

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

Monday, 25 March 2019

Dear Sir/Madam,

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

Merck Serono Australia (Merck) appreciates the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation on whether the TGA should publish that a prescription medicine is under evaluation.

As a sponsor of prescription medicines registered with the TGA, Merck supports the TGA's on-going commitment to better health and wellbeing for all Australians through regulatory excellence, including being appropriately transparent about our regulatory activities, as well as engaging in meaningful stakeholder engagement and education.

From the list of options made available in the consultation, Merck supports Option 2 only. It is believed that by implementing Option 2, list all applications accepted for evaluation, the TGA will achieve the following:

1. Improvement of transparency appropriately ensuring minimal disclosure of information that is of commercial value to the sponsors of the applications and providing equal avenue for commercial intelligence
2. Address the increasing demand from the public for knowledge of a potential marketing approval for medicines
3. Closer alignment with other current Australian Government policies and with key Comparable Overseas Regulators.



Merck

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The level of information expected to be disclosed from implementation of Option 2 are like those of EMA, Health Canada and Swiss Medic with applications for Generics included in the scope.

- Timing: upon acceptance of the application
- Active ingredient
- Therapeutic area
- Sponsor name

We would be happy to discuss or provide further comment on any aspect of our response and we appreciate being kept up to date on further developments.

Should you have any question or require further clarification on above, please do not hesitate to contact us.

Sincere regards,

[Redacted signature]

[Redacted name]

[Redacted title]

[Redacted contact information]



Merck

[Redacted address]

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