Australian Government
Department of Health
Therapeutic Goods Administration

Industry Bilateral Meetings

Strategic and Finance Outlook for 2021-22

December 2020

TGA Health Safety Regulation

Overview

- Recent Funding Decisions
- TGA Charging Review
- Cost Recovery Stakeholder Engagement
- 2019-20 Financial Results (full year)
- Continuing Trends
- Reflection – 2020-21 Fees and Charges
- Potential Changes to Fees and Charges – 2021-22
- Other Possible Changes – 2021 to 2022
- Next Steps

Recent Funding Decisions

- On 2 October 2020, Minister Hunt announced that the Government is investing $12 million over four years to digitise, transform and modernise TGA's business systems and infrastructure.
- This decision was reflected in the 2020-21 Budget – the funding will come from the TGA's special account cash reserves. Ongoing maintenance and support costs will be subject to cost recovery.
- This digital transformation is now in its discovery phase, which includes ongoing consultation with industry.
- In 2021, TGA will commence development of the first set of priorities, including:
    - leverage off the Health Products Portal to deliver a seamless experience for sponsors in their interactions with the Department of Health
    - 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 digital transformation will also result in business process improvement for a more consistent and integrated approach across multiple TGA business functions.

Recent Funding Decisions

- The 2020-21 Budget also included approval for access to $7.7m over four years 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 action, 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 TGA in order to align with international standards.
  - In 2021, TGA will work towards the legislative amendments to be able to build a UDI database along with scoping out the technical requirements.

Recent Funding Decisions

- The 2019-20 MYEFO included Government funding to partially cover activities where cost recovery is not appropriate – e.g. Special Access Scheme, orphan drug program.
- Ongoing funding of $15m is included from 2022-23 to partially fund increasing volumes and related costs that cannot be attributed to specific entity or do not relate to products on the ARTG.
- However it does not fully cover the cost of public good activities such as medicines shortages, support for emerging technologies and compliance & enforcement activities.

Title	Funded by	2019-20 $'m	2020-21 $'m	2021-22 $'m	2022-23 $'m	2023-24 $'m	TOTAL $'m
Improving access to medicines	Government	3.2	6.6	8.0	15.0		**32.8**
TGA digital transformation (DT)	Special Account Cash Reserves		5.6	5.4	4.0		**15.0**
Unique Device Identification (UDI) System	Special Account Cash Reserves		1.7	2.5	2.6	1.0	**7.8**
	Appropriation for each year	**3.2**	**13.9**	**15.9**	**21.6**	**1.0**	**55.6**

TGA Charging Review

- A complete review of TGA's activities is underway; Pricewaterhouse Coopers (PwC) have been engaged to assist with the Review.
- As is currently the case, the Australian Government Cost Recovery Guidelines will be used as the basis for costing the TGA activities and identifying activities not appropriate for cost recovery.
- Data from a six-week time recording exercise undertaken across most of TGA areas will be used as basis to build a new cost model.
- The cost model will be used to explore sustainable funding sources for the activities.
- Consultation with industry to be undertaken if the Review recommends significant changes to fees and charges.
- Any decision on changes to fees and charges will be made by Government after a public consultation.

Charging framework

- Industry cost recovery for regulatory activities is undertaken consistent with the Australian Government Charging Framework and the Cost Recovery Guidelines, as issued by the Department of Finance.

- The policy authority for the TGA to recover running costs for its regulatory activities was announced in the 1997-98 Budget (see Budget Paper No 2 Part II: Revenue Measures); while the legislative basis is set through the Therapeutic Goods Act 1989.

- The objective of the charging review is to assess TGA effort at a process level to determine if expenses and revenue align for each activity.

- Consistent with the Guidelines, the beneficiary of the activity is not what drives the price, but rather the cost of the staff effort and other resources that is attributable to an activity.

Cost Recovery Stakeholder Engagement

- ANAO recommended measuring performance of TGA's engagement with stakeholders specifically in relation to cost recovery.
- The TGA conducted a survey of around 6000 sponsors and 13 industry bodies; which received a response rate of 14%.
- 65% of responses were from the medical device sector, 15% from complementary medicines, and 20% from across other sectors.
- The responses show that there is a good level of awareness of TGA's cost recovery arrangements and public consultation.
- Exploring ways to increase engagement in relation to cost recovery by:
    - increasing direct communication to sponsors through direct emails, webinars and other forums
    - ensuring appropriate timing to allow stakeholders to get involved
    - providing advance notice for fee changes.

