



## **Therapeutic Goods Administration**

### Good Manufacturing Practice Fee Model Review

February 2018

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# Executive Summary

## Why was this review required?

The Therapeutic Goods Administration (TGA) engaged Deloitte to review its Medicines Good Manufacturing Practice (GMP) fees and charges to improve the accuracy and transparency of the cost recovery arrangements for that regulatory function and to address a significant under recovery of costs associated with Medicines GMP.

The Department of Health, through the TGA, has an obligation to conduct periodic review of existing and potential charging activities.

## What was our approach?

The 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. We then developed options for improving the cost recovery arrangements.

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).

Deloitte has also examined the fees and charges levied by the TGA's international counterparts for comparable functions.

A review of the overall level of the fees was beyond the scope of Deloitte's terms of reference. However, the TGA advises that it minimises GMP inspection costs through extensive use of desktop clearances and active involvement in Mutual Recognition Agreements (MRAs). The duration and number of inspectors for individual inspections (and thus their cost) also benchmark with comparable overseas regulatory agencies and international requirements under the PIC/S (Pharmaceutical Inspection Cooperation Scheme) guidelines.

## What did we discover?

The review identified three key issues:

1. Net under-recovery of regulatory costs across Medicines GMP;
2. The biggest contributor to that under-recovery is that the TGA has not been fully recovering the cost of all inspection hours; and
3. There is poor alignment of some fees and charges to the actual effort incurred

Across the four financial years 2013-14, 2014-15, 2015-16, and 2016-17, the average under-recovery for Medicines GMP was \$2.1 million per annum (Table 1).

*Table 1: Total GMP revenue and spend over a four year period*

	2013-14	2014-15	2015-16	2016-17	Average
	\$m	\$m	\$m	\$m	\$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

The single biggest area of under-recovery relates to GMP domestic inspection hours. The TGA is not presently recovering the cost of all inspection hours. The current practice of the TGA is to include a fixed number of inspection hours that will be undertaken but not billed over a three-year period. These have come to be known as 'free' hours (and for ease of reference, this is how they will be referred to throughout this report).

They are not, in fact, 'free'. The TGA incurs a cost for these inspections and should be recovering that cost as and when these inspections are undertaken. Under current arrangements, part but not all of these costs are implicitly recovered through the annual charge being higher than it otherwise would be.

Given the easily identifiable nature of the time spent on inspections, under-recovery is an issue that can be readily rectified.

As identified above, there is also a related distortion in the Medicines GMP annual charge which also needs to be rectified. The current annual charge includes an implied allowance for 'free' inspection hours, but the level of the charge is not based on the level of regulatory activity nor the regulatory costs incurred by the TGA.

Both the under-recovery of the cost of inspections and the distortion in the annual charge are inconsistent with the cost recovery guidelines (RMG 302) and should be rectified.

In recommending the TGA properly recovers the cost of all inspection hours, we also recommend the TGA simplify and reduce the level of the annual charge to remove any implied 'free' inspection hours.

We have also identified opportunities to improve the recovery of regulatory costs for GMP clearances and domestic licence variations.

### What do we suggest?

We have developed three options that all improve the level of cost recovery for Medicines GMP.

**Option One (Uniform Increase)** would address the under-recovery across the Medicines GMP function by uniformly increasing all fees and charges by 17.4% to arrive at an additional \$2.1 million in revenue. This option is administratively simple for the TGA and industry and proportionately spreads the additional cost.

All manufacturers and sponsors would share the cost of rectifying the under-recovery. However, it does not match cost recovery with regulatory effort and further complicates the misalignment of costs associated with the annual charge.

This option does not actively encourage a higher level of compliance by manufacturers. It does not align well with the cost recovery guidelines.

Full details of Option One are set out on page 11.

**Option Two (Minimal Change)** focusses on rectifying the two most obvious issues associated with the net under-recovery. This option would have the TGA recover the cost of all inspection hours. There would be no implied 'free' inspection hours within the annual charge. Under this option, the annual charge, currently set at different levels for 'high' and 'low' levels of activity, would be merged and reduced. This option does not actively encourage a higher level of compliance by manufacturers and does not specifically address under-recovery in GMP Clearances (which have become an increasing part of the Manufacturing Quality Branch's business).

Full details of Option Two are set out on page 13.

**Option Three (Optimise)** builds on Option Two but also addresses under-recovery in GMP Clearances and Licence Variations with the introduction of one new fee and an increase in another. This option also includes a reduction in the hourly fee for inspections when compared to Option Two, as these improved cost recoveries against GMP Clearances and Licences results in a lower level of remaining regulatory cost to be recovered through the inspection fee.

Full details of Option Three are set out on page 15.

**Recommended approach:** Considering the better alignment of regulatory activity costs with a mix of the fees and charges used to recover those costs, Deloitte recommends **Option Three (Optimise)**. This option encourages a higher level of compliance by manufacturers in order to reduce regulatory fees and charges and addresses all major areas of under recovery.

A summary of the elements of each option, with a comparison to the current arrangements, is set out on page 9, followed by a summary of the fees and charges that would change under each.

# The Problem

## Background

As part of the Department of Health, the Therapeutic Goods Administration (TGA) safeguards and enhances the health of the Australian community through effective and timely regulation of therapeutic goods. The TGA is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose.

