Transparency Reforms and Evaluation Support

Attention:

Transparency Reforms and Evaluation Support Section
Therapeutic Goods Administration
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Introduction and background

Specialised Therapeutics Australia (STA) welcomes the opportunity to provide comment on the introduction of new measures to improve TGA transparency.

STA is Australia's largest independent specialty pharmaceutical company, supplying specialist medicines and technologies to patients throughout Australia, New Zealand and across South-East Asia.

The company was co-founded in 2008 by pharmaceutical executives Carlo Montagner and Bozenza Zembrzuski, with a commitment to commercialising specialist therapies and technologies that meet the unmet medical needs of all patients in its regions. Underpinning this endeavour is a foundation of innovation, which must be protected by regulatory transparency.

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

STA's Preferred Option is Option 2

STA believes an open and transparent regulatory review system is vital not only for innovator companies, but for the entire healthcare community, including patients and all healthcare professionals. All parties should be able to access accurate, relevant and appropriate information about their diseases, including up-to-date detail about current medicines and new therapies that may be introduced. Any therapy that is being progressed through regulatory channels has the potential to impact lives and change health outcomes.

But to view healthcare through only a patient and healthcare provider lens does not take into account all the key stakeholders involved in ensuring a robust and sustainable healthcare system. Innovator companies like our own support increased transparency from a commercial perspective. It is STA's view that implementing **Option 2** will ensure that pharmaceutical innovators are afforded their rightful opportunity to protect existing intellectual property arrangements including patents.

If **Option 2** is adopted, any potential threats and/or breaches to these legal arrangements can be adequately and properly addressed prior to any patent expiry and ensure timely resolution of any legal issues.

ST supports the publication of:

- active ingredient
- tradename
- therapeutic area and
- sponsor.
- **ST does not support publication of a specific indication being targeted, as this may evolve and be subject to amendment.**
  ST contends that it is not in the best interests of any patient to publish the proposed indication as this could lead to the dissemination of misleading information if a patient does not fall within the subsequently approved criteria.

Discussion – Predicted Impact Financial and Otherwise:

ST contends that **Option 2: *List all applications being accepted for evaluation*** is the most appropriate and pragmatic approach to achieve the TGA's over-arching transparency goals.

Adopting this option will increase existing levels of regulatory transparency, and further provide innovators an opportunity to enforce protection of existing intellectual property arrangements where appropriate.

From a business perspective, **Option 2** will enable all companies to more realistically assess their own assets and longer-term commercial strategy. It will also minimise the payment of unnecessary legal costs and burden associated with current

interventions such as interlocutory injunctions. Maintaining a robust supply is critical and implementing **Option 2** further supports this goal.

Importantly, **Option 2** is also more closely aligned with the stance adopted by the TGA's international regulatory peers, including the European Medicines Agency and Canada Health.

Option One Discussion and Feedback

ST does not support Option One as presented by the TGA's Reforms and Evaluation Support Section.

Under this arrangement, innovator companies like STA can only be alerted to a potential patent infringement when a generic medicine is listed on the ARTG. If the goal is for greater transparency, this is unacceptable. It means that innovator companies are provided with minimal time and opportunity to determine whether there has been a patent infringement, and also whether legal action is appropriate. It also provides limited opportunity for an innovator company to appropriately manage the longer-term commercial implications of a viable in-market competitor.

Finally

Transparency is vital to ensure public confidence in regulatory review activities. For this reason, ST supports the stance taken by some of Australia's largest pharmaceutical companies and the industry body Medicines Australia on this issue. It is our contention that an amendment to the Therapeutic Goods Act 1989 is warranted and **Option 2** is the most pragmatic and transparent approach, as well as being consistent with the international framework.

We look forward to seeing an outcome published from this consultation.

Thank you for the opportunity to provide comment.

Best regards,
Carlo Montagner
CEO
Specialised Therapeutics Australia