Australian Government
Department of Health
Therapeutic Goods Administration

Fees and charges proposal 2019-20

Consultation paper

Version 1.0, December 2018

TGA Health Safety Regulation

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Contents

Introduction

The Therapeutic Goods Administration (TGA) 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 with an opportunity to comment on options for the TGA's proposed fees and charges for 2019-20. Specifically, we are seeking feedback on the potential impact/s of the proposed options, prior to seeking approval from the Government for any changes.

The TGA reviews its fees and charges annually, in consultation with stakeholders. We also use other consultation mechanisms, as needed, for any significant changes to fees and charges.

Consistent with the above approach, individual meetings with peak industry bodies were held during December 2018 to discuss the proposed changes to fees and charges for 2019-20.

Cost recovery obligations of TGA

The TGA is a part of the Health Products Regulation Group (HPRG) within the Department of Health. 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 and medical devices.

The TGA receives a small appropriation (less than $1 million annually) from Government to meet the cost of activities related to maintaining the Poisons Schedule. All other activities are funded through industry cost recovery.

The *Therapeutic Goods Act 1989* (the Act) provides the legal authority for the TGA to charge for its regulatory activities within the scope of the Act. The *Therapeutic Goods (Charges) Act 1989* (the Charges Act) provides the legal authority to levy annual charges 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 that has been 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 current Cost Recovery Implementation Statement (CRIS) expands further on the cost recovery activities and methodology.

Annual review of fees and charges

The TGA's operations are funded through the annual 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 as well as the annual wage and 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:

- in 2012-13 fees and charges were increased by 5.6%, including 2% to meet the costs of implementation of the TGA Blueprint Reforms; and
- in 2015-16 fees and charges were increased by 2.12% which was lower than the indexation formula (2.5%) and was based on known direct cost increases only.

The TGA budget outlook 2019-20

The TGA has undertaken a review of its financial performance and budget forecast for the 2019-20 financial year. In doing so, it has taken into account the anticipated increases in known costs as well other cost pressures which are mainly due to an increase in a number of regulatory activities that are not directly cost recovered. These anticipated cost pressures and increases are outlined briefly below.

a. Anticipated increase in salary and other costs

In 2019-20, it is estimated that TGA expenses will increase by $6 million - $8 million:

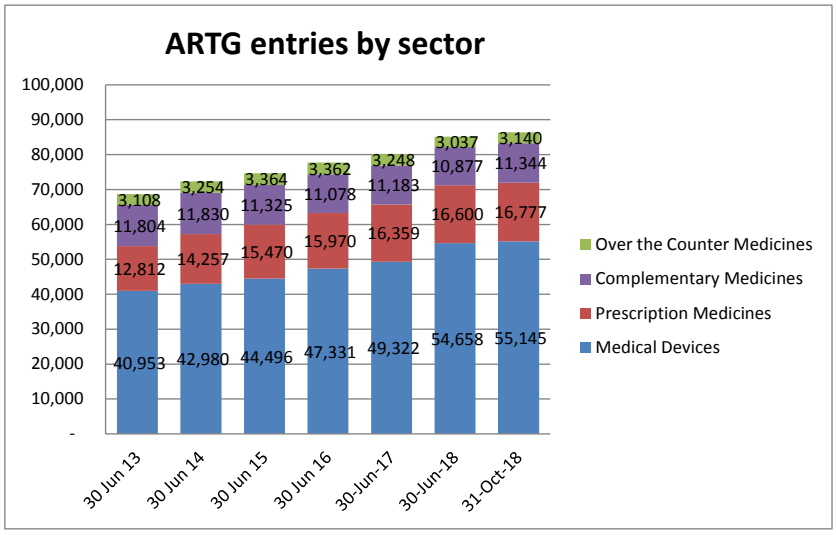
- The single largest component of TGA costs is salary and other staff related costs. The current Department of Health Enterprise Agreement expires in January2019 and negotiations with staff are underway for a new Agreement. It is expected that the new Agreement will be in place soon after the expiry of the existing one. It is anticipated that the new Enterprise Agreement will include an annual salary increase of 2% for non-senior executive staff, in line with the Government's bargaining framework. Additionally, many non-senior executive staff are likely to be due for salary advancement under the Enterprise Agreement. It is estimated that the TGA staff costs will increase by approximately $2.7million in 2019-20.
- The TGA has made a significant capital investment in its business systems (software) as part of the implementation of a range of reforms resulting from the recommendations of the Medicines and Medical Devices Review (MMDR) which the Australian Government accepted. The new items of software will require amortisation over their useful lives. The annual depreciation and amortisation costs of these items is estimated to be approximately $1.5 million annually.
- The broader Department of Health provides the TGA with a range of corporate services, such as information technology, property, human resource and financial management. The costs of these services are paid through a corporate charge back arrangement. In 2019-20, it is estimated that this corporate charge back could increase, mainly due to increases in the number of the TGA staff.

