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Ben Noyen
Assistant Secretary
Manufacturing Quality Branch
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Therapeutic Goods Administration
PO Box 100
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Submitted via online submission

Dear Ben,

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

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. Further information about ASMI and ASMI members is available on our website (www.asmi.com.au).

Thank you for the opportunity to provide feedback to this consultation. ASMI is supportive of ensuring an effective cost recovery model for TGA fees and charges. As members of TIWGG, we recognise the work that has been undertaken across the programs of the MQB to streamline and improve the processes within the capability of the existing infrastructure, improve the serviceability of the existing infrastructure for TGA and industry users, and provide updated guidance for the clarity of requirement. It is now appropriate to address the period of under-recovery of GMP fees and charges and the appropriateness of cost recovery of the activities of the MQB's programs.

ASMI has consulted with members to understand which options our members support and why, to understand the impact of the proposed options on their businesses and where possible to quantify the implications. It is important to state that this process has not been straightforward when based solely on the consultation document, which provided no data to describe the proportion of the under and over recoveries of the current GMP fees and charges structures. In the absence of this information members were unable to assess the relative merits of each the options to deliver a fairer and more appropriate cost recovery and were left with only the consideration of the options based on the likely impact to their budgets.
The initial reaction from members was:

- **Option 1** – a flat rate increase to all existing fees of 17.4% was not attractive to any of our members. and it was agreed did not provide the benefits to the Australian manufacturing industry of incentivising a high level of compliance, and was presented as not aligning well with the cost recovery guidelines.
- **Option 2** – addressed the "single biggest area" of under-recovery – that of *domestic manufacturing inspection hourly fee* (primarily domestic, also reattributing the 'free hours' implied in the annual

charges, but also included an unexplained small increase of *overseas manufacturing inspection hourly fee*) and simplified and reduced the Australian manufacturer's annual charges. There was no change to clearance fees in this option. This option was naturally preferred by sponsors importing products for supply (the majority of our ordinary members), many of whom maintain scores (x20s) and some hundreds (x100s) of clearances for overseas manufacturers. Option 2 represented no change to their current budget.

- **Option 3** - built on option 2 but also addressed an under-recovery in *GMP clearance application fees* by more than doubling the current fee and introducing a new Licence Variation Fee. These increases allowed for reduction the option 2 rates for the *domestic manufacturing inspection hourly fee* and the *annual charges* and removal of the small increase of *overseas manufacturing inspection hourly fee*. This options was naturally preferred by our Australian manufacturers. However sponsors struggled to understand this fierce increase to their GMP Clearance budget and how it could be the TGA's recommended option when the descriptive language of the paper hadn't prepared this expectation.

While members were unable to reach a consensus on the preferred option, the following points of principle were agreed by all members who participated in preparation of our response to the consultation. Members expressed:

- Strong support for a fee structure for licencing that incentivises high levels of compliance. A1 performance means longer periods between inspections and fewer inspection hours (lower cost) – where repeat A3 performance means annual inspections and longer inspection hours (higher cost).
- The importance of training and consistency of the inspectorate noting that inspection hours and hence cost of the inspection will be proportional to the skill, experience and efficiency of the inspector(s). A thorough understanding of appropriate risk based application of GMP principles, consistency of categorisation of deficiencies and effective inspection review processes will be important to ensure manufacturers are not unduly impacted by the revised fee structure.
- Support for the introduction of a Licence Variation Fee, consistent with cost recovery principles.
- The need to further investigate opportunity for improvement in the Clearance Process to reduce the duplication of review. The current process requires this duplication with its ratio of one overseas manufacturer to many sponsors applying for clearance with the same evidence. While we recognise there may be a level of complexity we still believe there must be a way further improvement can be achieved. Involvement of industry in identification and investigation of options may identify new approaches. We also recognise delivery of the improvement may require investment in new IT infrastructure. ASMI would like to see TGA invest in these improvements of processing timeframes and where appropriate Clearance fees reductions.
- The importance of Fees/charges closely reflecting the costs of the activities necessary to provide the services should future proof their continued provision. Given the continuing growth in number of Clearance applications year on year, effective attribution of fees to recover the necessary activity should enable TGA management to react and justify increasing resource to meet the demand.
- The adverse impact on sponsors regulatory budgets of the TGA's recommended option 3, will more than double Clearance Application Fees from 1 July 2018. The majority of company budgets are already established for the next financial year (indeed some companies who work on a calendar year are already in the midst of their fiscal year). ASMI therefore recommend that the commencement of any changes to Clearance fees should be delayed at least until January 2019 to allow sponsors to make budget provision.
- For Australian manufacturers – it is harder to estimate the impact. Depending on the timeframe of the next inspection, and given the transition allowance to use "unused free inspection hours until 30 June 2020" and the reduced annual manufacturing charge, the implications of the changes proposed in Options 2 and 3 are likely to be more gradual and somewhat easier for making provision.

Thank you for providing ASMI (and the wider medicines industry) the vital contextual information, that breaks down the proportion of under-recovery across the different GMP process activities. It better explains why TGA considers option 3 the most appropriate option based on consistency with cost recovery principles.

While this data was presented at the TGA's industry information sessions, the short notice period, particularly of the Sydney sessions meant few of our members were able to attend. Of those who contributed to the ASMI review of this consultation only one member representative and one of the ASMI secretariat attended the sessions.

After sharing this breakdown of the areas of under-recovery with members participating in the response, all but one has now accepted that option 3 provides for the fairest cost-recovery adjustment to the GMP fees and charges model. All the points agreed and presented above remain unchanged. One member however wishes to express dissent from the majority view. They cannot accept Option 3's more than 100% increase of the *GMP clearance application fee*. After the provision of this data their preference is now to support Option 1 - the flat 17.4% increase across all current GMP fees and charges. Their change from their initial preference of Option 2, is in recognition that this option would unfairly burden Australian manufacturing fees and charges such that Australian manufacturers would in effect be cross subsidising the under-recovery of the GMP clearance process.

During our Bilaterals discussions we were advised that the TGA executive have yet to consider the best approach to the revision of the GMP Fees after the consultation closes. Given the final fee structure could still be further amended, it will be important to provide the industry associations with the final GMP Fees and Charges structure and a supporting rationale before the final update to Therapeutic Goods (Charges) Regulations 1990 is presented to the Minister.

We hope this feedback on the proposal is helpful. Please don't hesitate to contact me if you require more information.

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