As an element of the regulation of therapeutic goods, Good Manufacturing Practice (GMP) describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality.

Manufacturers of medicines located in Australia are required to hold a licence to manufacture, unless exempt under the *Therapeutic Goods Act 1989*. To obtain a licence, a manufacturer must demonstrate compliance with the relevant code of GMP. This is usually, but not always, done through an on-site inspection.

Overseas manufacturers of medicines supplied to Australia are also required to meet an acceptable standard of GMP. TGA may issue GMP clearance to sponsors of a medicine or Active Pharmaceutical Ingredient (API) that is manufactured overseas if there is acceptable evidence demonstrating that the overseas manufacturer complies with the principles of GMP.

The TGA operates under a full cost-recovery model. To the extent reasonably possible, the TGA matches the costs of regulation with the revenue collected from industry for regulated activities. In a perfect scenario, revenue would exactly offset the cost of each activity - without any under-recovery, over-recovery or cross-subsidisation.

Where possible, the TGA bases its regulatory charges on an activity-based pricing methodology – meaning that regulatory fees and charges are set at levels that take account of the volumes and associated costs of the activities undertaken by the TGA. Aggregated prices (such as annual charges) are used to recover costs that cannot be easily or directly associated with chargeable activities.

The TGA is committed to continuous improvement in its regulatory and business practices. As the TGA continues to refine its pre-market and post-market activities to improve regulatory practices, it is also necessary to review the basis of cost recovery to maintain reasonable transparency and efficiency.

The TGA commissioned Deloitte to review fees and charges associated with Medicines Good Manufacturing Practice (GMP).

This review did not consider fees and charges related to medical devices, human blood, blood component, haematopoietic progenitor cells (HPC) and biologicals.

## Medicines GMP is under-recovering

Over the past four financial years, the Medicines GMP function has under-recovered an average of \$2.1 million per annum. The individual under-recoveries ranged from \$0.7 million in 2014-15 up to \$4.4 million in 2016-17. The variance in under-recovery is driven by differing activity mixes and volume movements in each year.

The largest component of under-recovery (average of \$2.1 million over the past four years) relates to the annual charge and the implied apportionment of some inspection costs within that annual charge. The aggregate pricing approach to the annual charge is problematic because:

- Inspection costs are reasonably identifiable activities that should more properly be activity-priced under the cost recovery guidelines rather than amalgamated within an aggregate charge;
- It does not differentiate between the relative compliance histories of different manufacturers and is likely to result in cross-subsidisation of those with a poorer compliance history by those with a good compliance history;

- It removes incentives and opportunities for industry to reduce the total amount it pays through improved compliance and fewer chargeable inspection hours; and
- The current fees and charges have not been specifically updated to allow for changes in the cost of the base/assumed inspection level.

The existence of each of these mismatches will result in some level of cross-subsidisation within the Medicines GMP environment and across the organisation more broadly. This reduces the transparency of cost recovery arrangements for industry and makes it harder for the TGA to demonstrate an efficient and accountable approach to its regulatory work.

One of the key consequences of the under-recovery, also highlighted above, is a lost opportunity to use regulatory pricing as a signal to improve compliance practices (manufacturers with strong positive compliance practices and records could reduce their regulatory costs if the TGA could maintain oversight with fewer inspection hours).

# Constraints

The following paragraphs set out the key constraints on the options we could consider, or approaches we could take, in conducting this review.

## Cost Recovery Compliance

The TGA has the legal authority to charge for regulatory activities that fall within the scope of the Act. It must also comply with the Australian Government Cost Recovery Guidelines (CRGs) that set out the framework for the design, implementation, and review of cost recovery activities.

## Administration effort

The TGA collects high quality data on the regulatory activities it undertakes and the cost of those activities. This data could have supported creation of a finely-grained schedule of fees and charges – with larger number of defined activities and associated costs – that was even more precisely matching activities and costs. However, the administrative burden of that approach would have been very high for both the TGA and industry. The additional administrative costs of the TGA would also need to be recovered through those same fees.

We formed the view that a more detailed schedule of fees and charges would not be efficient at this point in time. There is not enough differentiation in the mix of regulatory activities associated with different products and manufacturer/sponsor combinations to warrant such a large change. Hence, only one new fee has been proposed - within Option Three.

The TGA will continue collecting comprehensive data on its regulatory activities - enabling re-examination of the efficiency of further changes at the next review.

## Year-on-year volatility

When calculating the proposed fees and charges, there was a significant volatility in the fee amount depending on what year's data was used in the calculation. To mitigate against this year-on-year volatility, the calculations were conducted using data from the past four financial years. Under the options proposed, if volumes of GMP clearances or inspections are lower in a particular year than these averages, the total fee impact on industry will also be lower.

## Modelling

Modelling supporting this review is based on the data collection and analysis performed by the TGA costing team and provided to Deloitte. Deloitte has assumed data provided by the TGA are valid. Volume is based on TGA's forecast. Deloitte has not verified the accuracy of TGA data.

# Options Overview

## Option One (Uniform Increase)

Option One recovers the average deficit of the previous four financial years, however, maintains the same fee structure used presently. There is a uniform percentage increase in all fees and charges.

This option distributes the impact proportionately across all manufacturers and sponsors accordingly to the value of their mix of regulatory fees and charges.

