# Consultation: Proposal to change the current good manufacturing practice (GMP) fees and charges - February 2018

Pharma To Market would like to thank the Therapeutic Goods Administration (TGA) for the opportunity to provide comments in response to the proposal to change GMP fees and charges.

As an agent, Pharma To Market maintains GMP clearances on behalf of Australian sponsors. We regularly submit clearance applications for new sites, renewals, variations, administrative changes and extension requests.
We have also recently submitted overseas inspection applications for five sites across three sponsors.

Currently, we are responsible for the maintenance of about 200 GMP clearances for overseas sites (~65 compliance verification, ~135 mutual recognition agreement) across 7 sponsors.

## Scope of this submission

This submission will not comment on the changes to fees related to Australian manufacturing sites as we are not currently providing services to any sponsors or manufacturers for maintenance of such site licences.

Considering that the Option Three presented in the *TGA GMP Fee Model Review* is Deloitte's recommended approach, the response to this consultation will only focus on this option.

## Acknowledgements

Pharma To Market acknowledge that the current application fee of $390 is quite inexpensive relative to other similar types of TGA application fees.

It is understood that the proposed fee changes are to more accurately recover costs incurred by TGA and that proposed increases do not correlate to improved efficiencies in the clearance evaluation timeframes.

It is appreciated that there are TGA administration costs associated with many clearance activities (i.e. administrative changes, extension requests, etc) which do not incur a fee and that such costs may be recovered by TGA under the umbrella of the clearance application fee.

From the *Fee Model Review* and the TGA information session held in Brisbane on 16 February 2018, it is understood that under-recovery of costs associated with GMP clearance activities may have been increasing over the course of some years. As such, the proposed fee increase is likely to be significantly greater than the previously standard annual increase of $10 to the clearance application fee (e.g. 2016 - 2017 = $380; 2017 - 2018 = $390).

## Option Three (Optimise)

*GMP clearance application processing fee - increase from $390 to $790*

Pharma To Market do not support such a large increase to this fee whilst all other fees associated with GMP clearance remain unchanged.

A slide presented at the TGA information session (Figure 1), shows an analysis of the under-recovery associated with various GMP activities.

