Australian Government
Department of Health
Therapeutic Goods Administration

GMP Fees and Charges

2018 GMP Forum

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TGA Health Safety Regulation

Cost Recovery

- TGA operates on full cost-recovery (different to some O/S regulators)
- Cost recovery should align costs incurred with costs recovered
- Cost recovery mechanisms should:
  - optimise demand for activities
  - improve efficiency and responsiveness of government activities and accountability for those activities.

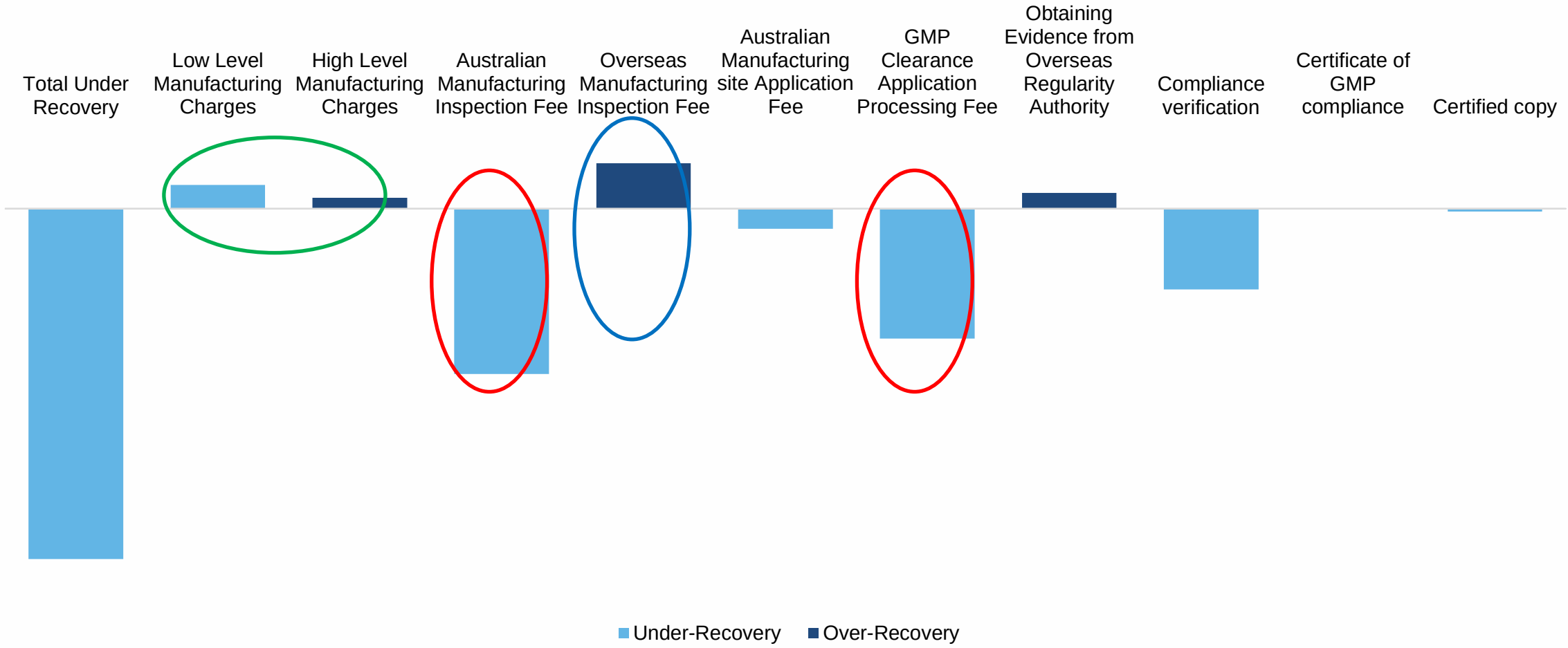
Review of the current model

- There has been consistent under recovery from sponsors and manufacturers in relation to Good Manufacturing Practice (GMP). While the level of under recovery increased significantly last year and this year, the average under recovery in the last 4 years was $2.1 million.

- Deloitte were engaged to review the fees and charges associated with Medicines Good Manufacturing Practice (GMP). The purpose of the review was to improve the accuracy and transparency of the cost recovery arrangements for that regulatory function and address a significant under recovery over the past four financial years.