Cost Recovery Stakeholder Engagement

- 57 respondents attended meetings in relation to fees and charges

	Nett satisfied	Neither	Nett dissatisfied	Not applicable
The notice provided for the meeting	61%	28%	9%	2%
The time of the year the meeting took place	61%	28%	7%	4%
The level of detail of the information provided at the meeting	70%	12%	16%	2%
The ease of understanding the information provided at the meeting	70%	18%	12%	0%

- While 352 respondents said they were aware of the public consultation, only 67 provided input directly or through a peak body
- TGA will explore ways in which we can improve stakeholder engagement and input into the public consultation

Satisfaction on the below topics	Nett satisfied	Neither	Nett dissatisfied	Not applicable
The timing of the public consultation on TGA website	63%	27%	7%	3%
The period for which public consultation is open for submissions(usually 6 weeks)	73%	16%	7%	3%
The level of detail of the information provided in the consultation paper	75%	18%	6%	1%
The ease of understanding the information provided in the consultation paper	75%	15%	9%	1%

2019-20 – 97 % income expended

	2019-20 Actual ($m)	2019-20 Budget ($m)
Application Fees	28.09	24.69
Evaluation/Conformity Assessment Fees	45.88	46.39
Annual Charges/Licences	74.77	77.42
Appropriation	8.53	2.26
Other Revenue	19.31	18.32
Total Revenue	**176.58**	**169.09**
Employee Expenses	87.92	92.15
Supplier Expenses	29.84	25.51
Corporate costs	45.41	42.23
Depreciation & Amortisation	8.00	9.20
Total Expenses	**171.16**	**169.09**
Operating Surplus/(Loss)	**5.42**	**(0.00)**

- The 2019-20 surplus was due to:
  - increased revenue in all categories except annual charges and evaluation fees combined with Government funding for the opioid reform program and some fee free services
  - while recruitment caps and delays impacted employee spend, this was redirected to contractor resources
  - funds moved into the Special Account reserve to reinvest later (eg; UDI & TGA transformation) $22.8m to be spent in next four financial years)

