

Efficiency and Effectiveness: Inquiry based on Auditor-General's reports No. 25, 29,
38, 42, 44, 45 and 51 (2018-19)



Australian Government

Department of Health

**Inquiry into Efficiency and Effectiveness: Auditor-General
Report No. 38 (2018-19) Application of Cost Recovery
Principles**

Joint Committee of Public Accounts and Audit

Department of Health Submission

October 2019

Introduction

This submission seeks to provide the Committee with:

- An implementation status update on the Australian National Audit Office (ANAO) recommendations from Report No.38 (20218-19) *Application of Cost Recovery Principles*; and
- An outline of future plans and milestones for actions against recommendations that are still to be completed.

Background

The Therapeutic Goods Administration (TGA), within the Department of Health (Health), is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products. In 1998-99 the TGA moved from partial cost recovery to full cost recovery of its functions from the regulated industry¹. The TGA now recovers its costs from the sponsors and manufacturers of therapeutic goods in accordance with the Australian Government Cost Recovery Guidelines.

On 14 May 2019, the ANAO published the audit report into the *Application of Cost Recovery Principles*. Entities designated for this audit included the Department of Finance (Finance), the Australian Maritime Safety Authority (AMSA), the Department of Agriculture and Water Resources (Agriculture), and Health. The report concluded Health, Agriculture and AMSA were partially effective in implementing the cost recovery principles of the Australian Government's cost recovery framework. The report included the below recommendations:

Recommendation 1

Health should:

- (a) ensure that the TGA's Cost Recovery Implementation Statement is fully compliant with the Cost Recovery Guidelines, including in relation to required updates; and*
- (b) report annually in the Cost Recovery Implementation Statements on its cost recovery performance at the regulatory activity level.*

Recommendation 5

Health should:

- (a) implement a consistent quality assured approach for the collection of staff effort data for use in the cost recovery model of the TGA;*
- (b) adjust charges to reduce cross-subsidisation across industry sectors; and*
- (c) further review the cross-subsidisation of fee-free services and seeks a decision from the Government on how the cost of the services should be met.*

Recommendation 6

Health should:

- (a) implement ongoing stakeholder engagement strategies for the TGA's cost recovery arrangements in consultation with stakeholders;*
- (b) include these planned engagement strategies in the draft Cost Recovery Implementation Statement each year; and*
- (c) include performance measures for engagement on cost recovery in the Cost Recovery Implementation Statements.*

In accepting these recommendations, Health noted the audit stated the TGA's cost recovery policies and methodology are largely compliant with the Australian Government Cost Recovery Guidelines.

¹ 1997-98 Budget, Budget Paper No.2, Part II: Revenue Measures

Health remains fully committed to the effective implementation of the requirements set out in the Cost Recovery Guidelines and has undertaken significant work to address the recommendations within the ANAO report.

Completed actions to address the ANAO recommendations

Recommendation 1

*(a) ensure that the TGA's Cost Recovery Implementation Statement is fully compliant with the Cost Recovery Guidelines, including in relation to required updates; and
(b) report annually in the Cost Recovery Implementation Statements on the TGA's cost recovery performance at the regulatory activity level.*

- a) Cost Recovery Implementation Statements are fully compliant with the Cost Recovery Guidelines

The TGA Cost Recovery Implementation Statements for 2019-20 were updated in accordance with the ANAO audit recommendations to ensure full compliance with the Cost Recovery Guidelines. The assessment of entity Cost Recovery Implementation Statements against the Cost Recovery Guidelines provided in Table 2.2 (page 25) of the ANAO report can be updated as follows:

CRIS criterion	TGA status
Each cost recovered activity, regardless of financial value, must be documented in a CRIS before charges commence.	Fully met
A CRIS is published at the commencement of each financial year and updated progressively throughout the year.	Fully met
Background information on the cost recovered activity, including its purpose, policy outcomes and outputs and description of the activity and the stakeholders who pay charges or may be affected by the charges.	Fully met
Details of the Australian Government policy approval to cost recover the activity.#	Fully met
Details of the legislation authorising the cost recovery charges, including links to primary and secondary legislation	Fully met
An explanation of the costing model for the activity – a description of how the model has been broken into outputs and processes and how these have been costed, including cost drivers and assumptions.	Fully met
An explanation of the design of cost recovery charges – which types of charges have been used and why, including their link to the outputs and processes of the activity.	Fully met
The cost recovery risk assessment rating – the result of the assessment and factors contributing to the rating.	Fully met
A stakeholder engagement strategy, including a summary of the latest engagement round – who was consulted and when, what their views were and how these views have been considered.	Fully met
Financial estimate for the activity (i.e. expenses and revenue) for the budget year and forward estimates.*	Fully met
Reporting on the financial and non-financial performance of the activity.	Fully met
Key forward dates and events, including the next portfolio charging review.	Fully met