## Option Two (Minimal Change)

Option Two recovers the average deficit of the previous four years and improves the logic of the fee structure by recovering inspection hours at cost, whilst consolidating and reducing annual charges.

This option is a mild improvement in the efficiency of cost recovery but misses the opportunity to make more significant improvements.

## Option Three (Optimise)

Option Three builds on Option Two. In addition to recovering inspection hours and consolidating annual charges, Option Three also sees the GMP Clearance Application Processing Fee increase and the introduction of a new Domestic Licence Variation Fee - which would be more consistent with regulatory requirements.

This option accounts for the year-on-year deficit as well as spreading the recovering the average deficit over multiple fees and charges.

*Table 2 (on page 10) provides a summary of the three options for the recovery of Medicines GMP regulatory costs.*

Table 2 - Three options for the recovery of Medicines GMP regulatory costs



	Current State	Option One	Option Two	Option Three
Average of four financial years used to determine cost of activity	ü	ü	ü	ü
<b>Uniform Increase</b> of all fees and charges	x	ü	x	x
<b>Fully Recover</b> Inspection Hours	x	x	ü	ü
<b>Merge</b> Low and High Annual Licence Charge (which also leads to a reduction in charge)	x	x	ü	ü
<b>Introduce</b> Application Fee (\$770) for licence variation applications (domestic licence application will also reduce from \$1,000 to \$770)	x	x	x	ü
<b>Increase</b> GMP Clearance Application Processing Fee	x	x	x	ü

Fees and Charges	Current Fee (\$)	Option 1 (\$)	Option 2 (\$)	Option 3 (\$)
Annual Manufacturing Charges	-	-	6,000	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
Overseas Manufacturing Hourly Inspection Fee	1,330	1,562	1,400	1,330
GMP Licence Application Fee	1,000	1,174	1,000	770
GMP Licence Variation Fee	-	-	-	770
GMP Clearance Application Processing Fee	390	458	390	790
Obtaining Evidence from Overseas Regularity Authority	680	799	680	680
Compliance Verification	2,030	2,384	2,030	2,030
Certificate of GMP Compliance	170	200	170	170
Certified Copy	60	70	60	60

Table 2: Cost Recovery Option Overview

# Option One

## Uniform increase across all fees

### Rationale

Option One recovers the average deficit across the previous four financial years, maintaining the same fee structure used presently. There is a uniform percentage increase of 17.4% across all fees and charges.

This option was developed to uniformly (proportionately) distribute the impact across all manufacturers and sponsors.

### Impact on Industry

- All fees and charges will increase;
- All manufacturers and sponsors will pay more; and
- The impact is distributed according to financial value. Those who currently pay least will incur the smallest increase.

### Consistency with Cost Recovery Guidelines

- Of the three options, this has the least consistency with the cost recovery guidelines, because cross-subsidisation will still occur.

### Benefits of this option

- Minimises disparity across industry (no 'winners and losers') as there is a uniform increase of all fees and charges;
- Relatively simple to administer and forecast; and
- Retains 'free' inspection hours.

### Limitations of this option

- This option retains the broad pattern of under and over recovery across all fee types;
- Cross-subsidisation of activities will still occur because the cost of 'free' inspection hours is absorbed in other fees and charges. This is inconsistent with the TGA's cost recovery obligations – especially where the activities and costs can be so easily identified and quantified; and
- No incentives created for highly compliant manufacturers (fewer chargeable inspection hours).

### Assumptions

#### *Inspection Fee*

- Volume was calculated by multiplying average variable hours per inspection by the number of annual inspections.
- Total variable hours are assumed to be 24 hours for domestic inspections and 35 hours for overseas inspections. Provided and validated by TGA.

## Fee Table

Table 3: Option One – Uniform increase across all fees

<b>Fees and Charges</b>	<b>Current (\$)</b>	<b>Future - Option 1 (\$)</b>
Annual Manufacturing Charges	-	-
Low-Level Manufacturing Charges	6,260	7,352
High-Level Manufacturing Charges	12,200	14,328
Australian Manufacturing Hourly Inspection Fee	660	775
Overseas Manufacturing Hourly Inspection Fee	1,330	1,562
GMP Licence Application Fee	1,000	1,174
GMP Licence Variation fee	-	-
GMP Clearance Application Processing Fee	390	458
Obtaining Evidence from Overseas Regularity Authority	680	799
Compliance Verification	2,030	2,384
Certificate of GMP Compliance	170	200
Certified Copy	60	70

# Option Two

## Minimal changes to the fees and charges construct

### Rationale

Option Two recovers the average deficit across the previous four years and improves the logic of the fee structure.

This option:

- Recovers all inspection hours at cost;
- Increases the domestic and overseas inspection hourly rate, when compared with current fees; and
- Merges low licence annual charge and high licence annual charge into a single annual licence charge for all domestic manufacturers.

This option was developed to rectify some areas of under recovery with a 'minimalist' change in the structure of fees and charges.

### Impact on Industry

- High-level annual charge manufacturers will see an annual charge decrease of \$6200 when compared with the current charge;
- Low-level annual charge manufacturers will see an annual charge decrease of \$260 when compared with the current charge;
- The practice of accruing unbillable ('free') inspection hours will cease; and
- The inspection hourly rate will increase by \$490 per hour for domestic inspections, and \$70 per hour for overseas inspections, compared with the current fee.

