Technical Alert

Public Consultations Open: GMP Fees & Charges; TGO 77 Remake.

Proposal to change the current good manufacturing practice (GMP) fees and charges: Please send your response to CMA by **26 February**.

Over the last four financial years, the TGA has been significantly under cost-recovered for GMP fees and charges in relation to medicines, averaging $2.1 million per year. The under recovery is due to several factors, the most significant being under-recovery in time spent auditing domestic Australian manufacturing facilities. They have engaged Deloitte to improve the accuracy and transparency of the cost recovery arrangements and address that under-recovery.

The TGA is conducting a consultation to seek feedback from the potentially impacted stakeholders within the medicinal product industry. The Deloitte consultation paper puts forward 3 options for stakeholders to consider, in summary:

1. *Uniform Increase*. Increasing all fees and charges by 17.4% to arrive at an additional $2.1 million in revenue.
2. *Minimal Change*. This option would have the TGA recover the cost of all inspection hours. There would be no implied 'free' inspection hours within the annual charge. Under this option, the annual charge, currently set at different levels for 'high' and 'low' levels of activity, would be merged and reduced.
3. *Optimise*. This option builds on Option Two but also addresses under-recovery in GMP Clearances and Licence Variations, with the introduction of one new fee and an increase in another, which will reduce the hourly fee for inspections when compared to Option Two.

Deloitte's preferred and recommended direction is Option 3, which encourages a higher level of compliance by manufacturers in order to reduce regulatory fees and charges, and addresses all major areas of under recovery.

Submissions to the TGA, via CMA

The TGA are asking industry associations including Complementary Medicines Australia to collect and consolidate their members' feedback into a single submission to TGA where feasible. They request stakeholders to lodge submissions via your TIWGG Industry Association representatives. **Therefore, please send your responses to submissions@cmaustralia.org.au by *26 February 2018*, in preparation for the 5 March submission.**

It is important that every stakeholder consider the impact of changes to the current GMP fees and charges on their product/s and business/s. Responses should include:

- Which option(s) you would support and why.
- An assessment of how the proposed options will affect you and/or your businesses (either positively or negatively). Please attempt to quantify this (e.g. financial impacts).
- Any other information you would like to provide.

The remaking of TGO 77 - Microbiological Standards for Medicines - without technical amendment

The Therapeutic Goods Order No. 77 – Microbiological Standards for Medicines (TGO 77) is a legislative instrument that has been in force since 1 January 2010. Most legislative instruments are automatically repealed after a fixed period of time, called 'sunsetting'. TGO 77 is due to sunset on 1 October 2018.

The new Order will reflect the current requirements of TGO 77 without technical amendment; it is not intended to substantially alter existing arrangements. Upon commencement it will replace the existing TGO 77 before it is due to sunset.

The closing date for submissions to the public consultation is **6 March 2018**.

ENDS

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