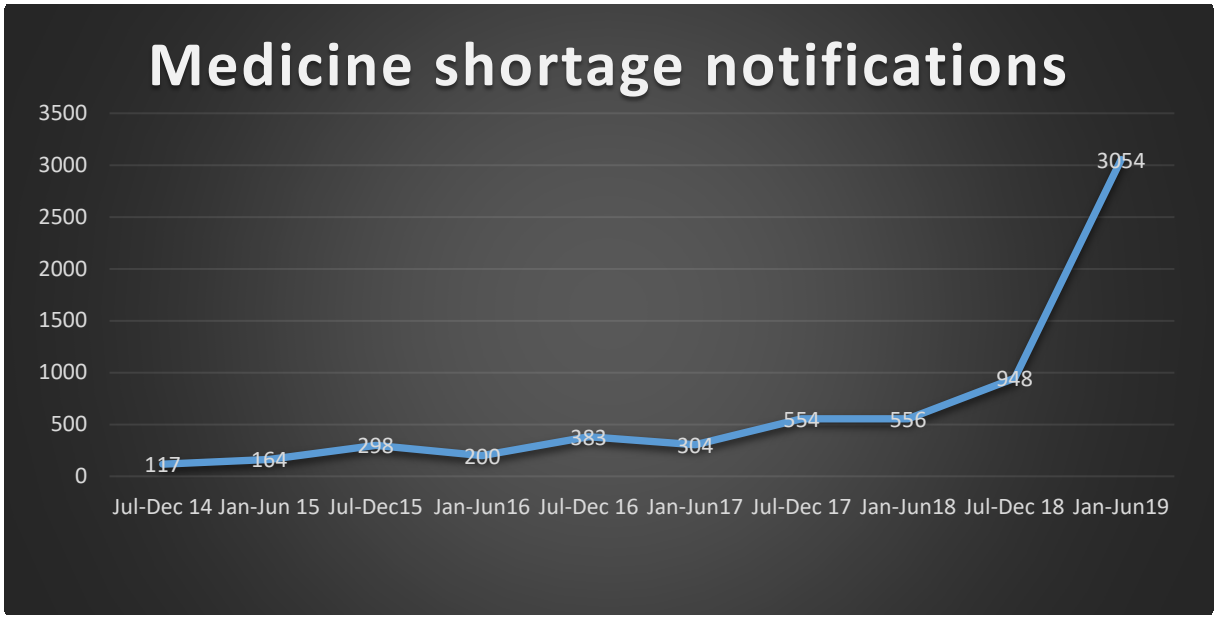


A ten-fold increase in approved SAS applications for medicinal cannabis over the 12-month period from October 2018 to October 2019 has placed significant pressure on resources and budget required to process these applications. An anticipated monthly increase of 10% until June 2020 and 2% thereafter would see the number of applications rising to 10,000 a month by May 2021 but is expected to flatten after this.

The legislation provides for a fee waiver for registration of certain critical medicines as orphan drugs (for rarer diseases) in the Australian Register of Therapeutic Goods (ARTG). This service is provided to ensure timely availability of certain critical medicines which would not be otherwise financially viable for the sponsors.

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

There has been 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 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 of medicine shortages commenced on 1 January 2019. Since then there has been an increased role for the TGA in mitigating medicine shortages. As such, the workload required to manage medicine shortages has increased significantly, from a monthly average of 20 in July-December 2014 to 500 in January–June 2019. Additionally, there has been a corresponding increase in the number of approvals under section 19A of the Act to allow the supply of alternative goods from overseas.

The total costs of fee free and other services where cost recovery is not appropriate is estimated to reach $23 million in 2020-21, an increase of $12 million since 2016-17.

Cost of fee free services and new mandatory and legislated activities since 2017					
	2016-17 Actual $m	**2017-18 Actual $m**	**2018-19 Actual $m**	**2019-20 Forecast $m**	**2020-21 Estimate $m**
Orphan drugs	4.20	3.77	3.30	3.70	3.56
Special Access Scheme (SAS) - non medicinal cannabis	7.20	6.77	6.38	5.95	6.45
SAS - medicinal cannabis	-	-	-	0.75	1.87
Medicines shortages	0.38	0.14	1.00	1.00	1.31
Advertising compliance, enforcement and legal	4.51	5.74	6.67	8.21	11.72
SME Assist	-	-	0.68	0.68	0.68
Emerging technologies	-	-	-	0.60	1.23
Total	***12.09***	***12.65***	***14.73***	***17.19***	***23.27***
Funding				3.50	6.60
Remaining to be absorbed within fees and charges	***12.09***	***12.65***	***14.73***	***13.69***	***16.67***

c. Corporate costs

The Department of Health 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 additionally to this figure.