### Consistency with Cost Recovery Guidelines

- While making small improvements, this option still misses simple opportunities for improving consistency with cost recovery guidelines.

### Benefits of this option

- Annual charges reduce, compared with current charges;
- All inspection hours recovered at cost;
- Simplifies the regulatory process through introduction of a single annual charge; and
- Incentives created for highly compliant manufacturers (fewer chargeable inspection hours).

### Limitations of this option

- Increases in inspection hourly rates and changes to the annual charge allowances are accounting for the four-year deficit across all fees and charges;
- GMP clearance and domestic licence variation remain under-recovered (cross-subsidised by other fees and charges); and
- No further accrual of 'free' inspection hours from 1 July 2018

## Assumptions

- As per Option One and the following:

### Annual Charges

- The cost base for the merged annual fee was calculated as a total of the high-level and low-level annual charge cost bases; and
- Volume was a total of the high-level and low-level annual charge volumes.

## Fee Table

Table 4: Option Two

<b>Fees and Charges</b>	<b>Current (\$)</b>	<b>Future - Option 2 (\$)</b>
Annual Manufacturing Charges	-	6,000
Low-Level Manufacturing Charges	6,260	-
High-Level Manufacturing Charges	12,200	-
Australian Manufacturing Hourly Inspection Fee	660	1,150
Overseas Manufacturing Hourly Inspection Fee	1,330	1,400
GMP Licence Application Fee	1,000	1,000
GMP Licence Variation fee	-	-
GMP Clearance Application Processing Fee	390	390
Obtaining Evidence from Overseas Regularity Authority	680	680
Compliance Verification	2,030	2,030
Certificate of GMP Compliance	170	170
Certified Copy	60	60

# Option Three

## Efficiently optimise the fees and charges construct

### Rationale

Option Three builds on Option Two and includes the following:

- Recovers inspection hours at cost;
- Increases the domestic inspection hourly rate when compared with current fees;
- Merges low licence annual charge and high licence annual charge into a single annual licence charge for all domestic manufacturers;
- Increases the GMP Clearance Application Processing Fee;
- Decreases the new GMP Licence Application Fee; and
- Introduces a new Domestic Variation Application Fee to recover the cost of activities such as review of variation applications for GMP licences and to make a determination if an on-site inspection would be required.

This option was developed to rectify the under-recovery with a more efficient/optimal set of changes in the structure of fees and charges.

### Impact on Industry

- High-level annual charge manufacturers will see an annual charge decrease of \$7610 when compared with the current charge;
- Low-level annual charge manufacturers will see an annual charge decrease of \$1670 when compared with the current charge;
- GMP licence application fee will reduce by \$230 when compared with the current charge;
- Introduction of a new domestic licence variation fee;
- Domestic manufacturers better off than under Option Two as there is less of an increase to the domestic inspection hourly rate and they will no longer be cross-subsidising GMP clearances;
- The domestic inspection hourly rate will increase by \$310 per hour, compared with the current fee; and
- The practice of accruing unbillable 'free' inspection hours will cease.

### Consistency with Cost Recovery Guidelines

- With better matching of cost and recovery, this option has the best alignment with cost recovery obligations.

### Benefits of this option:

- Annual charges reduce further than Option Two;
- Lower domestic inspection fees than Option Two;
- Simplifies the regulatory process through introduction of a single annual charge;
- No changes to overseas inspection fees;
- Incentives created for highly compliant manufacturers (fewer chargeable inspection hours);
- The changes are spread over a broader range of fees and areas;

- Fully recovers the costs associated with GMP clearance and domestic licence variation activities; and
- Activities are recovered in accordance with the cost recovery guidelines, with greater transparency, leading to a reduction in cross-subsidisation.

### Limitations of this option

- No further accrual of 'free' inspection hours from 1 July 2018
- Requires minor changes to TGA's online application lodgement system.

### Assumptions

- As per Option One and Two.

### Fee Table

Table 5: Option Three

<b>Fees and Charges</b>	<b>Current (\$)</b>	<b>Future - Option 3 (\$)</b>
Annual Manufacturing Charges	-	4,590
Low-Level Manufacturing Charges	6,260	-
High-Level Manufacturing Charges	12,200	-
Australian Manufacturing Hourly Inspection Fee	660	970
Overseas Manufacturing Hourly Inspection Fee	1,330	1,330
GMP Licence Application Fee	1,000	770
GMP Licence Variation fee	-	770
GMP Clearance Application Processing Fee	390	790
Obtaining Evidence from Overseas Regularity Authority	680	680
Compliance Verification	2,030	2,030
Certificate of GMP Compliance	170	170
Certified Copy	60	60

# Industry Impact Analysis

The following analysis depicts the nature of changes that would be experienced by domestic manufacturers under the recommended option (Option 3). These examples are indicative. Manufacturers should consider their own specific circumstances.

## Domestic Manufacturers Overview

The TGA classifies the risk of manufacturing sites depending on the products being manufactured and processes utilised. Further explanation is available on the TGA website.

<https://www.tga.gov.au/manufacture-inspections-risk-based-approach-frequency>  
<https://www.tga.gov.au/manufacture-inspections-productprocess-risk-classifications>

High risk manufacturers may include for example the manufacture of sterile products, lower risk manufacturers may include the manufacture of listed medicines and sunscreens.

