Australian Government
Department of Health
Therapeutic Goods Administration

Fees and charges proposal 2021-22

Consultation paper

Version 1.0, February 2021

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 2021-22 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 2020 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 with $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. This is in addition to appropriation funding 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).

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.

Recent funding decisions

On 2 October 2020, Minister Hunt announced the Government's decision to invest $12 million over four years starting from 2020-21 to digitise and modernise the TGA's business systems and infrastructure. The funding will be drawn from the TGA special account cash reserves. However the ongoing maintenance and support costs for these investments (operating costs) will be subject to cost recovery. This investment will result in business process improvement for a more consistent and integrated approach across multiple TGA business functions. In 2021, the first set of priorities will include developing a plan to:

a. integrate some features of the existing Health Product Portal into the TGA business processes to deliver a seamless experience for sponsors in their interactions with the Department of Health, and

b. improve accuracy and accessibility of the Australian Register of Therapeutic Goods (ARTG) and introduce new analytics and reporting capabilities making it easier to search for information.

The 2020-21 Budget also included approval for access to $7.7 million from the special account over four years starting 2020-21 for the implementation of a Unique Device Identification (UDI) system. The UDI will allow tracking and tracing of medical devices that have been implanted in patients. This will allow for faster and targeted responses to safety issues and recalls, and improved data device information for patients and health practitioners. Feedback from consultations shows strong consensus across all stakeholders for introduction of UDI system by the TGA in order to align with international standards. In 2021, the TGA will work towards the legislative amendments to be able to build a UDI database along with scoping out the technical requirements.

Review of TGA fees and charges

In conjunction with the Department of Finance, and supported by PWC, a review of all TGA fees and charges is currently underway, with results anticipated to be provided to government in 2021. The purpose of the review is to provide Government with options for a sustainable funding model that enables TGA's regulatory and public health responsibilities. The review will include a separate consultation with industry.

Note: This consultation paper only focuses on changes required to the TGA fees and charges for 2021-22, and does not address any changes that may arise from the charging review.

Annual review of fees and charges

The TGA's operations are mostly funded (approximately 93%) 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 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 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:

c. 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

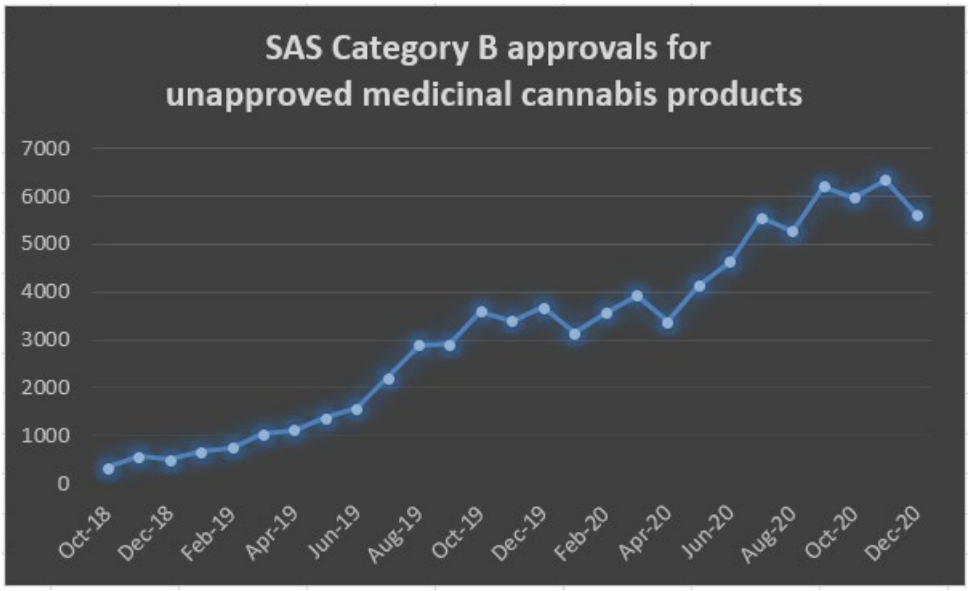
d. in 2015-16 fees and charges were increased by 2.12% (slightly lower than the indexation formula) as it was based on known direct cost increases only.

