Level 5, 478 George Street, Sydney NSW 2000
Patient Voice Initiative

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Transparency, Reforms and Evaluation Support Section
Therapeutic Goods Administration
PO Box 100 WODEN ACT 2606

Response to consultation
Whether the TGA should publish that a prescription medicine is under evaluation

Thank you for the opportunity to provide feedback on the four options currently under consideration by the Therapeutic Goods Administration (TGA) regarding at which point in time the TGA should publish that an evaluation is taking place.

The Patient Voice Initiative (PVI) Incorporated (NSW Association) is a not-for-profit collaboration between patients, industry and researchers who share the goal of improving the patient voice in decision-making about medicines and other health treatments in Australia. Under the leadership of Cystic Fibrosis patient advocate and PVI Chair, Jessica Bean, PVI has undertaken stakeholder workshops around Australia to identify barriers to consumer involvement in health care. This response is informed by that work and discussions with health consumers and representatives of health consumer organisations who attended our recent series of capacity building workshops in each of the state capitals (working with members of the Department of Health's Health Technology Assessment Consumer Consultative Committee).

PVI welcomes increased transparency in TGA evaluations as an important element in nurturing informed, active health consumers who have confidence in their health system. Our preferred option is:

> *Option 2: the TGA would publish that a prescription medicine has been accepted for evaluation for new chemical entities (including biological prescription medicines); extensions of indications; and all generic and biosimilar medicines*

In addition to offering the highest level of transparency, Option 2 enables health consumers and health consumer organisations:

- To better monitor the progress of a medicine in the Australian system and to respond appropriately (for example, a health consumer could discuss the potential of the medicine with their doctor if it had been accepted for evaluation; an organisation could advocate for a sponsor to submit a medicine for evaluation if it had not been submitted to the TGA; and organisations could begin collating lived experience information from their members in preparation for submitting a consumer comment to the Pharmaceutical Benefits Advisory Committee)
- To more easily understand one element of our complex health system by publishing information that is consistent among prescribed medicines and consistent with two key jurisdictions (which is especially important at a time when information about medicines flows freely over borders among online communities and well-connected health consumer organisations)
- To decide which medicine evaluations are of interest to them, rather than assumptions about their interests being made on their behalf.

This information may help active health consumers and their organisations develop realistic expectations (e.g. in terms of timelines and responsibilities) and reduce their frustrations when, sometimes desperately, searching for information that is currently not publicly available.

In addition to publishing the active ingredient, tradename, therapeutic area versus indication (as specific as possible) and sponsor name, PVI would encourage the TGA to include plain language information about what acceptance to evaluate means for health consumers, including process and

expected timelines. We would also encourage the TGA to link such information to more commonly accessed sources of information for health consumers, such as Health Direct, to increase public awareness of the work of the TGA.

Below, we have summarised our feedback on each of the options.

Option	Yes/No	Why – Impact for health consumers/health consumer organisations	Proposed change
1 No change	No	• Inability to respond with appropriate action • Inconsistencies with other jurisdictions who may share information • Source of frustration and distrust due to information needs not being met	-
2 List all	Yes	• Better ability to monitor progress of medicine • Improved ability to undertake appropriate action • Consistency makes health system easier to understand • Consistency useful when communicating with health consumers in Europe and Canada • Allows health consumers to decided which medicines are of interest	Supported with plain language information to explain what it means for health consumers. Linked to websites health consumers are more likely to use
3 Two different time points	No	• Requires more education for health consumers to understand the different time points • Potential to create confusion • Makes unnecessary assumptions about health consumers' interests	
4 List innovator, high profile only	No	• Requires more education for health consumers to understand the different time points • Potential to create confusion • Makes unnecessary assumptions about health consumers' interests	

We welcome the TGA's efforts to increase transparency. Listening to the experiences of health consumers at our workshops leads us to conclude that in the absence of information, misinformation and suspicion flourish resulting in stress and wasted time and resources among people who can least afford it.

Yours sincerely

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Patient Voice Initiative Chair