

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

Dear Madam/Sir

Accord commends the TGA for undertaking the consultation process to seek stakeholder feedback on fees and charges for 2019-20.

Accord is pleased to provide the following comments to the TGA's Consultation paper: *Fees and charges proposal 2019-20*.

Accord supports Option 3 which proposes a general increase of 2.05% for fees and charges.

We note the commencement of other proposed charges for 1 July 2019. Regarding that proposed for the listed assessed medicines variations (L(A) C1), we consider the application fee for a simple product label change which does not affect the efficacy and where no evaluation of the product is required, as proposed at \$1990 appears to be rather too high. We recommend that this be reconsidered.

We note that the TGA undertakes a considerable amount of work in the public interest which should be taxpayer funded. We would urge the Government to consider appropriately funding these elements of the TGA's work.

Please do not hesitate to contact Accord should you have any questions in relation to Accord's comments. The contact officer is Ms Dusanka Sabic, Director, Regulatory Reform who can be contacted on 02 9281 2322 or by email at dsabic@accord.asn.au.

Yours sincerely



Bronwyn Capanna
Executive Director

04 February 2019