	2013-14 $m	2014-15 $m	2015-16 $m	2016-17 $m	Average $m
Revenue	12.1	12.1	11.2	10.0	11.3
Spend	13.5	12.9	13.2	14.4	13.5
Under – Recovery	-1.4	-0.7	-2.0	-4.4	-2.1

Analysing the under-recovery



Exploring the possibilities

- TGA provided comprehensive activity-based cost data on its regulatory activities as well as de-identified data on the fees and charges currently levied on medicines manufacturers and sponsors utilising overseas manufacturers.

- Deloitte analysed data across four financial years and built costing models to help identify key issues. The review of Medicines GMP cost recovery was conducted in accordance with relevant requirements of the *Therapeutic Goods Act 1989* (the Act) and Cost Recovery Guidelines (RMG 302).

- A number of potential solutions had an administrative burden that could not be justified. While it may be more accurate to introduce a longer list of disaggregated fees under the cost recovery guidelines, the additional administrative burden in some cases would outweigh the additional benefit from the process efficiency perspective.

Consultation summary

- Deloitte's consultation paper was published on the TGA website and stakeholders were asked to submit feedback.

- Deloitte's paper included 3 options. Option 3B was developed following further analysis by Deloitte and feedback from Industry at the roadshows

- As part of the consultation, a number of roadshows were held in Sydney, Brisbane and Melbourne between 14th and 19th February 2018.

- The proposed fees and charges for 2018-19 were also discussed at bilateral meetings with peak therapeutic Industry bodies in December 2017 and February 2018. Several follow-up meetings were also arranged. In addition, the proposed fees and charges were also discussed at the TGA Industry Working Group on GMP (TIWGG) meeting on 15 March 2018.

Outcome of industry consultations

Most stakeholders supported the TGA's need to fully cost recover activities and a model which encourages increased compliance.

Several stakeholders separately suggested a modified version of option 3; introducing an increased fee for CV's while reducing the increase to the GMP Clearance fee.

Option 2 was generally support by sponsors and option 3 by manufacturers. There was very little support for option 1

Feedback indicated that some stakeholders had already set their budgets or had a different budget cycle to the TGA and as a result, implementation of GMP Clearance increases at 1 July 2018 would have an adverse affect on their business.

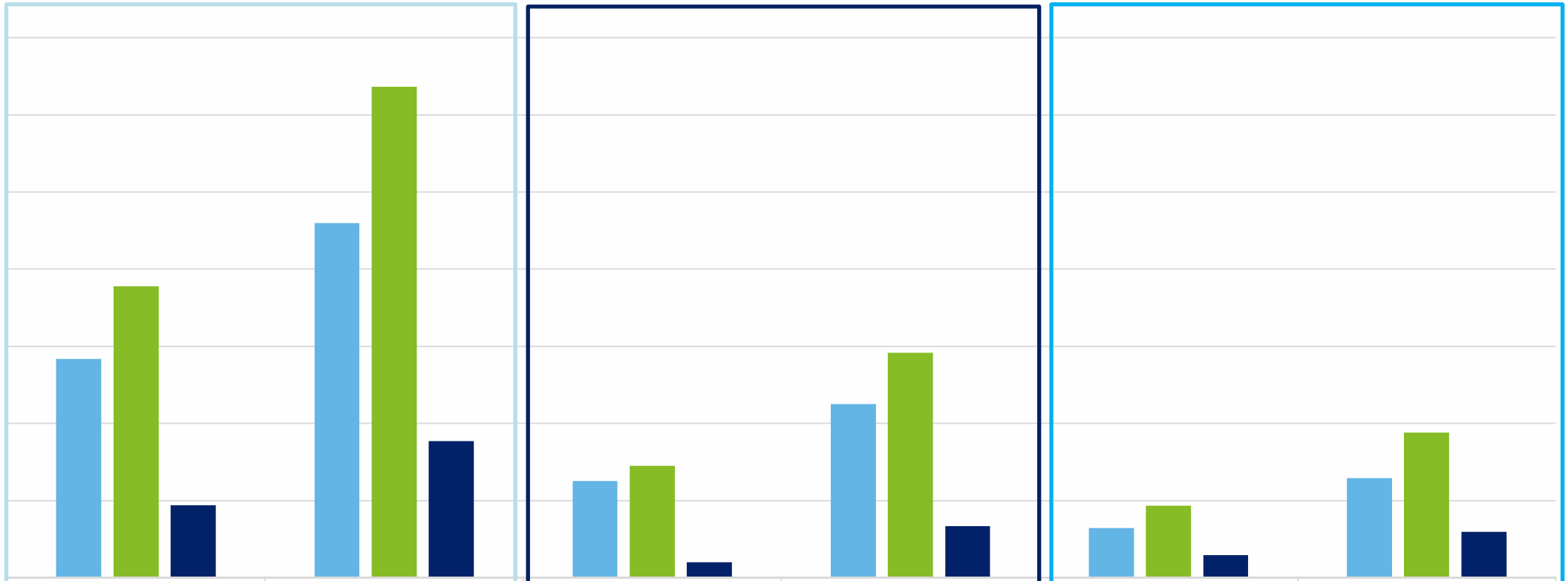
Stakeholders requested a phased implementation arrangements to reduce the impact of the increases. In response TGA developed a phased implementation strategy.

