Apotex Pty Ltd

Submission to the Open TGA Consultation:

Proposal to change the current good manufacturing practice (GMP) fees and charges (08 February 2018)

Roger Millichamp
Managing Director
19 March 2018

Table of Contents

APOTEX
Innovating for
patient affordability

About Apotex

Apotex Inc., founded in 1974 by Dr. Barry Sherman is a proudly Canadian global pharmaceutical company that produces high-quality, affordable medicines (both generic and innovative pharmaceuticals) for patients around the world.

Today, the Apotex product portfolio represents one of the most comprehensive ranges within the Australian market, comprising over 2500 registered products across a broad range of therapeutic areas and schedules (Prescription, Over The Counter and Complementary Medicines).

Apotex is committed to improving outcomes for patients through access to affordable, innovative, and high-quality healthcare solutions.

We believe in a strong healthcare system, and a thriving generic medicines industry. Apotex works to sustain Australia's world-class Pharmaceutical Benefits Scheme (PBS) and ensure the viability of our business into the future.

Executive Summary

Apotex welcomes the opportunity to provide feedback to the Therapeutic Goods Administration (TGA) open consultation on the "Proposal to change the current good manufacturing practice (GMP) fees and charges (08 February 2018)" and acknowledges that the Department of Health periodically conducts a review of existing and potential charging activities as the TGA operates on a cost-recovery basis.

Apotex doesn't accept the cost recovery target of $2.1 million per annum, nor the three fee structure options proposed in the Deloitte consultation paper. Instead we propose an alternate revised Option 1.

A revised Option 1 shares the fees burden evenly amongst Sponsors and takes into account an estimated ratio of one (1) Local manufacturer to ten (10) Overseas manufacturers engaged in supplying products to the Australian public. The amplitude of the proposed recovery effort is unsustainable - a 10% flat fee increase is seen as more appropriate with a staged implementation over 1-3 years. Furthermore, a target of $1.2M is more aligned with deficits observed in financial years 2013/14, 2014/15 and 2015/2016; 2016/17 being a statistically significant outlier.

Introduction

The main goal of the Australian generic industry is to ensure that everyday Australians have affordable access to needed medicines. This is achieved through cost containment.

Generic medicines are less expensive than the original brand primarily because the generic medicine manufacturer does not have to recoup the high research and development costs usually associated with new medicines. Also, generic medicine manufacturers typically spend less on advertising and promotion, so the savings can be passed onto consumers.[1]

However, the recent reimbursement and regulatory reforms have created unprecedented business uncertainty on the true Australian generic industry thus threatening its viability.

At the same time as we are preparing this response to consultation on Good Manufacturing Practice (GMP) fees, the Health Department is looking to impose administrative fees for products on the PBS. This directly impacts the economics of our business and represents a large financial burden to a true generic company such as Apotex, which maintains around 510 items on the PBS schedule.

Furthermore, recent TGA reforms to packaging and labelling from 01 Aug 2016 and reformatting Australian Product Information requirements from 01 Jan 2018 have required companies to plan and implement changes to marketed products creating an administrative and manufacturing cost burden to Sponsors over the next two financial years.

Therefore, the financial impact of the proposed GMP fees increase needs to be considered along with all financial pressures our industry is facing.

Background

Apotex acknowledges TGA goals for cost recovery. Cost recovery involves the government entities charging individuals or non-government organisations some or all of the efficient costs of a specific government activity. This may include goods, services or regulation, or a combination of these [i].

The current Department of Health 2016-17 Financial Statements report, shows the TGA ran at a loss of $5.1 million in the 2016/2017 financial year [ii]. The Deloitte paper has identified the GMP cost under-recovery of $4.4 million as the major contributor.

[1] GBMA website : Generic Medicine Facts

Discussion of Proposed Options

Deloitte has identified an average net loss of $2.1 million based on an assessment for the last 4 financial years, however, the 2016/2017 financial year shortfall stands out as a significant outlier at $4.4 million. An average of the prior three years $1.4+1.7+0.4 = $3.5/3 = $1.2 million which seems a more reasonable target for future cost recovery efforts.

