



AusBiotech's response to the TGA's proposed fees and charges for 2019-20

To:
Regulatory Pricing and Decision Review Section
Regulatory support and Drug Control Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
TGA Fees and Charges@health.gov.au


8 February 2019

From: AusBiotech Ltd
ABN 87 006 509 726
Level 4, 627 Chapel St
South Yarra VIC 3141
Telephone: +61 3 9828 1400
Website: www.ausbiotech.org

Context

AusBiotech is pleased to provide comments to the Therapeutic Goods Administration (TGA) in response to its proposed changes to fees and charges for 2019-2020.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology, industrial and agricultural biotechnology sectors. Within AusBiotech, the medical device and diagnostic industries are represented by AusMedtech, an industry group dedicated to the development, growth and prosperity of the Australian medical technology industry.



AusBiotech is providing comment as requested by the TGA in relation to proposed changes in fees and charges for 2019-2020.

This builds on previous comments made by AusBiotech during meetings conducted by the TGA in December 2018.

Response to proposal

AusBiotech agrees with the TGA on option 3 – ‘Increase all fees and charges by indexation factor.’

As per the TGA consultation paper, under this option, fees and charges would increase by 2.05%. The indexation-only increase is not only consistent with long established practice but also provides opportunities for efficiency gains through business process improvements.

In applying the indexation factor, fees and charges would be rounded to the nearest \$10 for items less than \$10,000 and to the nearest \$100 for items \$10,000 and above.

Should this proposal be accepted by the Government, the financial impact on sponsors will be a 2.05% increase from 1 July 2019. For example a company that paid \$10,000 annual charges this financial year would be required to pay \$205 more next financial year, assuming constant volumes of the Australian Register of Therapeutic Goods entries and annual charges exemption exemptions.

Option 1 (no increase) is not recommended as this would run the department into deficit, likely resulting in layoffs due to cost. This would only result in delays in getting products to market. Option 2 (percentage increase in line with costs) is possible but this does result in a larger increase for sponsors.