Continuing cost pressures

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

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 and the Orphan Drug Program. These services are now partly covered by appropriation funding, however the demand for such services are increasing significantly.

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. There has been a three-fold increase in approved SAS Category B applications for medicinal cannabis over the 12-month period from October 2019 to October 2020. The TGA has approved on average 5,800 applications per month in the last 6 months.

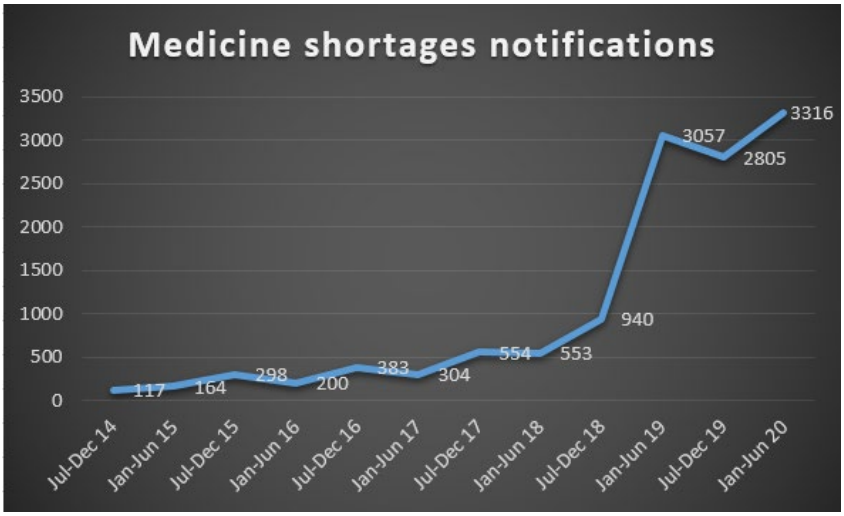


Due to regulatory changes planned to be in place from October 2021, products containing nicotine that support smoking cessation like e-cigarettes will only be able to be obtained with a doctor's prescription. The medical practitioner will apply to get access to the product via the SAS-B or AP pathway. The Australian Bureau of Statistics estimates over 300,000 persons above the age of 18 in Australia use e-cigarettes. The TGA anticipates an increase in SAS or AP applications from October 2021 for which the TGA will require additional resources, however there is not sufficient information to gauge volume of such applications.

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 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 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 550 in January-June 2020; an increase of 50 notifications per month compared to 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 such services where direct cost recovery is not appropriate is estimated to reach $25 million in 2021-22, an increase of $13 million since 2017-18.

Cost of fee free services and new mandatory and legislated activities	2017-18 Actual $m	2018-19 Actual $m	2019-20 Actual $m	2020-21 Forecast $m	2021-22 Estimate $m
Orphan Drugs	3.77	3.30	3.99	3.60	3.60
Special Access Scheme (SAS) - non medical cannabis	3.00	3.00	2.89	2.89	2.91
SAS Medicinal Cannabis			1.27	1.87	2.01
Medicines Shortages	0.14	1.00	1.00	1.31	2.32
Compliance, enforcement and litigation	5.74	6.67	11.60	12.31	12.33
SME Assist		0.68	0.68	0.68	0.69
Emerging Technologies			0.6	1.23	1.53
Total	**12.65**	**14.65**	**22.03**	**23.89**	**25.39**
Direct Government funding			3.20	6.60	8.00
Remaining to be absorbed within fees and charges	**12.65**	**14.65**	**18.83**	**17.29**	**17.39**

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 additionally to this figure.