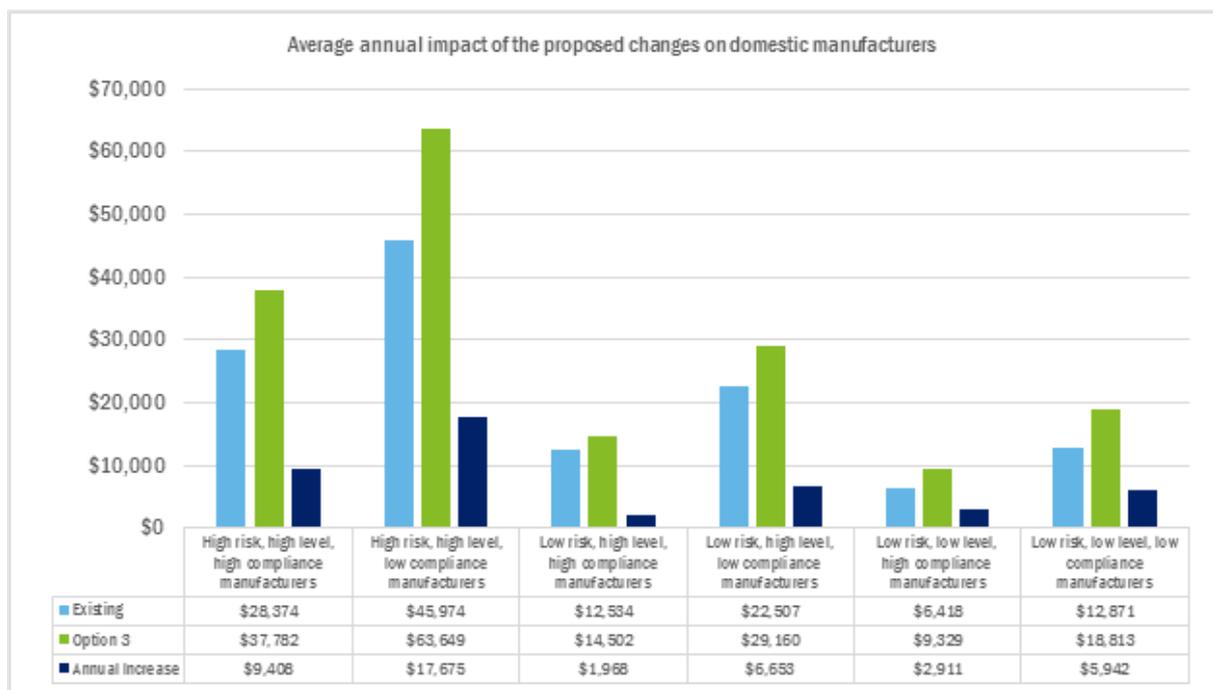
For the purpose of this analysis, domestic manufacturers and sponsors have been separated into six key groups based on data provided by the TGA:

- High-level annual charge, high risk, low compliance manufacturers
- High-level annual charge, high risk, consistent high compliance manufacturers
- High-level annual charge, low risk, low compliance manufacturers
- High-level annual charge, low risk, consistent high compliance manufacturers
- Low-level annual charge, low risk, consistent high compliance manufacturers
- Low-level annual charge, low risk, low compliance manufacturers.

A manufacturer's mix of annual charge, risk and compliance will have a material impact in the forecasting of future fees and charges.

Figure 1 depicts the average impact of the change in fees and charges that domestic manufacturers would face, per licence, annualised over a nine-year period (picking up multiple inspection cycles).

Figure 1: Average annual impact of the proposed option on domestic manufacturers

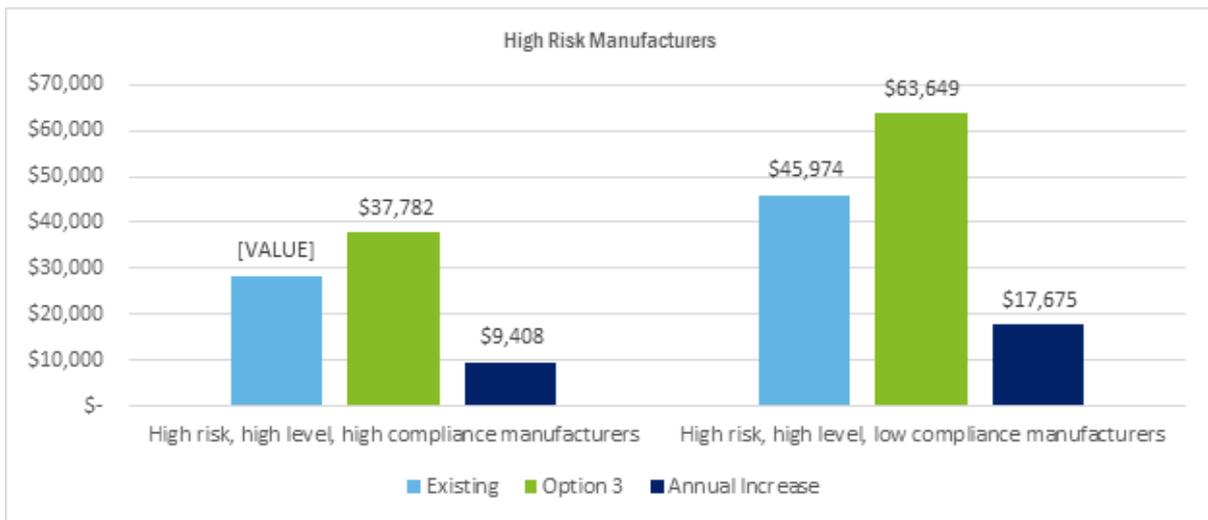


The assumptions used in the calculations are listed on page 20.