b. Other budget pressures

Revenue from services has increased annually in line with an increase in volume of regulatory activities for which a cost recovery fee is charged. Similarly growth in the number of entries on the Australian Register of Therapeutic Goods (ARTG), subject to the annual charges exemption (ACE), also brings in additional revenue.

The chart below shows growth in ARTG entries by industry sector.

Chart 1

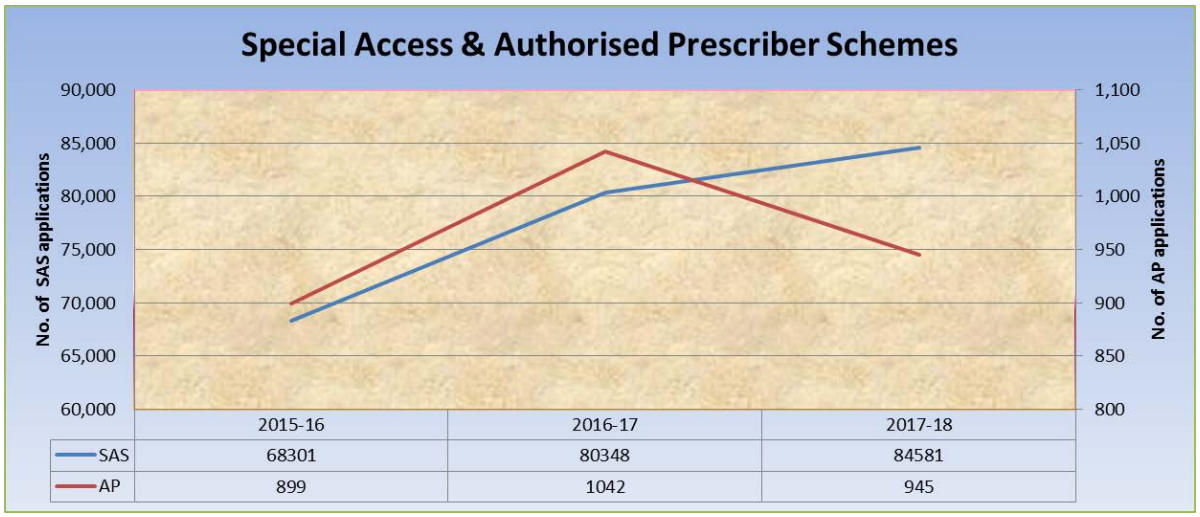


Last year alone the ACE entries grew by 11% to 19,933 compared to a 6% growth in the ARTG entries. The revenue foregone due to the ACE scheme is approximately $39 million. A disproportionate increase in the ACE entries puts pressure on the rates of annual charges.