Corporate Expense	2017-18 Actual $m	2018-19 Actual $m	2019-20 Actual $m	2020-21 Forecast $m	2021-22 Estimate $m
Corporate expenses for IT, HR and Property	36.5	36.04	42.27	43.01	43.5
Residual corporate expenses such as parliamentary, legal and admin support	4.69	4.79	4.88	4.98	5.08
Total	**41.19**	**40.83**	**47.15**	**47.99**	**48.58**

Known cost increases in 2021-22

It is estimated that known increases to the TGA expenses on 2021-22 will be approximately $7.6 million as 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 $2.2 million for 9 months from October 2021 to June 2022. The Department's Enterprise Agreement (EA) mandates an annual increase of 2% for non-senior executive staff during 2021-22 (the increase planned for April 2021 was delayed for 6 months due to the economic impact of the COVID-19 pandemic) with no further increase under the current EA which ends April 2022. Any salary increases as part of future enterprise agreements will comply with Government requirements for staff agreements. The Government has paused pay increases for senior executive staff in response to the economic impact of the COVID-19 pandemic.

b. Increase in other costs

The majority of increase in other costs are due to the current lease for the TGA facilities at Symonston expiring in mid-2022. As a result of the decision to move into new premises in Canberra, the TGA will incur around $4.2 million in 2021-22 which include write down of Symonston assets, make good for the Symonston building and contribution to the new site. In addition to the above, around $1.2 million is estimated as increase in depreciation and corporate chargeback.

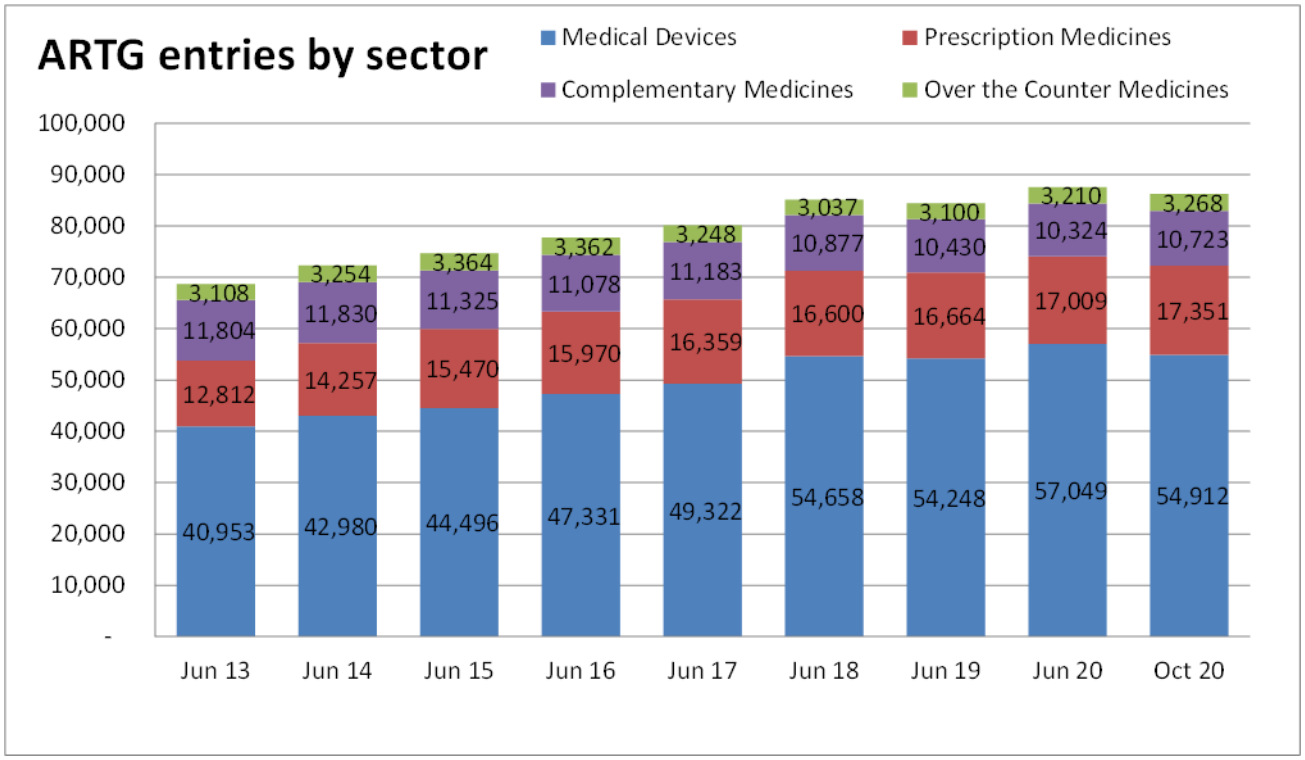
Limited revenue growth

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.