Manufacturers who pay the high-level annual charge and are high-risk manufacturers are impacted the most by the proposed new fees and charges. It is evident from the examples below that manufacturers who consistently have high compliance rating will not see a dramatic rise in total fees and charges, providing an incentive for manufacturers to continuously seek high compliance ratings during inspections.

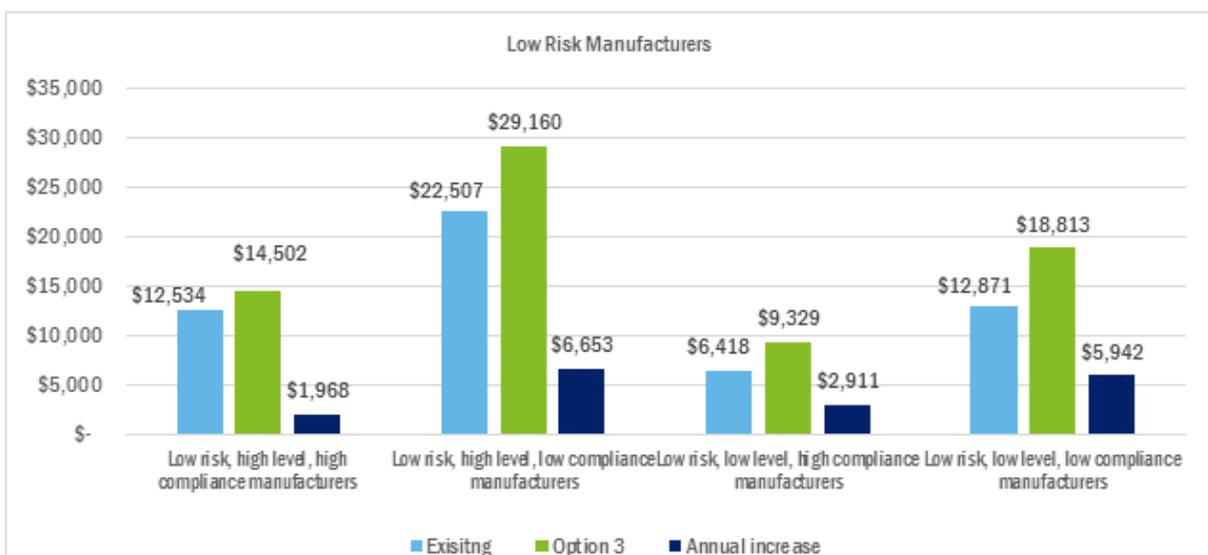
High-risk manufacturers (Figure 2) are impacted more than all other categories due to the increased complexity of inspections. Inspections that are conducted are longer in duration when compared to inspections of low-risk manufacturers and usually requires more than one inspector. Low compliance, high-risk manufacturers are impacted the most because of the increase in the frequency and duration of inspections for repeat A2/A3 compliant manufacturers, increasing inspection hours charged.

Figure 2: Impact on High-Risk Manufacturers Annually



Manufacturers with low risk, low compliance levels will be impacted more by the increase in fees when compared to low risk, high compliance manufacturers (See Figure 3). This is due to the increase in the frequency and duration of inspections. Manufacturers with low compliance will have more frequent inspections if they continue to attain A2/A3 ratings.