There are a range of other regulatory activities which the TGA undertakes as part of its regulatory obligation but for which a fee is not charged. These include:

- Orphan drug evaluations conducted through the orphan drug program are undertaken for the public good, with the objective of assisting sponsors bring medicines for rare diseases or new dose forms for special patient populations to market that may otherwise not be viable financially. The incentive provided is in the form of a fee waiver. The estimated revenue forgone in 2017-18 was approximately $3.8 million.
- Patient access to certain unapproved therapeutic goods is critical for the health of the Australian public. The TGA does not charge a fee directly to the users of these services. The patient access schemes are referred to as the special access scheme (SAS) and the authorised prescribed (AP) scheme. In 2017-18, the number of applications under the SAS and AP scheme were 84,581 (an increase of 5% compared to last year) and 945 (a drop of 10% compared to last year) respectively. The annual cost of these services is estimated to be $3 million. Chart 2 below sets out the recent trends in SAS and AP schemes.

Chart 2



- As part of enhancement of its post market and monitoring framework for medicines, the TGA recently introduced a pharmacovigilance inspection program. The program ensures that sponsors are complying with the legislated pharmacovigilance requirements. It also benefits sponsors by providing advice and best practice examples on setting up and running pharmacovigilance systems, which may benefit the sponsor in both productivity and outputs. The pharmacovigilance inspections are risk based, depending on data on current reporting statistics, Good Manufacturing Practice intelligence, high risk products and other issues. The possibility of an inspection occurring for a sponsor at any point in time helps improve compliance and general pharmacovigilance in Australia. The annual cost of this program is approximately $1.3 million.
- The TGA recently launched a medicines shortages framework to enhance the transparency of the availability of the critical medicines. This ensures timely action by the sponsor and/or manufacturer of those medicines.
- In early 2019, the TGA will introduce a domestic Good Clinical Practice (GCP) Program. Under this program, inspections of clinical trial sites for unapproved therapeutic goods will be conducted by the TGA for compliance with GCP standards. The annual cost of this program is estimated to be $0.3 million.
- The medical devices single audit program (MDSAP) has been designed and developed to ensure and provide an efficient yet thorough coverage of the Quality Management System requirements implemented by medical devices manufacturers. These requirements are based on ISO 13485 – Medical devices - Quality management systems, and the specific requirements from the medical device regulations of the Regulatory Authorities that are participating in the MDSAP. The estimated annual cost for MDSAP is around $0.7 million.
- The regulatory policy, design and reform work will continue for a number of areas of advancement of therapeutic goods regulations, including:
  - regulation of companion in-vitro diagnostic medical devices (IVDS);
  - opioid prescription medicines to ensure patient's safety;
  - scoping work for design of a unique device identifier system;
  - software as medical device (SAMD); and
  - managing cybersecurity risks.
- Significant investment is required in the TGA's business and regulatory systems such as:
  - a proposed unique device identification system;
  - updates to TGA's legacy IT systems, for example prescription medicine's premier systems is lotus based and is difficult to maintain or enhance this system; and
  - new medical devices adverse event reporting system is underway.

Indexation factor for 2019-20

The indexation factor for 2019-20, based on the previously used formulae of 50% of the cost price index (CPI) and 50% of the wage price index (WPI), is 2.05%:

- 50% of cost price index Sep 2017 to Sep 2018: 1.9%
- 50% of wage price index Sep 2017 to Sep 2018: 2.2%.

Proposed changes to fees and charges for 2019-20

a. Annual increase to fees and charges

A number of options were considered before arriving at the preferred proposal for 2019-20. These options are briefly 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 $4.5 million. This approach is likely to be inconsistent with the CRGs. In order to minimise the impact of a potential budget deficit, the TGA would likely need to reduce up to 40 staff. This in turn would likely cause delays in completing the increasing number of 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 costs

If the TGA were to increase its revenue to absorb the anticipated increase in known costs only an increase of 2.8% would be required. The other indirect cost pressures would be met through the continuous internal efficiencies and business process improvements. While the 2.8% increase is likely to be consistent with the CRGs, a fee increase that is inconsistent with the long established practice may compromise certainty and transparency for the TGA sponsors and manufacturers.

