

23 February 2024

Therapeutic Goods Administration (TGA)

Australian Government, Department of Health and Aged Care

Via: TGA consultation portal

To whom it may concern,

**RE: TGA Fees and Charges Proposal 2024-25**

Medicines Australia welcomes the opportunity to provide feedback on the Therapeutic Goods Administration's (TGA) proposed fees and charges for the 2024-25 financial year. Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members discover, develop and manufacture medicines and vaccines that help people live longer, healthier lives and bring social and economic benefits to Australia.

Medicines Australia formally submits:

- **Not to oppose** the inflation-based increase of 4.7% to fees and charges.
- **To oppose** the increase to annual charges beyond the inflation increase of 4.7% to fund the TGA's digital transformation and enhancement of the Unique Device Identification (UDI) system.
- **To request clarification** on the new fees to request variations to conditions of listing and registration of medicines.

Medicines Australia notes that the fees and charges increase of 4.7% for 2024-25 is in line with previous years' indexation formula, calculated on the average of the wage price index (WPI) and the consumer price index (CPI). We therefore do not oppose this inflation-based increase in the fees and charges.

We however oppose increases to TGA fees and charges beyond the indexation formula of 4.7%, resulting in a total increase of annual charges to 6.30% to 9.13%. We believe that these additional costs are unreasonable, do not allow sufficient business planning for industry and continues cross-subsidisation of other sectors. Specifically, Medicines Australia opposes the proposed increase in annual charges to cost recover TGA's digital and business transformation, and implementation and expansion of the Unique Device Identification (UDI) system.

Moreover, the cost recovery of such a significant investment should include a comprehensive analysis and reporting framework to enable the assessment of the benefits of the digital transformation initiative and UDI enhancements and its cost effectiveness to industry. We therefore request more fulsome and transparent reporting on the areas of expenditure and the deliverables achieved, as well as reporting on the remaining cost items and expected deliverables. Medicines Australia acknowledges TGA's efforts to date in consulting, engaging and communicating with industry on the digital transformation program of work. However, a more comprehensive and transparent reporting of current and expected expenditure linked to deliverables would help industry better consider the appropriateness of the annual industry charge increases. This suggestion is supported by the Cost Recovery Guidelines which states that that a government entity must measure and assess its

performance in achieving government policy outcomes, which includes assessing whether desired outputs and outcomes have been attained.<sup>1</sup>

In addition to the increase in fees and charges, we note the new proposed fees (ranging from \$1,710 to \$2,750) for request of variations to conditions of listing and registration of medicines conditions. It is unclear what variations are in scope for the proposed new fees and whether the fees will apply to TGA initiated, as well as sponsor initiated variation requests.

Furthermore, Medicines Australia would like to request further information on how the fees were determined. For example, do the proposed variation fees reflect the amount of time and resources required by the TGA to process the variation request and what modelling or analysis were undertaken to determine the proposed fees? Medicines Australia requests this information before we can support these new fees and we would be happy to meet with the TGA to discuss further.

Thank you for the opportunity to provide feedback on the proposed TGA fees and charges for 2024-25. To discuss any information in relation to this submission, please contact Ms Tham Vo, Senior Manager, Policy on [tham.vo@medicinesaustralia.com.au](mailto:tham.vo@medicinesaustralia.com.au).

Yours sincerely



Ms Tham Vo  
Senior Manager, Policy  
Medicines Australia

---

<sup>1</sup> Ibid.