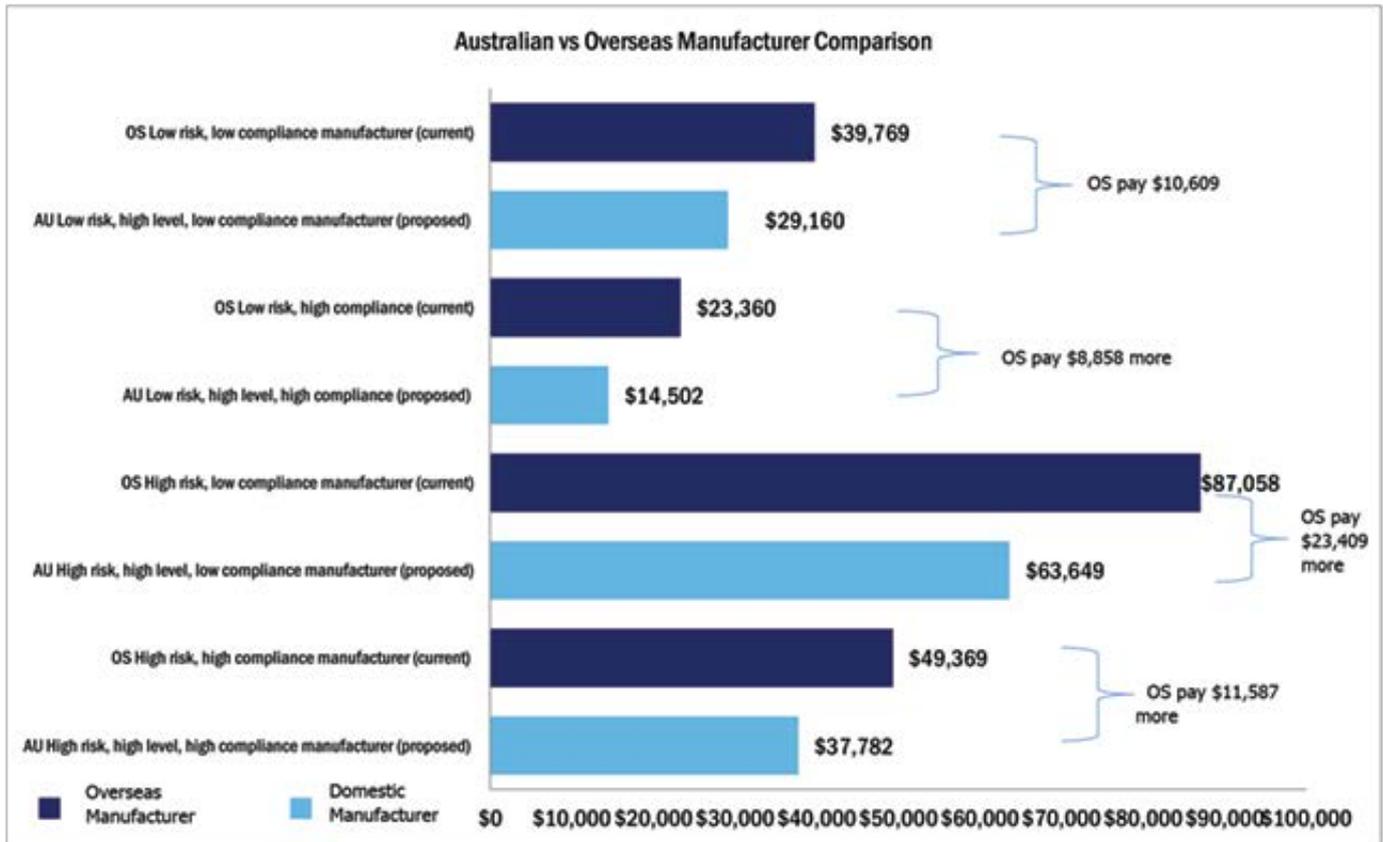
Figure 3: Impact on Low Risk Manufacturers Annually



### Domestic Manufacturers and Sponsors and Overseas Manufacturers Comparison

Although Option 3 does not see any proposed increases to the overseas hourly inspection fee, overseas (OS) manufacturers, through their Australian sponsors, will still pay more than a domestic (AU) manufacturer annually. As shown in Figure 4, in all categories, sponsors of overseas manufacturers, where an on-site TGA inspection is required, will be charged at least \$8,800 more annually than the comparable domestic manufacturer. It should be noted that overseas travel costs are recovered at cost by the TGA while domestic travel costs are recovered through the hourly inspection fee.

Figure 4: Domestic and Overseas Manufacturer



### Industry Impact Analysis - Assumptions

Industry impacts were calculated based on the following assumptions – approved by the TGA.

Impacts on overseas manufacturers have not been included as there are no proposed changes to the overseas inspection hourly rate.

The data presented in the case studies have been calculated and validated by TGA. The data is based on a nine-year cycle recommended by the TGA.

#### Annual Licence Charge

- Annual Licence Charge was charged annually for domestic manufacturers. This is not applicable for overseas manufacturers.

#### Risk-based inspection program

- High-Risk High Compliance – repeat A1
- High-Risk Low Compliance – repeat A3/A2 (more frequent inspections)
- Low-Risk High Compliance – repeat A1
- Low-Risk Low Compliance – repeat A3/A2 (more frequent inspections).

“Free” Inspection Hours

- For the current/base scenario, ‘free’ utilisation rates were included.
- Using TGA’s historical data, the average ‘free’ hour utilisation rate for low level licence is 82% (13 hours over 3 years) and for high level licence is 59% (28 hours / 3 years).

Inspection Hours

- The difference between the current fees and charges for domestic manufacturers and the proposed option assumes cessation of implied ‘free’ hours (16 hours for low-level licences, 48 hours for high-level licences over a three year period).

Inspection team composition & duration

- High-risk high-level licence domestically = Two inspectors for five days e.g. sterile finished product manufacturer (80 inspection hours).
- Low-risk high-level licence domestically = One inspector for four days e.g. non-sterile finished product manufacturer (32 inspection hours).
- Low-risk low-level licence domestically = One inspector for two days e.g. secondary packaging facility (16 inspection hours).
- High risk overseas = Two inspectors for five days e.g. sterile finished product manufacturer (80 inspection hours).
- Low risk overseas = One inspector for four days e.g. non-sterile finished product manufacturer (32 inspection hours).

Inspection Travel

- Domestic travel time for inspectors, travel allowance airfares, ground transport and accommodation amounts are included in the inspection hourly rate.
- For overseas manufacturers the travel allowance airfares, ground transport and accommodation are recovered at cost. Typically for overseas inspections, two or more inspections will be performed on a single trip overseas, reducing the travel costs (than if travelling for a single inspection).
- For the purposes of the calculations an estimate of \$10,000 was used as the cost of overseas travel for each inspection.