In 2019-20 the cost of this departmental charge back increased from $36 million to $42 million. A further increase of approximately $2.5 million in 2020-21 is anticipated.

Corporate costs					
	2016-17	2017-18	2018-19	2019-20	2020-21
	Actual $m	Actual $m	Actual $m	Forecast $m	Estimate $m
Corporate expenses					
Corporate expenses for IT, HR and Property	36.50	36.50	36.04	42.07	44.61
Residual corporate expenses such as parliamentary, legal and admin support	4.60	4.69	4.79	4.88	4.98
Sub total	**41.10**	**41.19**	**40.83**	**46.95**	**49.59**

Digital transformation of TGA services

As foreshadowed in December 2018, a significant investment is required in the TGA's business and regulatory systems. Most of the TGA's legacy IT systems are based on old IBM Lotus Notes technology. As these systems are more than 20 years old, maintaining/enhancing them is not only expensive, it is becoming increasingly difficult to find experienced resources to maintain the technology. In addition, there is a need for a unique device identification (UDI) system for effective post market and surveillance of medical devices and to enhance patient safety.

In October 2019 the TGA undertook a series of workshops with industry to inform the development of a business case for the replacement of the TGA's IT and business systems.

Subject to Government approval through the 2020-21 Budget process, proposed IT enhancements are expected to provide benefits to stakeholders, including:

- increased accuracy of the ARTG with industry able to update own data
- better ARTG search capacity
- better linked systems that are designed for simplified content updates
- the redirection of TGA staff to skilled technical functions rather than doing low level administrative work-around
- capability to securely upload dossiers, and to download submissions
- assurance of cyber security of product applications
- an easy way to see where a submission is at in the process
- ensuring sponsors can clean up their data when appropriate
- improved administrative processes, like automated credit card payments
- better guidance documents available
- improved adverse events management and reporting systems.

It is anticipated that these enhancements will require an investment of $15-18 million over three years. Additionally, an investment of $5 -7 million over 3 years will be required to establish the medical device Unique Device Identifier (UDI) system.

If approved by Government, it is proposed that this investment will be drawn from the TGA Special Account cash reserves, rather than increasing TGA fees and charges to cover the cost.

Known cost increases in 2020-21

It is estimated that known increases to TGA expenses on 2020-21 will be approximately $7 million as outlined below.

a. Anticipated increase in salary, contractor and related costs

The single largest component of TGA costs is salary, contractors and other staff related costs. The Department's Enterprise Agreement mandates an annual increase of 2% for non-senior executive staff during 2020-21. Additionally, many non-senior executive staff are likely to be due for salary advancement under the Enterprise Agreement. It is estimated that staff and contractor costs will increase by approximately $3.8 million in 2020-21.

b. Increase in other non-discretionary costs

The TGA has made a significant capital investment in software as part of the implementation of a range of reforms resulting from the Medicines and Medical Devices Regulation Review. All this new software will require amortisation over their useful lives with annual depreciation and amortisation costs estimated to increase by $0.8 million in 2020-21.

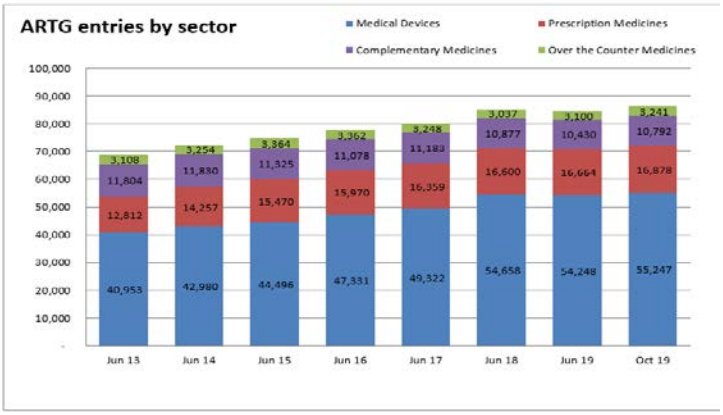
The corporate charge back is estimated to increase by $2.5 million mainly due to increase in labour and data management costs.

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.

After a number of years of significant growth in the number of products registered on the ARTG, a decline was noticed, for the first time, in 2018-19. The total number of active products in the ARTG dropped from 85,172 at 30 June 2018 to 84,442 at 30 June 2019. While this decline was a result of rationalisation of medical devices and complementary medicines, little or no growth is projected in annual charges revenue in the coming year. Additionally, the revenue foregone due to the Annual Charge Exemption (ACE) scheme continues to be significant (approximately $41 million in 2019-20). Of the 84,442 active products in the ARTG at 30 June 2019, only 66,301 were invoiced for the 2019-20 annual charges with remaining products being exempt under the ACE scheme.