Several submissions included suggestions that improvements/efficiencies to GMP processes could reduce the need to increase fees and charges.

Options – Fee Table

Fees and Charges	Current Fee	Option 1	Option 2	Option 3	Option 3B
Fees and Charges for Australian Manufacturers					
Annual Manufacturing Charges	-	-	$6,000	$4,590	$4,590
Low-Level Manufacturing Charges	$6,260	$7,352	-	-	-
High-Level Manufacturing Charges	$12,200	$14,328	-	-	-
Australian Manufacturing Hourly Inspection Fee	$660	$775	$1,150	$970	$970
GMP Licence Application Fee	$1,000	$1,174	$1,000	$770	$770
GMP Licence Variation Fee	-	-	-	$770	$770
Certificate of GMP Compliance	$170	$200	$170	$170	$170
Certified Copy	$60	$70	$60	$60	$60
Fees for Overseas Manufacturers					
Overseas Manufacturing Hourly Inspection Fee	$1,330	$1,562	$1,400	$1,330	$1,330
Overseas Inspection Travel costs	Recovered at cost				
Fees for GMP Clearance					
GMP Clearance Application Processing Fee	$390	$458	$390	$790	$640
Obtaining Evidence from Overseas Regularity Authority	$680	$799	$680	$680	$680
Compliance Verification	$2,030	$2,384	$2,030	$2,030	$2,430

Industry Impact – Domestic Manufacturers



	High risk, high level, high compliance manufacturers	High risk, high level, low compliance manufacturers	Low risk, high level, high compliance manufacturers	Low risk, high level, low compliance manufacturers	Low risk, low level, high compliance manufacturers	Low risk, low level, low compliance manufacturers
Existing	$28,374	$45,974	$12,534	$22,507	$6,418	$12,871
Option 3	$37,782	$63,649	$14,502	$29,160	$9,329	$18,813
Annual Increase	$9,408	$17,675	$1,968	$6,653	$2,911	$5,942

Industry impact - Sponsors

- Under option 3
  - Increased cost of $400 per GMP Clearance application. Sponsors who have more GMP clearances are more impacted.

- Under option 3B
  - Increased cost of $250 per GMP Clearance application and $400 per Compliance Verification (CV) application. Sponsors who have more CV GMP clearances are more impacted.

Phased implementation

- **1 July 2018**
  - New Fees and Charges for Australian manufacturing activities become effective
  - No more ‘free’ inspection hours will be accrued
  - Existing ‘free’ hours will be honored by TGA
- **1 July 2019**
  - Existing ‘free’ hours continue to be honored by TGA
  - Introduction of increased GMP Clearance application processing fee
  - Introduction of increased Compliance Verification fees
- **1 July 2020**
  - All free hours will have been honored; Full implementation

- Fees related to Domestic Manufactures to become effective from 1 July 2018
- Introduction of a single annual licence charge, with no further accrual of ‘free hours’
- Introduction of increased domestic inspection hourly rates
- Introduction of licence variation fee
- Fees related to GMP Clearances to become effective from 1 July 2019
- There are no proposed changes to the fees related to overseas inspection



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