[redacted]

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

Dear Sir/Madam,

Re: Whether the TGA should publish that a prescription medicine is under evaluation – transparency reforms

The Western Australian Drug Evaluation Panel (WADEP) welcomes the opportunity to contribute to the Therapeutic Goods Administration (TGA)'s consultation paper on whether the TGA should publish that a prescription medicine is under evaluation – transparency reforms.

WADEP was established in 2008 as an expert committee under the WA Therapeutics Advisory Group banner. Its primary role is to develop and maintain the WA Statewide Medicines Formulary (SMF) and to act as a regulatory and advisory body for WA public hospitals and health services with regards to medication access. WADEP's vision is to deliver optimal patient outcomes in an equitable and cost-effective manner through a single list of approved medicines for all WA public hospitals; evaluated, implemented and managed in a statewide approach.

WADEP considers increased information availability on medicines being evaluated by the TGA as an important step forward in increasing patient's accessibility to safe and effective medications. Increases in transparency will provide the WADEP and WA clinicians with greater means to make better informed decisions at a statewide level and for individual patient care. In an environment where information is extensive and freely available from both reliable and unreliable sources the value the TGA bring in providing vetted information in undeniably important.

WADEP is in support of *Option 2 – list all applications accepted for evaluation*, with preference for inclusion of all of the aforementioned information terms in the consultation document (i.e. active ingredient, trade name, therapeutic area versus indication and sponsor name).

The WA SMF's scope includes non-registered medications or those used in an off-label manner and as such the WADEP are often required to review medications which may not have substantial evidence of safety or efficacy in the Australian context. Instead, decisions are made by considering information available from international regulatory bodies or are extrapolated from other TGA information. Knowing about impending TGA reviews and decisions allows the WADEP's decisions to be a) made with greater confidence and b) aligned with the conclusions made by the national regulator.

Furthermore, medications, including those on the ARTG are increasingly used for novel indications. Future submissions to the TGA by sponsors for extensions of indications for registered products will allow WADEP to review current off-label prescribing, reduce variation in clinical practice and reduce less than optimal prescribing.

Lastly, WADEP acts as a strategic advisory body providing information and support to State and national bodies on medicines use, governance, cost and cost-effectiveness. As part of this, WADEP considers and evaluates any potential opportunities or risks by horizon scanning the immediate environment to make recommendations to appropriate stakeholders. Understanding what could potentially enter the Australian market would enable this function greatly.

To highlight the value of increased transparency in information provided by the TGA to WADEP would be the increasing presence of biosimilar medications on the Australian market. As biosimilars poses risks and benefits, clinically and financially, it is important to know when the biosimilar may enter the market. Measures can be taken to ensure their timely, safe and effective implementation into the WA hospital system and manage clinician and consumer expectations.

Should you have any questions or concerns please do not hesitate to get in touch.

On behalf of the WA Drug Evaluation Panel.

Yours Sincerely,

[redacted]

29 March 2019