The chart below shows the numbers of ARTG entries by industry sector.



Indexation factor for 2020-21

The indexation factor for 2020-21, based on the previously used formulae of the average of the CPI and the WPI, is 1.95%

- 50% of CPI September 2018 to September 2019 of 1.7% = 0.85%
- 50% of WPI September 2018 to September 2019 of 2.2% = 1.1%

Potential changes to fees and charges for 2020-21

a. Annual change to fees and charges

A number of options were considered before arriving at the preferred option for 2020-21. These options are discussed below.

Option 1 – No increase in fees and charges

In this option, without any increase to fees and charges for 2019-20, the TGA may run into a deficit of up to $7 million. This approach is unlikely to be consistent with the Government's Cost Recovery Guidelines (CRGs). In order to minimise the impact of a potential budget deficit, the TGA would need to reduce its staffing significantly. This in turn would likely cause delays in completing applications for new medicines and medical devices within the agreed timeframe as well as hinder 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 absorb the anticipated increase in known costs an increase in fees and charges of 4.3% would be required. The other indirect cost pressures would need to be met through internal efficiencies and business process improvements. While the 4.3% increase is likely to be consistent with the CRGs, 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 (preferred)

Under this option, all fees and charges would increase by 1.95%, 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.

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 preferred option be accepted by Government, additional annual charges revenue of $3.2 million would be generated, assuming constant volumes of the ARTG products and the products exempt from annual charges under the ACE scheme. The financial impact on sponsors of this proposal, if implemented, will be a 1.95% increase from 1 July 2020. For example, a company that paid $10,000 in annual charges this financial year would be required to pay $195 more next financial year.

b. Early scientific advice for generic medicines

Early scientific advice is designed to assist companies to confirm the data requirements prior to submitting an application for registration of a new generic medicine where current guidance is not suitable due to the unique technical complexities of the product. Companies will be able to choose if and when they submit a request to the TGA for early scientific advice.

The TGA consulted externally in 2019 on a proposal to introduce early scientific advice on proposed justifications for biowaivers for prescription medicines. The proposal has been consistently supported by industry. Many submissions, including from peak industry bodies, supported introduction of a new fee that is commensurate with the time required to review requests.

It is proposed to introduce a fee of $8,500 which is based on staff effort as per activity-based costing. This will be an optional step (and associated fee) for applications for registration of certain generic medicines although sponsors can continue to submit their applications through the current processes without the proposed fee.

Under the current legislation, the TGA is unable to provide detailed scientific advice or perform any evaluation of scientific data outside the formal application process. Therefore, providing formal scientific advice requires changes to the Act and the associated regulations. Thus the above fee is subject to the passage of legislation. It is anticipated that legislation will be introduced into Parliament in early-mid 2020.

c. Consent to supply goods that do not comply with applicable standards

Under sections 14 and 14A of the Act sponsors can seek the Secretary's consent to supply medicines and biologicals which do not comply with the applicable standards. Similar provisions exist in sections 41MA and 41MAA for seeking the Secretary's consent to supply medical devices which do not comply with the Essential Principles. Generally, any non-compliance relates to labelling and changes to the details (name/address etc.) of the sponsor or manufacturer. Consent is granted by the Secretary's delegate when the sponsor/manufacturer can provide evidence of an appropriate risk mitigation strategy.

The application to seek such a consent requires payment of an application fee prescribed in the regulations. Currently different fees apply for medicine (including biologicals) and medical device consent applications:

- $460 for each medical device entry
- $480 for each medicine or biological application.

Most applications under this category contain multiple ARTG entries. Recently a number of medical device sponsors have raised concern that the current fee is too high particularly for

applications with a large number of entries. There is currently no legislative authority to reduce this fee.

A review of costing was undertaken on the basis of current business processes. The costing estimate has found that the current fee is set at the appropriate level where a consent application contains a single ARTG entry. The cost of processing an application containing multiple entries rises marginally for each additional entry included in the same application, and not proportionately to the increase in the number of entries.

It is proposed to replace the current fee structure for obtaining the Secretary's consent with a tiered fee structure for all types of therapeutic goods from
1 July 2020:

- application containing one entry - $480 (plus indexation from 1 July 2020)
- application containing multiple entries - $480 (plus indexation from 1 July 2020) for the first entry plus $100 per additional entry included in the application.

