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**Via email: [GMP@tga.gov.au](mailto:GMP@tga.gov.au)**

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

Medicines Australia (MA) appreciates the time allowed for response, and the ability to review the Deloitte report, which is superior to other current cost recovery consultations. MA does not however support the three options outlined in the Deloitte consultation document as an optimal model for fee recovery for Medicines GMP and is concerned over the proposed timeframe for implementation of any changes as a result of this consultation.

Section 31 of the cost recovery guidelines states that entities should actively engage with stakeholders throughout all stages of the cost recovery process, from policy development to implementation and review. The global nature of the innovative pharmaceutical industry requires the consideration of business planning cycles, which we do not believe have been taken into account in this consultation. Annual budgets for most companies have already been set for 2018-19. Implementing significant unexpected fee changes mid budget is unreasonable. Any changes to Clearance fees should be subject to an appropriate notice period to allow sponsors sufficient time to make budget provision.

**Recommendations:**

MA recommends that implementation of new GMP fees is delayed to enable further consultation and allow reasonable notice of proposed changes.

MA believes that further consultation is warranted and necessary to achieve the goal of establishing a more effective fee structure. In that light please find some comments on the proposals presented in the Deloitte paper.

**Comments:**

Irrespective of the model developed to lessen apparent under-recovery of costs, any overall increase in fees and therefore costs to industry should be associated with a clear proposal to improve services. This should include baseline metrics, target processing and decision-making milestones, and increased transparency of processes, including tracking of applications. Basic customer service standards such as defined times for replies to queries and clear routes of communication should be introduced and monitored. Improved services may also help to mitigate increased cost associated with a changed GMP fee structure by reducing time industry personnel spend on follow-up to

queries and reduce difficulties in planning associated with uncertain timelines for processing and decision making.

MA supports a licencing system that incentivises high levels of compliance by companies. Better performance can mean longer periods between inspections, therefore fewer inspection hours and subsequently a lower cost. Consistent training of inspectors to ensure an understanding of GMP review processes and the inspection review process may also reduce inspection hours and provide cost efficiencies. This would raise question on the argument put forward in the paper, that only option 3 would encourage higher compliance rates. A clear cost recovery process could also help future-proof the system, whereby the TGA can allocate the most efficient and appropriate resources necessary to support the number of applications received.

In exploring opportunities for increased effectiveness outside of simple fee increases, there would also appear to be the potential to gain efficiencies and reduce costs for the TGA and industry through closer collaboration of Medicines GMP with comparable overseas regulators' inspectorates. This would be in line with the opportunity to leverage expertise of comparable overseas regulators, identified in the Medicines and Medical Devices Review and currently being implemented in the Prescription Medicines Authorisation Branch (PMAB) in various forms. Adoption of a similar concept by Medicines GMP could reduce both the number of overseas inspections undertaken by the TGA and the number of compliance verifications required to be assessed, freeing TGA resources to focus on areas of high priority.

It would also be appropriate for the TGA to address wider cost recovery considerations. If the TGA has been able to manage an under-recovery in GMP from other areas of revenue, this suggests a potential over recovery elsewhere. For example, if the over recovery has been from Category 1 or Category 3 fees, there could be justification to reduce fees in these areas, thus leaving the overall impact cost neutral to industry. For example, option 3, which proposes the more than doubling of the GMP Clearance Application Processing Fee to address both GMP Application Fees and Compliance Verification (CV), could be modified to avoid cross subsidisation whereby a smaller increase to the Clearance Application Fee is accompanied by an increase in the CV fee.

We would strongly encourage the TGA to further engage with stakeholders before committing to any specific changes in GMP fees and charges. We are always more than happy to discuss any aspect of this submission further. I can be contacted on 02 6122 8525 or by email [edesomer@medaus.com.au](mailto:edesomer@medaus.com.au).

**Yours faithfully**



**Elizabeth de Somer**

**Director, Policy & Research**