CMA Submission to the TGA Consultation

Fees and Charges proposal 2019-20

To:

Regulatory Pricing and Decision Review Section
Regulatory support and Drug Control Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
TGAFeesandCharges@health.gov.au

From:

Complementary Medicines Australia

PO Box 450

MAWSON ACT 2606

Telephone: 02 6260 4022

E-mail: carl.gibson@cmaustralia.org.au

Website: www.cmaustralia.org.au

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Consultation - Annual review of fees and charges

Complementary Medicines Australia (CMA) met with the Department of Health's Therapeutic Goods Administration (TGA) as part of its annual bilateral meeting on the 13th December 2018 to discuss the TGA's budget outlook for 2018-19 and the proposed changes to fees and charges for 2019-20. CMA appreciates the opportunity to provide further feedback on TGA's consultation paper: Fees and charges proposal 2019-20.

The consultation provides the following three options for the annual review of fees and charges:

- Option 1: No increase in fees and charges
- Option 2: Percentage increase in line with costs
- Option 3: Increase all fees and charges by indexation factor (TGA preferred)

Consistent with previous years, CMA has no objection to the TGA's preferred Option 3 to adjust fees and charges in relation to the indexation factor. This is consistent with long-established practice, and provides opportunities for efficiency gains through business process improvements. To that end, CMA have the following comments to make in relation to cost efficiencies and fees and charges management.

Cost efficiencies and maintaining risk commensurate approach to regulation

CMA does not support Option 2, a percentage increase in line with costs, but that are beyond the indexation figures. The majority of other Commonwealth Government departments are required to create efficiency improvements to operations to decrease costs. The TGA is a risk-based, cost recovered regulator that must also control costs through efficiency means.

In recent years we recognise the regulatory Branch has taken some steps to increase efficiencies by reducing red-tape, such as the removal of the requirements around herbal component names. In other areas the Complementary Medicines sector has seen increasing inefficiencies such as requests for information and investigation of minor or insignificant details, an approach that is overall less reflective of an efficient, risk focussed management approach than the system is designed for.

We support risk based management and recognising the overall challenge, in the previous financial year, the sector accepted a significant fee rise to account for increased reviews to assist the regulator in meeting obligations. This is the limit of the amount of increased costs that parts of the sector can absorb. It must be met by a balanced approach that is pragmatic in terms of prioritisation of higher risk versus low risk, low impact items to ensure efficient operation of the regulatory Branch to managing overall risk in what is a very low risk sector.

Unnecessary costs through misaligned reform transition periods, increasing red tape, and lack of fee relief.

The complementary medicines sector had the bulk of reform recommendations to implement. There are a number of reforms to listed medicines that are creating significant additional costs to businesses through misaligned transition timeframes or increasing complexity of red-tape. Resulting costs include significant direct costs (such as ARTG grouping fees) and indirect costs (additional staff and consultancy fees), often when such costs have not been accounted for through regulatory impact assessments.

Requests for fee relief in such circumstances have not been accepted by the TGA despite significantly increased real costs and impacts of reforms. Cost and regulatory requirement inefficiencies place businesses and jobs at risk and unnecessarily raise the costs of products for end consumers.

The TGA, as a cost recovered regulator, needs to recognise there are continuing very high direct and indirect costs involved in meeting reform transition requirements for this sector and do more to reduce costs that have been inadvertently created through major reforms.

Direct costs examples:

a. The costs of changing ARTG entries to protect trademarks through unaccounted for effects resulting from changed legislation.

   At a cost of $820 per changed entry, sponsors required to change all product ranges are facing costs in the hundreds of thousands of dollars.

b. It appears increasingly likely that there will be costs of changing ARTG entries after the fee free period where indications or qualifiers that are required for product continuation are not made available through the fee free period.

c. Direct loss of manufactured and labelled product batches if inadequate transition periods are provided for low risk changes to ingredient requirements.

d. Costs of printing advertising materials for minor and insignificant changes that do not permit the harmonisation of existing statements in advertising despite acknowledgment of no consumer risk, issues that were raised by multiple associations through consultation periods.

Indirect costs examples:

a. Misalignment of label and advertising warning statements creating insignificant differences with no effect on consumer health and safety, but creating additional red-tape and possible compliance issues through different requirements.
The MMDR reform objective was to remove unnecessary and duplicative areas of regulation, however the sector has seen the significant addition of unnecessary and duplicative red tape, which also increases the possible costs resulting from inadvertent non-compliance from complex and non-streamlined requirements.

b. Costs of hiring new contractors to meet the increasing red-tape demands and tight or misaligned transitional timeframes.

c. Costs of changing labels or advertisements multiple times due to continuing changes in legislative documents and policy interpretation of documents, or misaligned timeframes.

d. Costs of regulatory consultants to manage the increasingly complex and continually changing regulatory requirements.

e. Increased batch production run sizes to due to increasing GMP and other manufacturing requirements. This is particularly tough on small businesses.

f. Reduced brand and trademark recognition due to required brand labelling changes in TGO 92.

Listed assessed medicine variation fee

CMA understands the need to assess variations and do not oppose the fee proposal. However, we note that this is a relatively untested pathway and any unforeseen issues may need to be raised in the future. A response to the level and type of variations for listed assessed medicines will be provided separately to the regulatory Branch.

Good manufacturing practice (GMP) fees

CMA has previously responded to fee proposals associated with Good Manufacturing Practice.

Summary recommendation

CMA strongly recommends the TGA regulatory Branch for complementary medicines place an increased emphasis on creating internal efficiencies, **provide a period of fee relief for inadvertent and unaccounted for regulatory cost impacts**, make genuine and meaningful efforts to reduce indirect costs through effective policy setting, reduce other internal or external unnecessary red-tape that isn't risk-commensurate, and creating better and more streamlined requirements to ensure increased efficiencies for both businesses and the TGA's core purpose of risk-based, cost-efficient regulation.