Option 3: Increase all fees and charges by indexation factor (preferred)

Under this option, fees and charges would increase by 2.05%. 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 this proposal be accepted by the Government, the financial impact on sponsors will be a 2.05% increase from 1 July 2019. For example a company that paid $10,000 annual charges this financial year would be required to pay $205 more next financial year, assuming constant volumes of the ARTG entries and ACE exemptions.

b. Other changes for 1 July 2019 commencement

Lowering the application fee for export only in-vitro diagnostic (IVD) medical devices

Following a review of business processes and subsequent recent change in fees for export only Class I medical devices, the TGA has taken the opportunity to review the process for export only IVD devices. While export only IVD medical devices are included in the ARTG as Class 1 IVD medical devices, the assessment process for these applications is not the same as for other Class 1 devices, resulting in lower costs. This lower cost is because for export only medical devices, TGA principally focusses on verifying the correctness of the information provided by the sponsor. The streamlined process also includes modification of existing software to automatically include export only IVD medical devices in the ARTG. As the process and the work effort related to this is similar to inclusion of export only Class I medical devices, a similar application fee of $90 is proposed. The proposed fee is set to cover not only the direct staff effort required for managing new export only medical device entries but also a component of IT costs required to make a small modification to the TGA business system for such entries.

Listed assessed medicines variations fee

The listed assessed pathways were implemented on 1 July 2018. Since then work has been undertaken to introduce variation fees in line with other pathways. The proposed variation fee structure reflects risk-based application categories and aligns fees to the cost of evaluations. The existing fees for new listed assessed applications as well as for variations to other complementary medicines have been considered in setting the new variation fees for listed assessed medicines. The table below sets out the proposed new fee structure.

Listed Assessed Pathway Variations	Application Fee ($)	Evaluation Fee ($)	Total Fee ($)
L(A) CN include changes to quality and non-quality aspects of a medicine that do not require assessment of efficacy data (or a justification for not providing such data)	790	-	790
L(A) C1 include changes to the product label that do not affect efficacy of the product	1,990	-	1,990
L(A) C2 include changes that may affect efficacy of a medicine	920	7,770	8,690

Good manufacturing practice (GMP) fees

The Government approved a number of changes in GMP fees and charges in June 2018, however delayed the implementation of the following revised fees to 1 July 2019:

- GMP clearance application fee: $640; and
- Compliance verification fee: $2,430.

Note: the above fees would be subject to the indexation change for 2019-20 approved by the Government.

Stakeholder engagement

The following industry representative groups were consulted on the proposed changes to fees and charges in December 2018:

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
11. Assistive Technology Suppliers Australasia
12. Australian Medical Device Distribution Association
13. MTP Connect (although not a peak body) 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 annual fees and charges by the indexation factor. No additional issues were raised in respect of the proposed changes to next year's fees and charges. The TGA asked the peak bodies to bring the proposals to attention of their members.

In order to obtain broader feedback from industry, the TGA encourages all stakeholders to provide their comments on the proposed options for 2019-20 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 Government for consideration and decision.

Regulatory impact assessment

The TGA is not required to prepare a regulatory impact statement (RIS) for amendments to increase fees and charges for therapeutic goods and manufacturing licences. There is a standing agreement in place between the Office of Best Practice Regulation and the Department of Health when using the well-established formula used to calculate these amendments.

The proposed change to the TGA fees and charges that is linked to indexation is within the parameters of the agreement. The proposed indexation increase of 2.05%, as well as the other changes, 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

The TGA will consider stakeholder feedback before seeking approval of the proposed fees and charges 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 would be submitted for consideration by the Federal Executive Committee prior to the next Federal Budget. This will allow sufficient notice to sponsors about changes to fees and charges effective from 1 July 2019.

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	Section/Office	21/12/2018

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

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