After several years of significant growth in the number of products registered on the ARTG, there was a slight decline of 1% in 2018-19, bringing the total number of ARTG entries to 84,442 at 30 June 2019. A 4% increase in entries was noticed for 2019-20, however 90% of this was due

to COVID-19 related medical device entries. The level of increase in COVID-19 related medical device entries experienced in March-June 2020 is not expected to continue. The October 2020 year to date figure indicates a slight drop of 2% in overall ARTG entries which is expected to continue as COVID-19 related products are removed from the ARTG. Additionally, the revenue foregone due to the ACE scheme continues to be significant (approximately $43.5 million in 2020-21). Of the 87,592 active products in the ARTG at 30 June 2020, only 68,419 were invoiced for the 2020-21 annual charges with the balance of products exempt under the ACE scheme.

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



Indexation factor for 2021-22

The indexation factor for 2021-22, based on the previously used formulae of the average of the CPI and the WPI, is 1.05%:

a. 50% of CPI September 2019 to September 2020 of 0.7% = 0.35%, and

b. 50% of WPI September 2019 to September 2020 of 1.4% = 0.7%.

Potential changes to fees and charges for 2021-22

a. Annual change to fees and charges

A number of options were considered before arriving at the preferred option for 2021-22. These options are discussed below.

Option 1 – No increase in fees and charges

In this option, without any increase to fees and charges for 2020-21, the TGA may run into a deficit of up to $6.2 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 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 absorb the anticipated increase in known costs an increase in fees and charges of 3.6% would be required. The other indirect cost pressures would need to be met through internal efficiencies and business process improvements. While the 3.6% 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 1.05%, 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 preferred option be accepted by Government, additional annual charges revenue of $1.8 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 1.05% increase from 1 July 2021. For example, a company that paid $10,000 in annual charges this financial year would be required to pay $105 more next financial year. Any fee or charge below $470 will not change due to the rounding policy.

b. Evaluation fee for disinfectants

Prior to 1 July 2020, an evaluation fee of $18,600[1] was prescribed at item 9B of Schedule 9 of the *Therapeutic Goods Regulations 1990* to assess whether a therapeutic device is safe for the purpose for which it is to be used. This fee also applied to assess safety of disinfectants (as applicable under Chapter 3 of *the Act*). The term "Therapeutic Device" has become redundant and as part of removing all references to this term in the regulations, item 9B was also removed. Due to an administrative oversight the fee was not retained for disinfectants.

It is proposed to reinstate the evaluation fee at $18,600 from 1 July 2021, subject to the indexation increases for 2020-21, and 2021-22, if approved. Due to the low volume of applications, there is a minimal impact on the TGA's budget and not a wide spread impact on sponsors due to the reinstatement of this fee as we received only one such application this financial year.

[1] *The fee would have increased to $19,000 if the 1.95% indexation increase was applied in 2020-21.*

Stakeholder engagement

a. Consultation on 2021-22 fees and charges proposals

The following industry representative groups were consulted on the proposed changes to fees and charges in December 2020:

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]
11. Assistive Technology Suppliers Australasia
12. Australian Medical Device Distribution Association, and
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 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 the 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 2021-22 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.

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 sections 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 stakeholder 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 the thirteen peak industry bodies which attend the annual bilateral meetings.

A brief summary of the survey results is included in the current 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 updated on the TGA website. We will aim to distribute the next survey in the second half of 2021. Similar to the survey distributed in October 2020, this survey is to specifically obtain industry feedback on TGA's engagement with stakeholders in regards to setting of the TGA's fees and charges.

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 Office of Best Practice Regulation. The proposed indexation increase of 1.05%, 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 2021-22 fees and charges. The TGA will consider the feedback before seeking approval of fees and charges for 2021-22 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 2021. This will allow sufficient notice to sponsors about changes to fees and charges effective from 1 July 2021.

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 Pricing and Decision Review Section	4/02/2020

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