



25 March 2019

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

Dear ██████████,

RE: Whether the TGA should publish that a prescription medicine is under evaluation

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional, for-purpose organisation for over 5,300 leading pharmacists and pharmacy technicians working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. The SHPA Specialty Practice Program convenes a Medicines Information and a Medication Safety stream whose leadership committees have informed our submission.

SHPA welcomes the opportunity to comment on this consultation and is pleased to see that the Therapeutic Goods Administration (TGA) is increasing their commitment to transparency. SHPA strongly supports *Option 2: list all applications accepted for evaluation*, which proposes listing all applications for new chemical entities, extensions of indications and all generic and biosimilar medicines accepted for evaluation.

Maximal transparency as described in *Option 2: list all applications accepted for evaluation* will assist Medicines Information Pharmacists to provide accurate and up-to-date information for all medicine information enquiries. Medicines Information Pharmacists provide an essential service for hospitals and routinely receive queries from doctors, pharmacists, Drugs and Therapeutics Committees and the public about medicines. Medicines Information Pharmacists guide safe, effective, and efficient use of medicines by providing tailored clinical advice to support clinical decision making, particularly for very unwell patients who have not clinically responded to conventional treatments. Providing reliable information on the appropriate use of medicines is an essential component of pharmacy practice and patient care. Medicines information pharmacists work with other health professionals to enhance the quality use of medicines. Thus, it is critical for Medicine Information Pharmacists – and all pharmacists more broadly – to know which medicines have been accepted for evaluation by the TGA to support the accuracy and appropriateness of their advice.

Overall, SHPA believes that a blanket approach to all applications independent of the type of application, is important to achieve the highest level of transparency and support industry, clinician and consumer confidence in Australia's regulatory environment, as such, Options 1, 3 and 4 are not supported.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact

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Yours sincerely,

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