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

[redacted]

Dear Madam/Sir

Accord is pleased to provide our submission to the TGA's Consultation: *Fees and charges proposal 2022-23*.

Accord is the peak national industry association representing the manufacturers and marketers of formulated hygiene, personal care and specialty products, their raw material suppliers and service providers. Accord member companies make and/or market a broad range of consumer and commercial goods that play integral roles in safeguarding public health, promoting personal hygiene, boosting confidence and emotional wellbeing, maintaining comfortable homes and enhancing quality of life, as well as keeping the wheels of commerce and industry turning. Member companies include large global manufacturers as well as small dynamic Australian and family-owned businesses. A list of Accord member companies is available on our website: http://accord.asn.au/about/members.

Headline statistics[1] for our industry's economic footprint include:

- Accord's membership is approximately 100 companies.
- Collectively, Accord member companies directly contribute more than 12,000 full-time equivalent jobs.
- Nationally, more than 175 offices and more than 65 manufacturing sites are operated by Accord member companies.
- 80% of member companies export products overseas.

Accord supports the TGA's preferred Option 3 for an increase in all fees and charges by an indexation factor of 2.6% subject to rounding. Option 3 maintains the predictability in price increases established over a number of years, minimises the impost on business compared to Option 2 while at the same time allowing for the TGA to provide for efficiency gains through business improvement processes which cannot be achieved under Option 1. This approach is consistent with government policies for cost recovery as well as public sector wage increases to be offset through productivity gains.

Accord notes the proposal to introduce fees for clinical trial variation applications. While Accord supports the provision to allow fees for variations which is consistent with the regulatory treatment of variations by other regulatory agencies, we do question however, why for a 30-day evaluation the cost, based on staff effort is $510 yet for a 50-day evaluation this rises significantly to $6,300. Similarly, there is the same cost discrepancy of the fees for a full evaluation with the 30-day evaluation for a clinical trial approval costing $1,810 and the 50-day

[1] Results from Accord Industry Size and Scale Survey 2018

evaluation costing $22,500. It would appear that the cost for a 50-day evaluation for both services i.e., approvals and variations compared to a 30-day evaluation is based on factors other than just staff effort required for these applications.

On a final note, we refer to the comments on cost recovery obligations of the TGA (p4). The Consultation Paper advises that the Act provides legal authority to charge for fees and that the *Therapeutic Goods (Charges) Act 1989* provides the legal authority to levy annual charges on medicines, biologicals and medical devices. No mention is made of Other Therapeutic Goods. While it may seem a trivial matter to the TGA not to recognise this category it is not to Accord Members given that for many their only relationship with the TGA is through their manufacture of other therapeutic goods such as disinfectants. To not recognise this category yet to charge for it adds to the frustration Members feel regarding the regulatory costs and burden associated with what are generally considered low risk products.

Accord remains concerned that many of its member products while recognised as low risk by the TGA continue to be subjected to a high level of regulatory intervention. This is inconsistent with their regulatory treatment by comparable regulatory authorities which recognises the low risk nature of these products and regulates accordingly. This higher regulatory burden reduces the availability of products to the Australian consumer, imposes additional costs and results in delays to market.

I trust Accord's comments are of assistance. Should you have any questions in relation to our submission please do not hesitate to contact Dusanka Sabic, Accord's Regulatory Advisor on [redacted]

Yours sincerely

Authorised for electronic submission

Catherine Oh
Director, Regulatory & Supply Chain Strategy

3 March 2022