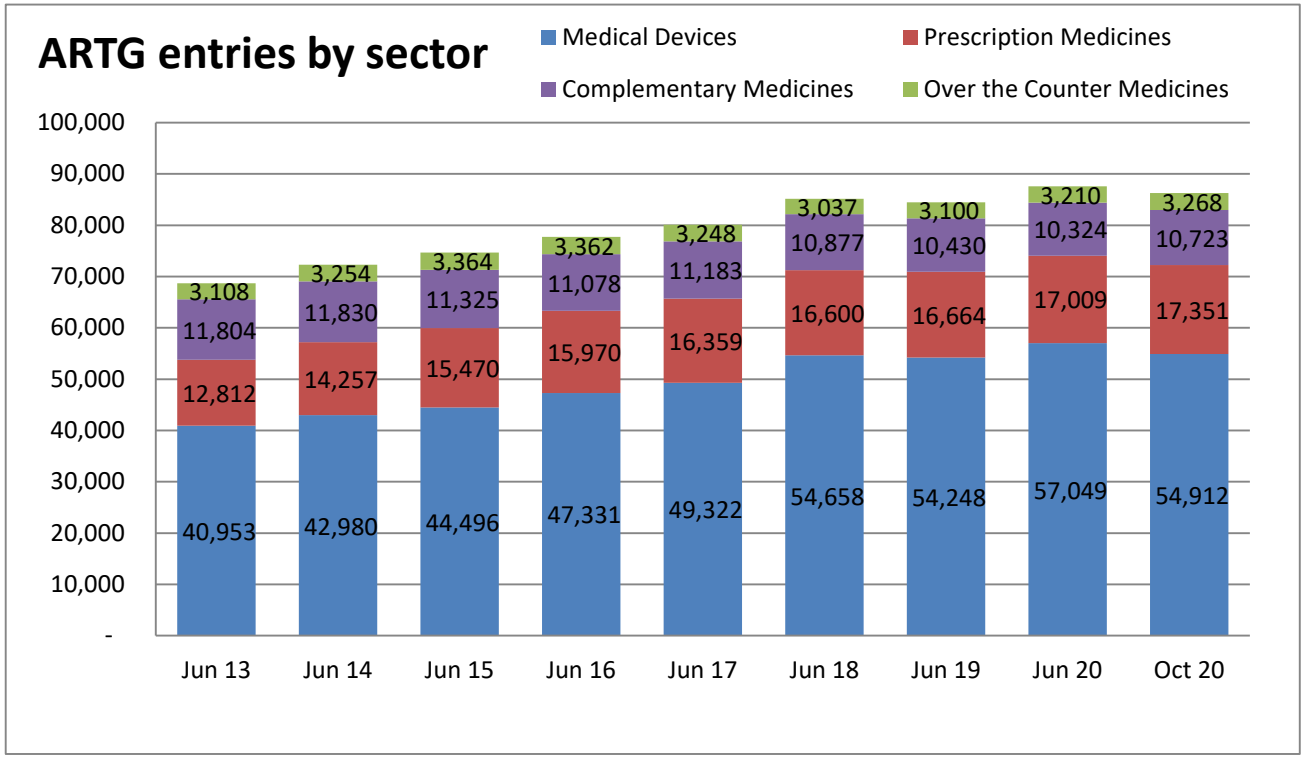
Revenue and Expenses

- Revenue was above budget by $7.49m (4.4%)
  - Dramatic increase in the volume of device applications processed in April and May 2020 due to COVID19 and the need for new pandemic therapeutic products
- Expenses were above budget by $1.76m (1.0%)
  - Employee expenses were below budget by 4.6% due to constraints in recruitments and staff turnover
  - Supplier and corporate expenses were higher than budget by 7.9% with increased spend on contractor resources

TGA cash position

- TGA cash reserves were $89.7m at 30 June 2020
  - Fees received but work yet to be performed - $19.2m
  - Mandatory employee entitlements - $27.0m
  - Available for investment (accumulated depreciation) - $36.6m, part of which will be used for UDI and transformation projects

Continuing Trends



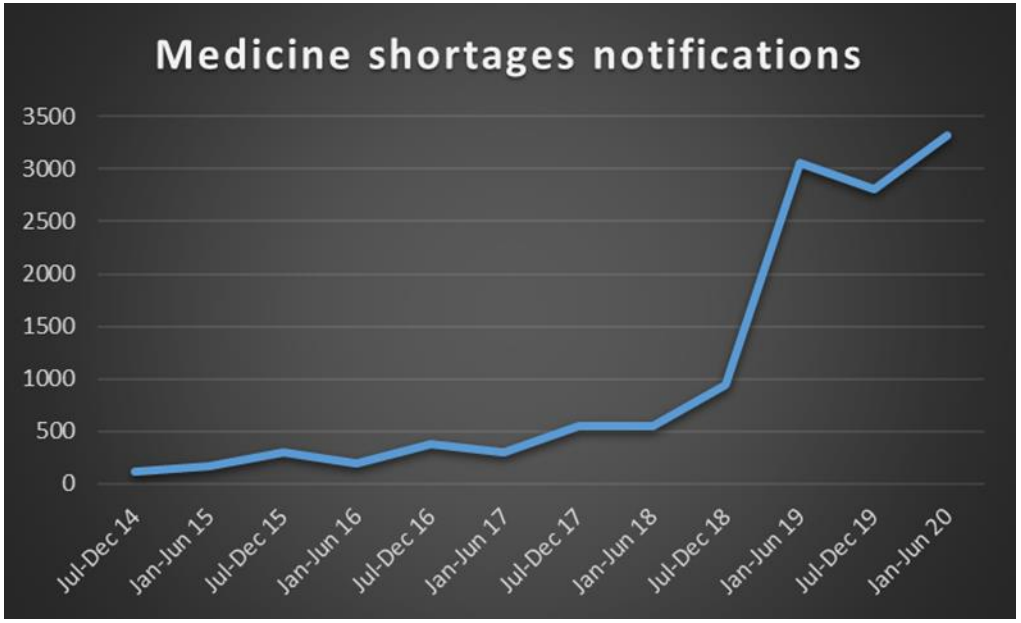
- 2019-20 saw increase in total ARTG entries – mostly from COVID demand for Device Class 1 entries
- 2020-21 no anticipated ARTG entry volume increase
- Forecast deficit of $1.17m for 2020-21 due to expenditure for UDI and digital transformation (funded by cash reserves, not revenue)