Variation Applications

- Domestic manufacturers were assumed to have one variation application fee every two years. These are not applicable for overseas manufacturers.

# International Counterparts

Deloitte undertook a high-level comparison against international regulators with the objective of identifying possible anomalies in fee structure or cost recovery arrangements.

We have not found any particular issues of concern. The proposed new fees and charges are not inconsistent with those imposed by the TGA's international counterparts.

Most of TGA's international counterparts use the level of active substances (or other objectively measured proxies to account for differences in the effort) when setting fees (see Table 6).

Table 6: Fee Methodology

International Partner	Methodology Findings
<b>New Zealand</b> (Medsafe)	Fees and charges are based on risk assessments of medicines. Lower fees charged for low-risk medicines and higher fees for high-risk medicines.
<b>United States of America</b> (FDA)	International comparison undertaken in late 2017 by Health Canada reported that USFDA fees are set based on revenue targets rather than on a cost recovery basis.
<b>European Union</b> (European Medicines Agency)	Base fees are based on the number of active substances and the intended variety of products using the active substances. Simplified forms are used for medicines with low amounts of active substances.
<b>Singapore</b> (Health Services Authority)	Fees and charges based on strength and amount of active substance. Simplified forms are used for medicines with low strength and low amounts of active substances.
<b>United Kingdom</b> (MHRA)	Fees and charges based on how the medicine will be distributed.
<b>Canada</b> (Health Canada)	Flat fee for any medicines that contain new active substances. Other medicinal fees based on the depth of research and development undertaken. Lower fees for submissions based on comparative studies.

Table 7: Current Fee Comparisons

	TGA (current)	MHRA	Health Canada
<b>CV (Desktop) Assessment fee</b>	\$2,030	\$3,338	-
<b>New Application Licence</b>	\$1,000	\$5,500	-
<b>Variation Application</b>	-	\$602	-
<b>Inspection rate</b>	\$660 (hourly/inspector)	\$4,646 (daily/inspector)	
<b>Domestic Application and Inspection</b>	-	-	\$45,000*
<b>Annual Licence Charge</b>	Low \$6,260 High \$12,200	\$819	\$45,000*

\*Fee is charged annually and is the aggregate of a number of application and inspection fee

Exchange Rate Used (28/11/17): UK Pound Sterling = AUD\$1.75 Canadian Dollar = AUD\$1.03

# Compliance

There are no immediate indicators of non-compliance in the current or proposed GMP fee arrangements based on our review of the *Therapeutic Goods Act 1989* (the Act) and the Cost Recovery Charging Framework (RMG 302).

The Act supports the inclusion of the requirement for Australian sponsors of overseas manufacturers to contribute funds required for inspection. Sections 25(1)(g), 25(2)(a)(ii) and 25(2)(b) of the Act provide the Secretary the authority to conduct an inspection on manufacturers outside of Australia to ensure that the manufacturing and quality control procedures are acceptable.

The Cost Recovery Guidelines administered by the Department of Finance provide guidance to agencies on best practice cost recovery. The proposed options see all stakeholders charged on the same basis, all charges are in line with the intent of legislative requirements, including the Act, and there is no evidence suggesting the costs charged are inefficient.

*Table 8: Australian Government Charging Framework - Key Government Charges and their Characteristics*

## Cost Recovery Guidelines

17. Regulatory charges should be consistent with the policy intent and legislative objectives of the activity and/or the entity. Where the charging activity is provided to government and non-government stakeholders, charges should be set on the same basis for all stakeholders

19. Entities should generally set charges to recover the full cost of providing regulatory activities. Some government charging activities may only partially recover the costs. These instances usually occur where:

- charges are being 'phased in'
- full recovery of costs would be inconsistent with community service obligations endorsed by the Australian Government
- the Australian Government has made an explicit policy decision to charge for only a part of the costs of the activity

Charging categories	Regulatory charges	
Pricing Models	Cost recovery fees	Cost recovery levies
Relationship between charges and costs	Charges must reflect efficient unit cost of a specific good or service	Charges must reflect efficient overall costs of the activity
Statutory authority to charge	Legislation required	Taxation Act required
GFS reporting classification	Non-taxation revenue	

## Appendix

- A fee is charged for a service, such as a product evaluation. Fees are listed in Schedule 9 and 9A of the Therapeutic Goods Regulations 1990
- A charge is a form of tax imposed on the regulated industry and is applied annually based on a 1 July to 30 June financial year. A list of charges can be found in the Therapeutic Goods (Charges) Regulations 1990.
- Annual licence charges in the Therapeutic Goods (Charges) Regulations 1990  
<https://www.legislation.gov.au/Series/F1996B00750>

## References

TGA Fees and payments: <https://www.tga.gov.au/fees-and-payments>

Current GMP Fees and charges: <https://www.tga.gov.au/book-page/manufacturing-medicines-and-otgs-0>

TGA GMP Inspections: <https://www.tga.gov.au/manufacture-inspections-risk-based-approach-frequency>

TGA GMP risk classifications: <https://www.tga.gov.au/manufacture-inspections-product-process-risk-classifications>

Therapeutic Goods Act 1989: <https://www.legislation.gov.au/Series/C2004A03952>

Therapeutic Goods Regulations 1990: <https://www.legislation.gov.au/Series/F1996B00406>