Furthermore, the Deloitte report was tendered at a cost of approx. $60 K to Department of Health (and therefore subsidized by Industry). This represents approx. 120 – 150 hours of work, which is not sufficient to develop a comprehensive understanding of the data or unintended impacts/outcomes for all stakeholders.

Option 1

Apotex believes the Deloitte Option 1 proposal of a uniform increase of all fees and charges is the fairest option for all Manufacturer's and Sponsors. However, the cost recovery target should be amended to $1.2 million as discussed above.

Given the financial impact Sponsors in our industry are facing, we believe a staged implementation of the cost recovery target should be spread over the next 3 years.

For example, if the cost recovery target was $1.2 million per annum, in 3 years the total recovery target is $3.6 million. 25% of the target could be cost recovered in the first year ($0.9 million), 35% of the target could be cost recovered in the second year ($1.26 million) and 40% cost recovered in the third year ($1.8 million).

Apotex estimates a ratio of 1 local manufacturer to 10 Overseas Manufacturers engaged in supplying products to the Australian public. We would propose that the cost-recovery efforts reflect this ratio.

Option 2

Apotex has not assessed Option 2 as it only impacts Local Manufacturing.

Option 3

Option 3 was flagged by Deloitte, as the preferred option, as it was geared to cost-recover based on inspection hours and annual charges for Local Manufacturer's and GMP clearance activities for Sponsors relying on Overseas Manufacturer's. The Deloitte report however, didn't elaborate on the actual costs to Sponsors.

Apotex prepared a Fee Model on the basis of small generic Sponsors maintaining 3-40 GMP clearances, medium generic Sponsors 40-80 GMP clearances and large generic Sponsors 80-160 GMP clearances annually. This model allows comparisons between Sponsors and the predicted impact of the proposed GMP fee increase.

Projections show the Option 3 fee structure impacts Generic Sponsors by doubling application fees (from up to $16K to $32K for small generic companies, $32K to $64K for medium generic companies and $64K to $130K for large generic companies).

With all other GMP clearance fees taken into consideration modelling shows the full impact of up to 47% total fee impacts, just for GMP clearance activities. Couple this with OS sites that may require TGA inspections, the impact on small or medium sized business has the potential to reduce competition in the generic medicines space.

Option 3 was flagged by Deloitte, as the preferred option, "encouraging a higher level of compliance by manufacturers" However, these compliance incentives only impact local manufacturers. No such incentive applies to GMP clearance for Sponsors using OS manufacturers.

The Option 3 proposal is unacceptable to Apotex as:

- Apotex has a large product portfolio with a large number of Overseas (OS) Manufacturers engaged in order to secure the continuing supply of affordable medicines to patients
- As a large Generic Sponsor, the 47% increase in total GMP clearance fee costs are unacceptable
- The proposal doesn't highlight the ratio of cost-recovery burden between Local Manufacturer's or Sponsors relying on Overseas Manufacturer's.

Further Cost Containment

Apotex estimates 30% of its GMP clearance sites are registered as contingency purposes in cases where source of supply changes can ensure continuity of supply.

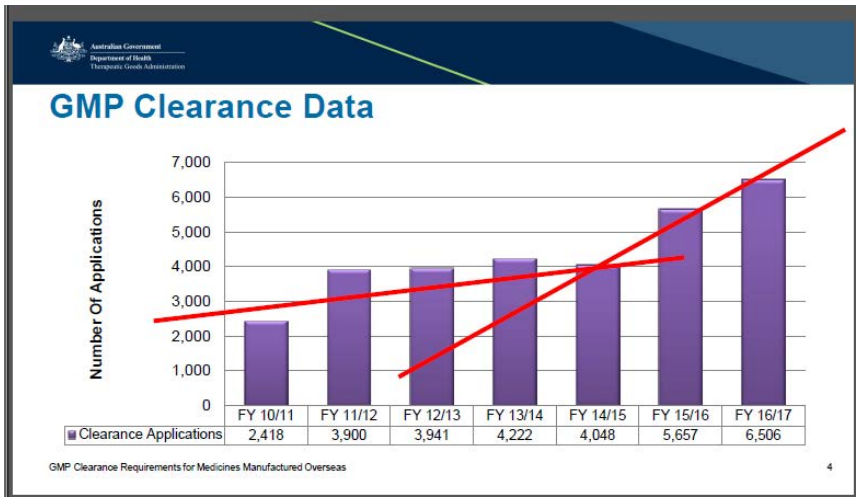
To contain rising regulatory costs, companies will be forced to rationalize their GMP clearance sites, potentially reducing the manufacturing options when faced with crises at manufacturing sites. One recent example of this are the recent events in Puerto Rico, where hurricane Maria decimated the pharmaceutical manufacturing industry in October 2017.