Blended workforce – total TGA numbers slowly increasing

	Public Servant staff	Contractors	Total Workers
2016-17	593	125	718
2017-18	562	88	650
2018-19	687	93	780
2019-20	630	172	802
2020-21 (31 Oct 2020)	627	197	824
HPRG Executive	4		4
Medicines Regulation	249	74	323
Medical Devices and Product Quality	244	71	315
Regulatory Practice and Support	114	50	164
Regulatory Legal Services	16	2	18

Non-discretionary TGA Functions

- TGA functions set in law through changes to the Therapeutic Goods Act/Regulations, or flow on from Narcotic Drugs Act changes
- Compliance and enforcement activity increased especially in the advertising space
- Medicines shortages notifications increased to around 500 notifications per month; Medicines shortages task force established



Non-discretionary TGA Functions

Cost of fee free services and new mandatory and legislated activities	2019-20 Actual $m	2020-21 Forecast $m	2021-22 Estimate $m
Orphan Drug	3.99	3.60	3.60
Special Access Scheme(SAS) - non medicinal cannabis	2.89	2.89	2.91
SAS Medicinal cannabis	1.27	1.87	2.01
Medicines Shortages	1.00	1.31	2.32
Compliance, enforcement and litigation	11.60	12.31	12.33
SME Assist	0.68	0.68	0.69
Emerging Technologies	0.60	1.23	1.53
Total	**22.03**	**23.89**	**25.39**
Direct government funding	3.20	6.60	8.00
Remaining to be absorbed within fees and charges	**18.83**	**17.29**	**17.39**

Corporate Expenses

Corporate Expenses	2019-20 Actual $m	2020-21 Forecast $m	2021-22 Estimate $m
Corporate expenses for IT, HR and Property	42.07	42.91	43.01
Residual corporate expenses such as parliamentary, legal and admin support	4.88	4.98	5.08
Total	**46.95**	**47.89**	**48.09**

Reflection – Fees and Charges 2020-21

- Most **fees and charges increased by 1.95%** (50% of CPI/ 50% of WPI)
- Fee for providing **early scientific advice on a bio waiver justification for generic medicines (optional for sponsors)**
- Fee standardisation across all therapeutic categories for **application to obtain Secretary's consent to supply goods that do not comply with applicable standards**
- 50% lower annual charges for **Class IIa, IIb, III and AIMD medical devices listed as prostheses** only in 2020-21 with impact of $2.1m on revenue

Potential Changes for 2021-22

- **Known cost increases alone** would require an increase of 4.4% ($ 7.6m) in fees and charges for 2021-22
  - Employee costs will increase by $2.2m mostly due to 2% salary increase for non-senior executives in 2021-22; no increase to contractor costs forecasted
  - Corporate cost increases of $4.9m (write-downs, depreciation, make good)
- **Propose an "indexation only" change** - composite index is 1.05%
  - 50% of cost price index Sep 2019 to Sep 2020: 0.7%
  - 50% of wage price index Sep 2019 to Sep 2020: 1.4%
  - Provides additional revenue of $1.8m due to indexation
  - Increase in appropriation revenue of $2.32m
  - A decrease of around $2m in COVID influenced revenue due to fewer tests and PPE

Other Possible Fee Changes

- Priority pathway for biologicals including designation fee
- Variations to Clinical Trial approvals
- Clinical trial inspections for medical devices
- Charging for provision of scientific advice
- More pre-submission meetings, especially for medical devices
- Might be more appropriate to consider these changes as part of TGA charging review

Next Steps (indicative)

- Collate peak bodies feedback to inform a consultation paper – Dec 2020
- Release a consultation paper for wider feedback – Jan 2021
- 6 week consultation closes – Mar 2021
- Ministerial approval of proposed changes – Mar 2021
- Prepare regulation amendment and seek approvals – April/May 2021
- Publish updated Cost Recovery Implementation Statement – Jun 2021
- New fees and charges for 2021-22 take effect – 1 Jul 2021