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Regulatory Pricing and Decision Review Section
Regulatory support and Drug Control Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Submitted by email to: TGAFeesandCharges@health.gov.au

Dear Sir / Madam,

Consultation: Fees and charges proposal 2019-20

We refer to your call for submissions re the above.

ASMI appreciates this opportunity to provide comment on the proposed reforms.

About ASMI

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. More information about ASMI and our membership is available on our website.

This submission has been prepared with input from the ASMI membership and reflects their combined views.

Principles

ASMI and its members are of the view that the following general principles should be applied in relation to all TGA fees and charges:

- TGA fees and charges should reflect the costs of the TGA's activities
- TGA processes should be focussed and optimised accordingly
- As a fully cost-recovered agency, the TGA has an obligation to perform their activities as efficiently as possible
- Any changes to fees and charges should be introduced with a suitable notice/transition period

- The TGA should only be spending sponsors' money on activities required under the *Therapeutic Goods Act* (more on this below)

In relation to cost-recovery, we note that the TGA's website[1] indicates that:

> *The TGA is required to recover its costs through fees and charges for all activities that fall within the scope of the Therapeutic Goods Act 1989, including the TGA's public health responsibilities.* [emphasis added]

Also, the TGA's Cost Recovery Implementation Statement[2] (CRIS) similarity states that:

> *The Therapeutic Goods Act 1989 (the Act) provides a legal authority for the TGA to charge for its regulatory activities within the scope of the Act.* [emphasis added]

Further to this, The TGA's CRIS and the Australian Government Charging Framework[3] both state that:

> *Where specific demand for a government activity is created by identifiable individuals or groups, they should be charged for it unless the Government has decided to fund that activity.*

On this basis, ASMI and its members continue to be concerned at the large amount of TGA resources (and hence industry fees and charges) that are spent on activities which are outside the scope of the Act and which should be paid for by the Government or by the individuals who benefit. Activities of concern include:

- SME assistance
- Training and education
- Community service activities and announcements directed to the public at large
- Social media promotion of the TGA itself

Consistent with Cost Recovery Principles, the fees and charges collected by the TGA should only be spent on activities within the scope of the *Therapeutic Goods Act* (i.e. only those activities that are relevant to the *"establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods"*[4]).

Annual increase to fees and charges

In keeping with established practice and with predictability, consistency and transparency in mind, ASMI and its members prefer Option 3 (i.e. an increase to all fees and charges by indexation factor).

[1] https://www.tga.gov.au/fees-and-payments
[2] https://www.tga.gov.au/sites/default/files/cost-recovery-implementation-statement.pdf
[3] https://www.finance.gov.au/resource-management/charging-framework/
[4] http://www.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/consol_act/tga1989191/s4.html

Other changes for 1 July 2019 commencement

Lowering the application fee for export only in-vitro diagnostic (IVD) medical devices

ASMI provides no specific comment in relation to this item.

Listed assessed medicines variations fee

The fees and charges for listed assessed medicines should be set according to the principles outlined above. At the time of writing, we understand that the TGA has not received any applications for new listed assessed medicines (and so there will be no experience from which to estimate the timings and costs for the efficiently delivered processes associated with this new class of listed medicines). As a starting point ASMI members have suggested benchmarking against the OTC fees and charges.

As this is a new process and the proposed fees can only be estimated at this stage, it will be important to monitor these fees and charges to ensure that they are proportionate to the resource requirements.

Good manufacturing practice (GMP) fees

ASMI provides no specific comment in relation to this item, having previously provided feedback in response to the earlier consultations on the matter.

We remain available to meet with you to discuss any of the above should you require any further clarification relating to this submission.

Yours sincerely,

Steven Scarff
Regulatory and Legal Director