CRIS criterion	TGA status
The CRIS is certified by the accountable authority, approved by the responsible minister, agreed for release by the Finance Minister if the cost recovery risk rating is high, and published on the entity's website before charging begins. *	Fully met

*Previously reported as "partially met" in ANAO Report No. 38 2018-19

Previously reported as "partially met" in ANAO Report No. 38 2018-19. Health has put forward a proposal for Government to consider and make a decision related to cross-subsidisation of fee-free services.

The 2019-20 TGA Cost Recovery Implementation Statement has been updated to incorporate actual financial performance for 2014-15 through to 2018-19 as well as forward year estimates for 2019-20 to 2022-23 (pages 34-35 of the Statement).

The 2019-20 TGA Cost Recovery Implementation Statement was certified by the Deputy Secretary Health Products Regulation Group, on behalf of the Accountable Authority, on 11 June 2019 and was approved by the Minister for Health on 19 June 2019. The 2019-20 TGA Cost Recovery Implementation Statement is available on the TGA website.

<https://www.tga.gov.au/cost-recovery-implementation-statement>

- b) Report annually in the Cost Recovery Implementation Statement on the TGA's cost recovery performance at the regulatory activity level.

The 2019-20 TGA Cost Recovery Implementation Statement includes financial performance information at the regulatory level in pages 41 to 46 of the Statement. Financial performance is provided by the following industry sector groups:

- Prescription medicines;
- Over the counter medicines;
- Complementary medicines;
- Medical devices, including in-vitro diagnostic devices;
- Good manufacturing practices;
- Blood, blood components and biologicals; and
- Other activities.

The annual performance statistics report (Appendix 3 in the CRIS) provides detailed non-financial performance information at the regulatory activity level.

Recommendation 1 of ANAO report No.38 of 2018-19 Application of Cost Recovery Principles was presented to Health's Audit and Risk Committee on 28 August 2019. A closure report and supporting evidence was considered and endorsed by Audit and Risk Committee members.

Improvement actions in progress that address the ANAO recommendation

Recommendation 5

- (a) Implement a consistent quality assured approach for the collection of staff effort data for use in the cost recovery model of the TGA;*
 - (b) Adjust charges to reduce cross-subsidisation across industry sectors; and*
 - (c) Further review the cross-subsidisation of fee-free services and seek a decision from the Government on how the cost of the services should be met.*
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- a) Implement a consistent quality assured approach for the collection of staff effort data for use in the cost recovery model of the TGA.

The ANAO assessment of the TGA cost recovery model indicated that it is well structured, calculates prices for regulatory activities based on expected volumes and the cost of outputs that contribute to those regulatory activities, and enables reporting of costs and revenues. Potential improvements were identified in the way Health allocates staff effort as an expected driver to help set charges. Allocation of staff effort has been based on annual surveys conducted across regulatory teams. Inconsistencies across teams in the way the surveys are conducted may create subjective results. For example, some managers utilise direct input from staff, while others provide their own estimates of how long it takes staff to complete a task.

Health has commenced a review and update of the TGA Cost Allocation Methodology and the Cost Recovery Policy. The approach in these updated documents will be mandated to ensure:

- there is consistency in staff effort data collection processes that addresses the previous subjectivity in reporting;
- appropriate quality assurance controls are in place; and
- there is an appropriate use of cost drivers in the TGA activity based costing process.

The revised TGA Cost Allocation Methodology and Cost Recovery Policy will be used to undertake the next staff effort data collection process to update the TGA activity based costing model in 2020-21. The review and update have an estimated completion date of 31 March 2020.

- b) Adjust charges to reduce cross subsidisation across industry sectors.

