CMA Submission to the TGA Consultation: Proposal to change the current good manufacturing practice (GMP) fees and charges

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Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry. CMA members represent greater than 80% of all product sales within Australia. Membership includes the entire value chain, including sponsors, retailers, manufacturers, raw material suppliers, distributors, consultants, allied health professionals and educators. We promote industry advancement, whilst ensuring consumers have access to complementary medicines of the highest quality. CMA is the principal reference point for members, the Government, the media and consumers to communicate about issues relating to the complementary medicines industry.

CMA welcomes the opportunity to provide input to the proposal to change the current good manufacturing practice (GMP) fees and charges.

Executive Summary

- CMA supports Option 3; however, recognising the increased costs for Australian manufacturing and consumers, we encourage further examination of the system to increase cost efficiencies.
- We request that consideration is given to the transition period to the new PIC/S Code and finalisation of guidance specific to the complementary medicine industry. Industry would like to continue to work collaborative with the Manufacturing and Quality Branch so that potential misunderstandings do not arise during audits in this transition and inadvertently increase costs for manufacturers and consumers.
- Other considerations are the balance of regulatory costs between similar industries (foods and complementary medicines), and between domestic and international inspections.

Discussion

Complementary medicines manufacturing in Australia occupies a unique position. While the majority of countries treat supplements as an extension of food manufacturing, complementary medicines in Australia are manufactured to the PIC/S Code in combination with TGA guidance materials, providing an increased level of quality assurance and consumer protection over food manufacturing.

While the TGA only has jurisdiction over therapeutic good regulation and not food, it is relevant that the industry exists in competition with foods in the Australian marketplace and with overseas suppliers in export dietary supplement markets. The Australian Trade and Investment Commission (Austrade) released a report in 2017 recognising and supporting the export value of supplying

complementary medicines to China[1]. It is necessary to consider this broad view to achieve best practice regulation for complementary medicines and the reduction of costs, to achieve balance in regulatory markets and therefore the best outcomes for Australian manufacturing, consumers, and the Australian Government. Consequently, CMA supports the better alignment of true costs to TGA services; however, we have some included some items for consideration below as this process moves forward.

Complementary medicines manufacturing for Australian firms is represented by both domestic and international manufacturers. Different cost analyses by different sponsors resulted in some sponsors preferring Option 2; however, the majority preferred Option 3 and support Deloitte's recommendation of this option.

The following considerations are further provided in relation to this process, particularly Option 3:

1. **Further examination of cost reductions to reduce impacts on manufacturers and consumers.**

   There are growing fees for many business processes associated with complementary medicine regulation. Some of these changes are introduced in relation the Review of Medicines and Medical Devices (MMDR) reforms, which was flagged as an overall deregulatory change to reduce regulatory costs and burdens. We recognise that TGA must conduct appropriate cost recovery mechanisms; however, the proposed changes introduce costs to all inspections which will have a financial impact on manufacturers.

   Manufacturers must also cover their overheads and ultimately increased costs become recovered from the end user, the consumer. Complementary medicines are not only taken for health maintenance and enhancement by healthy individuals, they are often recommended by doctors and dispensed as part of dose administrations aids such as Webster packs for elderly patients who are sensitive to cost considerations, and by others with financial pressures where there is no governmental cost relief, such as during pregnancy.

   While recognising the importance and value of TGA's GMP system, it is our preference for the further examination and reduction of the overall fee structure; in particular, overall framework efficiencies when conducting audits and any fee areas that have not been considered as part of this review.

[1] https://www.austrade.gov.au/news/latest-from-austrade/2017/new-report-spotlights-australias-complementary-medicine-capabilities

2. **Preventing inadvertent cost impacts during PIC/S implementation.**

This year, the TGA is introducing a new PIC/S Code for industry. Option 3 presents increased costs associated with increased frequency of audit for manufacturers who are considered by the TGA to have audit deficiencies and a lower compliance level. The CM industry strive for a high level of compliance with the PIC/S Code and TGA standards, therefore, we recognise and support the value of a system that rewards this with a decreased frequency of inspections.

However there is the consideration that a previous implementation of a new PIC/S Code took approximately 3 or more years before all associated implications and guidance was fully developed between the TGA and industry. The PIC/S Code is an international document designed for pharmaceutical standards and not specifically designed to recognise the unique challenges of manufacturing complementary medicines, which adds an extra burden of transition for CM manufacturers in particular.

Manufacturers will be undergoing a similar period of adjustment, guidance re-development, and settlement of 'grey areas' as during the previous implementation. It is imperative that this fee review does not result in significantly increased costs due to bumps during the transition period – that the auditing process adequately accounts for the transition time, which is very likely to take longer than the proposed 12 months for all issues to be resolved.

CMA is looking forward to actively working with the Manufacturing & Quality Branch during transition to help reduce any inconsistencies and difficulties in application of the updated PIC/S Code.

3. **Maintaining a regulatory balance between complementary medicines and foods**

In some areas, sponsors have a choice about how to present a product and as a result, whether that product is presented as a complementary medicine or as a food. Food manufacturers do not have to meet the same GMP requirements. Consumers are provided a much higher level of protection when products are manufactured through the therapeutic goods pathway. However, with the introduction of health claims for foods, there are increasing competitive pressures on complementary medicine suppliers in this space. There are also a number of examples of where food products are permitted to make much stronger health claims than TGA-regulated complementary medicines. This, in combination with increasing price pressures of GMP fees and charges, could encourage businesses to utilise the food pathway with lower price manufacturing, and in some instances more specific health claims (or no health claims, where the consumer relies upon their own knowledge to take the product). It is not in the interest of the Australian Government to decrease the quality standards of products supplied to consumers that are

otherwise similar, so the balance of these two regulatory areas must be considered as part of the wider framework.

In particular, it should be recognised that if manufacturing is increasingly pushed towards foods and food manufacturers, complementary medicine manufacturers lose volume while having to pay the same auditing fees, resulting in further price pressures and imbalance between industries.

4. **Impacts on sponsors that pay for overseas inspections.**
   There is an impact on sponsors that pay for overseas manufacturing site inspections, who have a comparatively larger increase in fees, and who also are required to repay travelling costs. Overall fees for inspections should be monitored and reviewed through implementation and beyond to ensure there are appropriate checks and balances between domestic and international inspections, that the system remains fair and aligned with incurred costs.

Further technical information can be provided by CMA during the TGA-Industry Working Group on Good Manufacturing Practice and related processes. Thank you again for this opportunity to respond to the proposal to amend the current good manufacturing practice (GMP) fees and charges.

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