This fee structure is likely to be more compliant with the CRGs and would benefit most sponsors of consent applications. For example, for a medical device sponsor an application with 10 device entries would require payment of a fee of $1,380. This is a saving of $3,220 on the current fee ($4,600).

d. Annual charge for designated Australian conformity assessment body

The legal framework that allows an Australian conformity assessment body to be designated was implemented in early 2018. The associated fee structure for making the application and assessment work was also introduced at the same time. The TGA continues to progress work to operationalise the legislative framework and there is a need to implement annual charges for designated Australian conformity assessment bodies. Targeted consultation on the appropriate annual charge will be undertaken in 2020. This charge relates to the costs associated with ongoing monitoring and assurance of a designated Australian conformity assessment body.

Stakeholder engagement

a. Stakeholder engagement strategy

The TGA has a long standing practice of undertaking targeted consultation with peak industry bodies regarding fees and charges. Bilateral meetings with peak industry bodies are conducted each year with a focus on financial outlook and fees and charges for the forthcoming financial year. Around the same time, a public consultation paper is released to provide an opportunity for wider industry and other stakeholders to comment on the fees and charges proposal.

Industry associations are also regularly consulted in the process of regulatory development and reform, and feedback is taken into account in developing regulatory impact statements, and any relevant cost recovery arrangements. The TGA also uses a number of forums to consult and disseminate information regarding the TGA cost recovery, including:

- the TGA Consultative Committee - a consultation forum with industry and non-industry bodies involved in the manufacture, use and consumption of therapeutic goods
- the TGA Industry Forum - a sub-committee of the TGA Consultative Committee, providing consultation and feedback on industry specific issues
- industry working groups for prescription, non-prescription and complementary medicines

- the TGA-Industry Working Group on Good Manufacturing Practice which facilitates consultation between TGA and the industry on matters relating to good manufacturing practice, and
- the Regulatory and Technical Consultative Forum for medical devices.

The TGA uses additional means of consultation to ensure that stakeholders have been provided with sufficient opportunity to comment on more significant changes in cost recovery policy, where more complex changes to fees are being considered or where multiple options are provided for consideration.

Under the Australian Government's guide to regulation, direct financial costs such as fees and charges attached to a regulation are excluded from the Regulatory Burden Measurement Framework. Accordingly, the TGA does not prepare a Regulation Impact Statement for amendments to fees and charges for therapeutic goods and manufacturing licenses. This is consistent with advice from the Office of Best Practice Regulation (OBPR). Activity-based costing is the well-established mechanism for setting fees and charges and a comprehensive targeted communication strategy is TGA's established consultation approach. As part of this strategy the TGA publishes a CRIS at least once a year.

Based on stakeholder feedback, the TGA has enhanced the consultation process for its cost recovery arrangement. In addition to inviting three additional medical industry bodies, the TGA has also brought forward the bilateral meetings by a few months to potentially provide more notice of changes to sponsors.

It is also proposed to include a set of questions, specific to stakeholder engagement on the TGA's cost recovery arrangement, in the broader TGA Stakeholder survey which is planned in June 2020. The results of this survey will be included in the CRIS.

The TGA also reports to stakeholders against a set of agreed Key Performance Indicators.

b. Consultation on 2020-21 fees and charges proposals

The following industry representative groups were consulted on the proposed changes to fees and charges in December 2019:

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. Australian Self Medication Industry
8. Complementary Medicines Australia
9. Accord Australasia
10. Optical Distributors & Manufacturers Association of Australia[2]

[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.*

11. Assistive Technology Suppliers Australasia
12. Australian Medical Device Distribution Association
13. MTP Connect were also involved in the consultation.

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 smaller bodies expressed general concerns about a range of current business pressures.

In order to obtain broader feedback from industry, the TGA encourages all stakeholders to provide their comments on the proposed options for the 2020-21 fees and charges (preferably through their relevant peak body). It is anticipated that the feedback will improve and inform the final proposal that will be progressed to the Government for consideration and decision.

Regulatory impact assessment

The proposed change to the TGA fees and charges that is linked to indexation is within the parameters of the carve-out of the OBPR. The proposed indexation increase of 1.95%, as well as the small number of other changes discussed in this paper, is not likely to change the regulatory burden on stakeholders. Therefore, the TGA is not proposing to develop a regulatory proposal, including a RIS 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 2020-21 fees and charges. The TGA will consider the feedback before seeking approval of fees and charges for 2020-21 from the Minister for Health. 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 Committee in May 2020. This will allow sufficient notice to sponsors about changes to fees and charges effective from 1 July 2020.

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	Original publication	Regulatory Services and Drug Control Branch	January 2020

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