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7 March 2022

Subject: 2022-23 TGA fees and charges proposal

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Complementary Medicines Australia (CMA), as the peak body for the complementary medicines sector, welcomes the opportunity to comment on the options for the TGA's proposed fees and charges 2022-23 financial year. We seek that a fair administrative operation of regulations and services for the industry are maintained.

The TGA is a cost-recovered entity with fees and charges set in accordance with the Australian Government's *Charging Framework and Cost Recovery Guidelines*. Over the last number of years, provided appropriate ongoing cost efficiencies are considered and implemented, CMA has regularly supported the increase to 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:

- 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 considered the outcomes of the TGA-CMA Bilateral meeting of the 10th of December 2021, in which the TGA consulted with the peak body in relation to the proposed fees and charges for the 2022-23 financial year. CMA therefore supports the indexation factor only approach to fees and charges, in this instance being a proposed increase to fees and charges by an indexation factor by **2.6%,** subject to rounding for FY 2022-23. Most fees and charges increased by 1.05% from 1 July 2021. The indexation only increase is consistent with the long-established practice and provides opportunities for efficiency gains through business process improvements.

CMA supports this approach contingent on the appropriate, no-policy change to the revision and application of the evidence guidelines for listed medicines. We appreciate due consideration of our feedback outlined below.

CMA would like to take this opportunity to comment on the *Fees and Charges Proposal 2022-23 Consultation* paper dated, 25 January 2022.

CMA continues to drive 'a healthy regulation for a healthy future' agenda for the sector. The introduction of a refreshed therapeutic goods regulatory regime over the years has included the establishment of a novel intermediate pathway for listed complementary medicines with higher level therapeutic indications, supported by product specific evidence (Assessed Listed Medicines). Other developments such as market exclusivity for new ingredients and a data protection scheme for Assessed Listed Medicines, coordinated by the Department of Health's Therapeutic Goods Administration, have advanced the sector's capabilities further.

We have however seen years of major reviews to the pillars of our world class regulatory framework for complementary medicines and now is the time for policy stability and certainty for business in concert with the next phase of the Government's Economic Recovery Plan.

The sector continues to see healthy growth, predominantly as a result of strong exports even with a decrease in overall exports during the COVID pandemic. Australian brands are recognised and trusted internationally, with China importing more complementary medicines from Australia than almost anywhere else in the world in 2019.

As Complementary Medicines Australia celebrates 50 years in promoting preventive health, it is a timely reminder of how indispensable health is as a prerequisite for overall well-being as well as the foundation of economic and social development.

<u>Cost recovery obligations of the TGA</u>

The TGA recently undertook a Charging Review conducted by PricewaterhouseCoopers (PwC), which assessed data during the second half of 2020. The costing data collected did not represent 'business as usual', with further data collection underway to enhance the costing model built by PwC. The outcomes of this work could herald urgent consultation with peak industry bodies, if significant costing changes are required for 2023-24 and beyond.

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.

Beyond Bank Building
105 Mawson Drive Mawson ACT 2607

PO Box 450
Mawson ACT 2607

P +61 2 6260 4022
F +61 2 6260 4122

W www.cmaustralia.org.au
E cma@cmaustralia.org.au

ABN 49 169 036 088

However, at the bilateral meeting in December 2021 the TGA provided that significant Budget Forecast pressures remain for the TGA, particularly around the cost of fee-free services and reform costs. Non-discretionary TGA functions encompass a wide verity of activities that are currently not appropriately cost-recovered under the agreed model, including significant compliance, enforcement and litigation actions. The result being where there is not enough direct Government funding, the remaining is to be absorbed by levied fees and charges imposed on the regulated industry.

Many of the significant costs associated with TGA compliance, enforcement and litigation actions have been seen as a result of those that operate largely outside of the regulated system, including where products are not appropriately registered on the Australian Register of Therapeutic Goods (ARTG) or represent an illegal food type product.

Continuing cost pressures include a forecast from TGA that ARTG entry volumes will remain stable. The TGA implementation of a third listing pathway, the Listed Assessed Medicine pathway needs to be fit for purpose for the industry to demonstrate quality evidenced based medicines and for the growth of the pathway to mature to what was envisioned and agreed by the expert panel when the reforms were designed. Currently, the administration and implementation of this pathway has seen more hurdles than successes when it comes to the clinical evaluation differences between registered and listed medicines. Should the pathway operate as an option for industry to apply for evidence evaluation that is appropriate and recognises that these listed medicines have already been assessed as safe for consumers, then growth in applications is envisaged.

Regulatory Impacts

CMA has provided significant contribution to years of important Medicines and Medical Devices Review (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 the last update to a suite of changes. As evidence forms the foundational basis supporting other requirements, including product labels and advertising materials, current review processes could result in an implied "restart" or change of approach to supporting indications. Thus, potentially impacting all the materials which have already changed in the last few years at significant cost to business, an impost 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. While the TGA state there are no policy changes in the proposed revised guidance, consultation and response is still open to the regulatory impact imposed on industry. Initial review shows there are in fact significant and high impact policy changes being presented, contrary to the agreed purpose and intent of the consultation.

All stakeholders, including industry should be afforded an appropriate time in order to respond meaningfully to TGA consultations, rather than the four week evidence guideline period that has been released especially at a time when many are responding to the direct impacts on their business from the flooding disaster across parts of the nation. Consultation should be used as a way to improve decisions, not as a substitute for making decisions. Depending on the significance of the proposal, 60 days is usually considered by government as appropriate for effective consultation. Longer consultation periods may be necessary when they fall around holiday periods such as the example above.

Appropriate recognition of the levels of evidence substantiation for the complementary medicine industry will be a critical, discerning component where the right balance must be struck in order for the CMA to support the proposed fees and charges increase as currently proposed in option 3 of the consultation paper.

Overall, CMA has long supported the review in order to simplify and streamline the Evidence Guidelines, without imposing policy change. This is in line with the purpose of the TGA's Transformation Program to lower the regulatory burden on sponsors. We support the approach 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 also 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 (until June 2025) will result in process improvements for a more secure and integrated approach across multiple TGA business functions, making it easier and simpler to do business with the TGA and to help health consumers and professionals find the information they need more easily.

The new digital processes will mean more straightforward, faster interactions between industry and Government, earlier approvals of medical products, reduced administrative effort, and timelier decision-making by the TGA.

CMA supports the first set of priorities related to this project which 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. A trial (beta) version of a new ARTG search tool is currently open to user feedback.

The CMA supports the TGA's continued efforts to progress its digital transformation project to streamline its business systems and modernise IT infrastructure. Crucial to the projects successful ongoing roll out will be an appropriate execution of reforms that serve to balance reasonable and transparent decision making. This will facilitate simpler, faster interactions with the TGA. It will also allow for greater transparency in the regulation of medicines and faster access to emerging and new health technologies in the international markets.

Complementary Medicines are identified as a high value-add Australian industry, earmarked for future growth as part of the whole-of-government strategy and national priority of the National Manufacturing Roadmap. The framework for and appropriate risk commensurate regulation of complementary medicines is crucial for this sector to leverage its comparative advantages; its capability, capacity and expertise.

Kind regards,

[redacted]

Emma Burchell | Director Operations
Complementary Medicines Australia

Beyond Bank Building
105 Mawson Drive Mawson ACT 2607

PO Box 450
Mawson ACT 2607

P +61 2 6260 4022
F +61 2 6260 4122

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