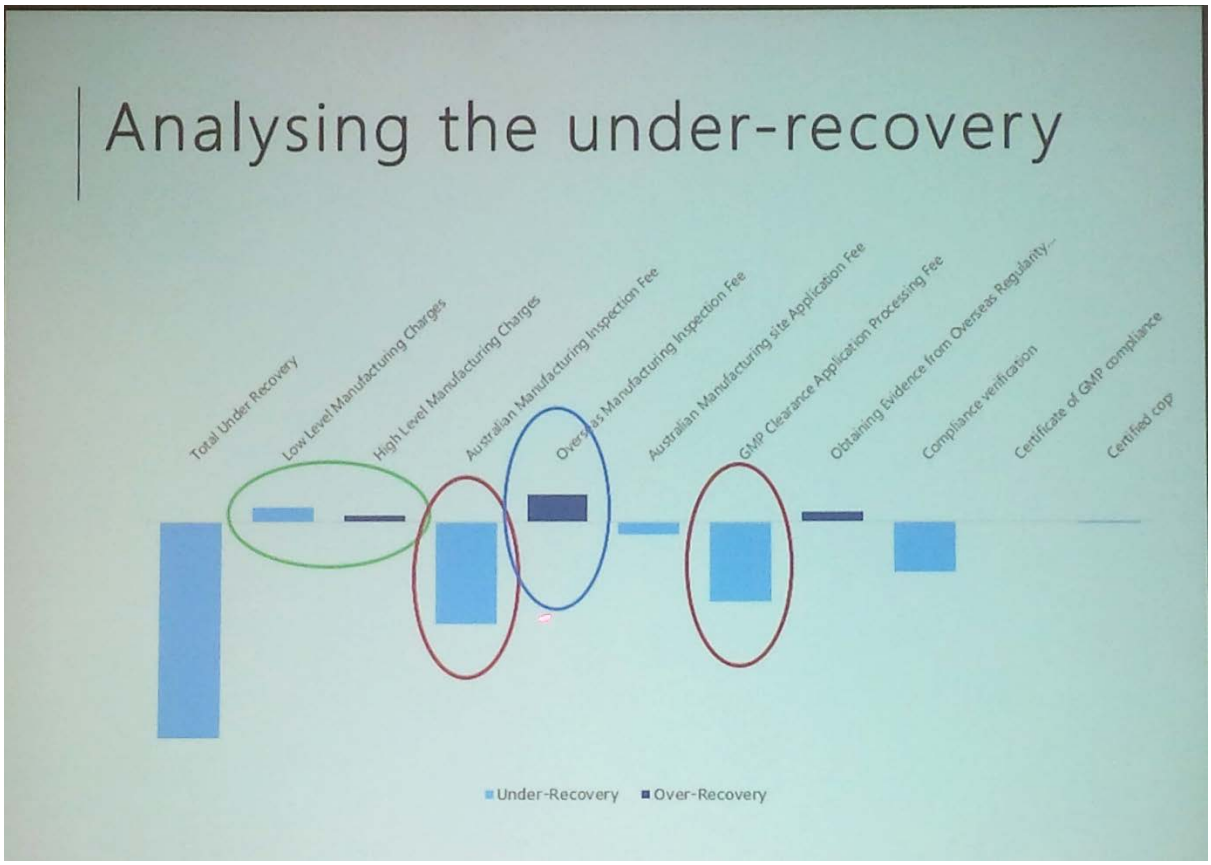


***Figure 1 Slide presented at TGA information session 16 Feb 2018, Brisbane***

This figure highlights the under-recovery associated with the application processing fee activities.

The graph clearly shows a significant under-recovery associated with compliance verification (CV) activities, however this has not been considered.

The under-recoveries associated with the application processing and compliance verification activities do not correlate to the proposed fee changes in option 3, i.e. only the application processing fee has increased.

Under-recoveries of CV activities are displayed as around half of those for the application processing. However, the CV fee in option 3 proposal remains unchanged whilst the application processing fee has more than doubled.

We believe that this is not a fair reflection of the amount of work undertaken by TGA with respect to mutual recognition agreement (MRA) applications versus compliance verification applications.

The short timeframe for introduction of this change has also impacted on company budgets for 2018. Especially for many pharma companies whose budgets are implemented on financial years of other regions and with strict limitations.

This increase, along with others that the industry as a whole have been asked to absorb (i.e. PBAC fee), increases the likelihood of sites being de-registered as back-up sites, thus risking shortages should the primary sites go offline for any reason. For smaller companies with a small number of sites the impact is potentially minimal, but for many of the larger companies and generics especially, this is of real concern.

## Suggestions for change to proposal

It is understood that separating out the clearance fee structure into; a) administrative fee; b) MRA fee; c) CV fee; would be too complicated for TGA at this time. In lieu of this we have the following recommendation.

Pharma To Market suggests that TGA model the increase in the application processing and CV fees to more accurately reflect the proportions of under-recovery as presented in Figure 1.

**1. A lesser increase in the application processing fee with a proportionate increase to the CV fee.**

Rationale for this suggestion:

- This would allow TGA to more closely align the fees to the respective under-recovered activity for future measurements and review.

- Sponsors appreciate the greater amount of work required for a CV application and are likely to be more accepting of an increase to the CV fee, if the processing fee increase is not as great as that currently proposed.

- Sponsors with a greater proportion of MRA clearances will not be disadvantaged by the fee increase recovering the cost of CV applications.

- With more foreign health authorities joining PIC/S, further increases in the number of CV applications are anticipated on top of the large increase in CV applications over the last few years. This will likely also result in less TGA inspection applications for overseas sites.

- From our experience, sponsors almost always prefer the CV option and exploring any extension options available over submitting inspection applications. They are usually hesitant to submit applications for TGA inspection due to the associated cost, length

of time and complexity of interaction between multiple stakeholders often across numerous regions.

- It is understood that the CV applications are often evaluated by TGA inspectors, in between their off-site inspection work. As the cost of using these experts is greater than the administrative roles associated with the application processing fee, this is another reason that a proportion of the processing fee change should be modelled to the CV fee instead.

**2. Phasing in period of fee increase**

In light of the short timeframe of implementation of this change, and with respect to the various company budgeting restrictions already in place, it is suggested that TGA could incorporate a phasing-in of the fee structure, if not a delay to the implementation date. This could reduce the risk of removal of back-up sites resulting in potential medicine shortages to the Australian population.

## Endorsements

On behalf of Pharma To Market Pty Ltd:

Daria Wain
Regulatory Publishing Specialist and Trainer
Pharma To Market Pty Ltd