Therapeutic Goods Administration
PO Box 100
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Australia
[redacted]

4 March 2022

Fees and charges proposal 2022-23

AusBiotech is supportive of the proposed fee increase outlined in *Option 3 - Increase all fees and charges by indexation factor,* as the fees are commensurate with the opportunities for efficiency gains. However, AusBiotech also strongly recommends that the TGA is afforded greater Federal Government funding for its fee-free services for public good.

AusBiotech is the Australian representative body for one of Australia's most innovative industries with 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 and agricultural biotechnology sectors. This response has been developed together with the AusBiotech's AusMedtech Regulatory Affairs Advisory Group, which provides guidance and advice on operational and policy-related regulatory matters.

As noted in the consultation, the TGA generally operates on a full cost recovery basis and, while some fee-free services for the public good are funded through the Government ($15 million per year ongoing from 2022-23) it only contributes, but by no means covers, all of the costs of these services. Therefore, while AusBiotech supports the proposed Option three, it also recommends additional funding is offered during the Federal Budget reviews.

Industry supports the Government's public good activities, however, it is already investing in these important activities itself and therefore it should not be paying for them again through their fees and charges. These public good activities include providing timely access to unapproved medicines such as cell and tissues therapies.

The AusBiotech-led Regenerative Medicine Consortium Project's *Global Pipeline Tracker* report recently revealed that the globe is anticipating a pipeline of new and novel regenerative medicine treatments, and that Australia may share in access to some. While there are currently six RM therapies already approved in Australia[1], the new data shows a rich pipeline with 140 therapies in late-stage development globally in multiple therapeutic areas, and up to nine may reach Australian patients in the next five years.

This is just one example in one access Scheme/Program, and is demonstrative of the continued pressure the TGA will face as it undertakes its regulatory functions. Therefore, additional funding to not only continue these activities but to also enable the significantly increasing demand is strongly recommended.

Yours sincerely,

AusBiotech

[1] *Australia's Regenerative Medicine Clinical Trials Database, August 2021.*

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