Health's financial performance for the TGA's cost recovery from 2011-12 to 2017-18 identified an over recovery of costs of \$28.8 million with the majority of over recovery taking place in the prescription medicines and medical devices sectors. Over recovery was mainly a result of delayed expenditure due to slower than anticipated implementation of major reform activities while the Medicines and Medical Devices Review was underway.

Under recovery was noted in the Good Manufacturing Practice and the Blood, Blood Components and Biologicals sectors. Changes were recently implemented in the Good Manufacturing Practice fee structure and reductions in medical devices annual charges to specifically address under and over recovery of costs and cross subsidisation. A similar review has also commenced focussing on fees and charges for the Blood and biological sector.

Health has committed to extending the review of cost recovery across all sectors to identify any systemic or structural issues underlying the over and under recovery of costs. A plan will be developed to address any systemic or structural issues over a three to five year period. The review is anticipated to be completed soon after the Government's decision on the cross subsidisation of fee-free services (discussed below) is known, with implementation of actions to commence from 2020-21.

- c) Further review the cross-subsidisation of fee-free services and seek a decision from the Government on how the cost of the services should be met.

The ANAO Report noted the provision of fee-free services for the Orphan Drug Program and the Special Access Scheme and the cross subsidising of the cost of these schemes results in Health being non-compliant with the Cost Recovery Guidelines. However, the portfolio charging review supported continued cross subsidisation of these schemes with information on scheme costs being reported in the TGA Cost Recovery Implementation Statement.

The Department is currently considering how TGA's fee-free services and other activities, where cost recovery is not appropriate, should be funded.

Recommendation 6

- (a) Implement ongoing stakeholder engagement strategies for their respective cost recovery arrangements in consultation with stakeholders;*
 - (b) Include these planned engagement strategies in their draft Cost Recovery Implementation Statement each year; and*
 - (c) Include performance measures for engagement on cost recovery in their Cost Recovery Implementation Statements.*
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- a) Implement ongoing stakeholder engagement strategies for their respective cost recovery arrangements in consultation with stakeholders.

ANAO's assessment of stakeholder engagement reported Health actively and regularly engaged with stakeholders on the TGA's activities through cost recovery policy development, implementation and review stages.

The TGA has a long standing practice of undertaking targeted consultation with peak industry bodies regarding fees and charges. Bilateral meetings are conducted each year with a focus on the forthcoming financial year. The TGA asks the peak bodies to bring any proposals for fees and charges to the attention of their members. Around the same time, the TGA publishes a public consultation paper on fees and charges to provide an opportunity for wider industry and other stakeholders to comment on the proposed fees and charges.

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 uses a number of forums to consult and disseminate information regarding the TGA cost recovery, including:

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

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

Based on stakeholder feedback, the TGA has enhanced the consultation process for the 2019-20 fees and charges. In addition to inviting three additional medical industry bodies, the TGA also brought forward the bilateral meetings to December 2018 to provide more notice of changes to sponsors. Additionally, a public consultation paper was released in December 2018 to seek feedback from stakeholders and other interested parties on the proposed changes to fees and charges for the 2019-20 financial year.

Health is committed to building on a solid base of sound stakeholder management and has commenced to document the TGA's Stakeholder Engagement Strategy on its cost recovery arrangement. This Strategy supports ongoing bilateral meetings with peak industry bodies and the drafting and release of public consultation papers on any proposed changes to fees and charges. The Stakeholder Engagement Strategy is anticipated to be finalised by 31 March 2020.

- b) Include these planned engagement strategies in their draft Cost Recovery Implementation Statement each year.

Stakeholder consultation and stakeholder engagement was included in the 2019-20 TGA Cost Recovery Implementation Statement (page 31 to 33).

- c) Include performance measures for engagement on cost recovery in their Cost Recovery Implementation Statements.

Health undertakes a stakeholder survey annually to seek feedback on its stakeholder engagement. While the next survey is planned in June 2020, Health has commenced an assessment of the current TGA Stakeholder Survey questions with a view to develop and add additional questions specific to engagement of stakeholders on cost recovery. This will include developing metrics to measure the engagement on cost recovery being incorporated into the 2020 Stakeholder Survey. The results of these Surveys will be included in TGA Cost Recovery Impact Statements from December 2020.