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Regulatory Services and Drug Control Branch
Therapeutic Goods Administration
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TGAFeesAndCharges@health.gov.au

16 March 2021

Subject: 2021-22 TGA fees and charges proposal

Dear Mr Masri,

Complementary Medicines Australia (CMA), as the peak body for the complementary medicines sector, appreciates the opportunity to comment on options for the TGA's proposed fees and charges for the 2021-22 financial year. We seek to maintain a fair administrative operation of regulations and services for the industry.

Over the last number of years, provided appropriate ongoing cost efficiencies are considered and implemented, CMA has regularly supported an increase of fees and charges in line with indexation (combination of wage price index and the consumer price index on a 50:50 basis and as per the preferred current consultation option 3).

In particular years, CMA has provided further support by way of agreement to an additional surcharge applied by the TGA in relation to specific increases in fees and charges, to extend the TGA's activities in general and listed medicine post market activities specifically:

- in 2012-13 fees and charges were increased by **5.6%** (2% higher than the indexation factor) to meet the costs of implementation of the TGA Blueprint Reforms; and
- 2018-2019, annual charges for Listed Medicines were increased by almost 10% (around $100 per annum per product), to account for additional post market monitoring activities of complementary medicines.

The CMA Board of Directors met on the 18 February 2021 to consider the outcomes of the TGA-CMA Bilateral meeting of the 17th of December 2020 in which the TGA consulted with the peak body in relation to the proposed fees and charges for the 2021-22 financial year. CMA Directors support the long-standing indexation approach to fees and charges, in this instance being a proposed increase of 1.05% for the FY 2021-22.

CMA would like to take this opportunity to comment on the *Fees and Charges Proposal 2021-22 Consultation* paper dated, February 2021.

Cost recovery obligations of the TGA

The 2019-20 Mid-Year Economic and Fiscal Outlook (MYEFO) announced that the Government would provide $33 million over four years for the TGA with $15 million per year ongoing from 2022-23. This funding is specifically earmarked for meeting the costs of a range of fee-free services provided by the TGA and which cannot be appropriately recovered.

Maintaining currency of records on the Australian Register of Therapeutic Goods (ARTG)

At the 17 June 2020 Complementary and OTC Medicines Regulatory & Technical Consultative Forum (ComTech) meeting, industry proposed the need to introduce a fee-free period for sponsors to amend ARTG records to ensure compliance against current legislative requirements. The CM sector has transitioned through some 32 recommendations from the Medicines and Medical Devices Reforms (MMDR) aimed at the complementary medicines sector, as a consequence a host of updates have been required to reflect changes in the regulatory landscape including but not limited to ingredients, quantities, and indications.

The proposal of a fee-free period to amend ARTG records would serve as an incentive for industry to make proactive changes and maintain ARTG records, without footing the financial burden currently imposed. This would have the extended benefit of reducing the TGA workload in this service area. Currently, the changes table for listed medicines provides only a limited range of circumstances where correction to an AUST L ARTG record can be made without incurring a charge. The fee exempt pathway is only used in exceptional circumstances in line with written approval to use a code which must be obtained from the TGA often involving Department of Finance approvals. However, if an error is found to be made by the TGA and a correction is required then this can be done fee-free on a case-by-case basis. The minutes from the 17 June 2020 meeting confirm that 'the TGA can remove these types of fees however, cost recovery implications would need to be taken into account'.

The ability to make multiple grouping changes for listed medicines in one application, rather than requiring separate applications for each change required would be supported. With the exception of indications and a name being changed together, this does not appear to be prevented by the Therapeutic Goods Groups Order. CMA suggests that making the above processes more efficient and streamlined, bolstered by the additional funding provided by government in the forward financial years for these types of services, would have the added benefit of strengthening overall compliance in the listed medicine sector.

Regulatory Impacts

CMA has provided significant contribution to years of important MMDR reforms. The implementation of these reforms however has introduced significant regulatory burden, in particular, changing labels, ARTG entries, and advertising in line with new legislative instruments.

The Evidence Guidelines for listed medicines has been one of the last reforms to finalise, but as evidence forms the basis of many other requirements including labels and advertising materials, we are concerned that current discussions could result in an implied "restart" or change of approach to indications and thus all the materials which have already changed in the last 3 years at significant cost to business, a cost that becomes reflected through increased cost to consumers, impacts on employment, and loss of international competitiveness and ability to scale up and increase other important sustainability and export opportunities.

We support the project to simplify and streamline the Evidence Guidelines provided that the requirements are not greater than those presented through the TGA's history as this would significantly limit relevant and reliable information available to consumers, and leave them vulnerable to information or international products that are less reliable and without the same quality control as Australian products. This approach is in alignment with the goals of the National Medicines Policy, which provides for the Government and industry working together to promote important objectives, including being responsive to people's needs and incentivising preventive health and cost effective care.

Digitise and modernise the TGA business systems

CMA supports the digitisation and modernisation of TGA's business systems and infrastructure. The $12 million investment over four years will result in process improvements for a more secure and integrated approach across multiple TGA business functions.

CMA supports the first set of priorities related to this project which are set to get underway in 2021 and include:

a) developing a plan to integrate features of the existing TGA business processes to deliver a seamless experience for sponsors.
b) improve the accuracy and accessibility of the ARTG and introduce new analytics and reporting capabilities, making it easier to search for information.

In realising priorities of the recent funding decision and the seamless experience for sponsors, aspects of maintaining currency of records on the ARTG on a fee-free or reduced fee basis, as mentioned above should be taken into account and cost recovery implications off-set accordingly.

Yours sincerely,

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