

Licensing and Certification Section  
Manufacturing Quality Branch  
Therapeutic Goods Administration  
Department of Health  
PO Box 100  
WODEN ACT 2606

Email: [GMP@tga.gov.au](mailto:GMP@tga.gov.au)

Dear Madam/Sir

Accord is pleased to provide the following comments to the consultation process on the TGA's Good Manufacturing Practice Fee Model Review.

### **Key point on Accord's position**

Accord supports Option Three (Optimise). Option Three appears to be the option which is most equitable for Accord members and is best aligned with the Government's cost recovery policy.

### **About us:**

Accord is the peak national industry association representing the manufacturers and marketers of formulated hygiene, cosmetic and specialty products, their raw material suppliers, and service providers.

Accord member companies make and/or market fast-moving consumer and commercial goods including hygiene, cosmetics and specialty products, sunscreens, food contact sanitisers, industrial and agricultural sanitisers, household pesticides, disinfectants and specialty commercial products.

Member companies include large global consumer product manufacturers as well as small dynamic Australian-owned businesses with 57 percent of members operating as SME (<200 employees). A list of Accord member companies is available on our website: <http://accord.asn.au/about/members>.

### **Accord's comments**

Accord supports government action which brings down the cost of doing business. The World Bank Group<sup>1</sup> places Australia at 14 out of 190 economies in its Ease of Doing Business Index. The Index is a benchmark study of regulatory burden. We note that New Zealand, our closest trading partner is ranked at Number 1. Australia, ranked 6 in 2006 has steadily lost its competitiveness and was ranked 10 in 2015; 13 in 2016 and is currently ranked 14 for 2017.

An area where Australia is also doing poorly is cross border trading where we are ranked 95. The government's policy of '*accepting trusted international standards and products*', was in part, an effort to address this problem by reducing duplication of regulatory approvals, align internationally to reduce delays, increase competition and improve business competitiveness in Australia. This supports the government's overall objective to reduce the regulatory burden

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<sup>1</sup> The World Bank Doing Business Index June 2017

on business, community organisations, families and individuals. One way of reducing regulatory burden is to remove unnecessary duplication of multiple regulatory processes. This includes recognition of overseas approvals and processes to avoid extra delays that result from imposing Australian-specific requirements when an approved system, service or product already exists in an international market. The cost to industry of importing the same products which are sold freely overseas but are then required to meet specific Australian requirements can be quite high. Members have indicated that the cost for sunscreens meeting PICs GMP requirements compared to the costs of supply for the same product as a cosmetic in the EU is around \$200K plus.

We therefore welcome the Deloitte Fee Review Model and support Option Three as it will provide some relief to Accord member companies, particularly those requiring overseas inspections. While we support Option Three, we are conscious that this is based on only limited data made available to us. We also note that a requirement of the Australian Government's Charging Framework is that the relationship between charges and costs for fees for service must reflect the **efficient** unit cost of a specific good or service.

The Deloitte Fee Review Model does not provide the data to substantiate that the TGA's costing model is the most efficient to provide the activity. While some international data is provided, this is not necessarily directly comparable. Of interest to industry is that the fee for service is the most efficient when compared to similar services in the private sector or by comparable regulators for the same activity.

I trust our comments are of assistance. The contact person for this matter is Ms Dusanka Sabic, Accord's Director of Regulatory Reform. Ms Sabic can be contacted on 02 9281 2322 or by email at [dsabic@accord.asn.au](mailto:dsabic@accord.asn.au).

Yours sincerely



Bronwyn Capanna  
**Executive Director**

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