While such rationalization has the potential to offset rising TGA fees for the generic industry, it does increase the risks of medicines shortages. This in turn would place additional pressure on the health system as well as the TGA (in managing and administering the ever-increasing medicines shortages).

Exploring Other Options?

Audit Report No.30 2013–14 clearly identified TGA Office of Manufacturing Quality (OMQ) was considering a model to enable the reuse of current evidence of a manufacturing site's compliance with the Code of GMP in subsequent assessments of the same site. In doing so cited "that approximately two-thirds of the effort spent processing clearance applications is a duplication of previous work". Refer overall conclusion 12, page 18 of this report [iii].

However, a recent TGA presentation to ARCS showed that the recent workload has in fact been steadily increasing from FY15/16 and FY16/17.



Further to the options tabled in the Deloitte report, Apotex, through the Generic Biosimilar Medicine Association, supports exploring ways to improve TGA GMP activities through a more efficient GMP clearance process that takes a risk-based approach to GMP clearances.

Three key initiatives proposed by GBMA for discussion include:

1. Risk-based approach to GMP clearance applications for overseas manufacturers;
2. Notification process for low risk manufacturers; and
3. Ability for manufacturers to provide letters of access to refer to GMP evidence.

Conclusion

Apotex doesn't accept the cost recovery target of $2.1 million per annum, nor the three fee structure options proposed in the Deloitte consultation paper. Instead we propose an alternate revised Option 1.

A revised Option 1 shares the fees burden evenly amongst Sponsors and takes into account an estimated ratio of one (1) Local manufacturer to 10 Overseas manufacturers engaged in supplying products to the Australian public. The amplitude of the proposed recovery effort is unsustainable. - a 10% flat fee increase is seen as more appropriate with a staged implementation over 1-3 years. Furthermore, a target of $1.2M is more aligned with deficits observed in financial years 2013/14, 2014/15 and 2015/2016; 2016/17 being a statistically significant outlier.

Apotex is committed to improving outcomes for patients through access to affordable, innovative, and high-quality healthcare solutions.

Apotex is looking forward to partnering and participating in forums to shape the future of GMP clearance activities for Overseas Manufacturer's by the TGA to achieve cost recovery while maintaining viability of the generic industry. Teaming up of cost-recovery efforts with further process efficiencies in line with TGA's overall de-regulation goals, as recently implemented as an outcome of Medicines and Medical Devices Regulation reform would secure Australians heath by maintaining access to affordable medicines.

References

[i] Cost recovery implementation statement, Version 1.2 December 2017, published 03 Jan 2018, Policy and statutory authority to cost recover https://www.tga.gov.au/book-page/policy-and-statutory-authority-cost-recover-6

[ii] Department of Health, Part 4.2: 2016-17 Financial Statements, Note 15B: TGA Comprehensive income (page 283) http://www.health.gov.au/internet/main/publishing.nsf/AttachmentsByTitle/annual-report2016-17-attachments/$FILE/2016-17%20Department%20of%20Health%20Annual%20Report%20-%20Financial%20Statements.pdf

[iii] Australian National Audit Office (ANAO), Administering the Code of Good Manufacturing Practice for Prescription Medicines, **Report number:** 30 of 2013-2014 https://www.anao.gov.au/work/performance-audit/administering-code-good-manufacturing-practice-prescription-medicines