GSK Comments on TGA Consultation: Whether the TGA should publish that a prescription medicine is under evaluation (March 2019)

Overall Comment

GlaxoSmithKline (GSK) welcomes the opportunity to comment on the TGA consultation *Whether the TGA should publish that a prescription medicine is under evaluation.*

GSK understands the role of the TGA to support a high-quality health system through regulations and contributing to this aim through best practice regulation of therapeutic goods such as generic medicines.

GSK supports transparency of marketing authorisation applications for all prescription medicines, including new chemical entities and extensions of indication, and generic and biosimilar medicines, by publishing that the application has been accepted for evaluation. GSK supports only option 2 from the consultation paper to ensure consistent transparency of regulatory activities.

Specific Comments to the Consultation Questions

GSK's responses to specific questions on the consultation paper are provided below and are preceded by the consultation question.

1. **Please specify your preference in terms of information that should be included in a potential published list (e.g. active ingredient, tradename, therapeutic area versus indication, sponsor name)?**

GSK Comments

GSK supports transparency to publish the active ingredient, tradename, therapeutic area and sponsor. This approach is in line with the EMA but has taken into the account the approach adopted by Medsafe (the NZ regulator), which discloses the sponsor of the application.

2. **Do you support option 1?**

GSK Comments

No. This option does not support transparency across the industry. The consultation paper identified circumstances where the Department of Health already publishes information on prescription medicines (e.g. agendas for PBAC meetings, determination of priority/provisional status), and GSK supports a consistent approach. Global news announcements that a TGA submission has been accepted for evaluation is another way that regulatory information is brought into the public domain.

3. **What would be the impact of maintaining Option 1 on you individually, or for your organisation (if affiliated)?**

GSK Comments

This option would not support free trade and competition in the market, thus suppressing potential growth and medicine development.

4. **Do you support option 2?**

GSK Comments

Yes. Transparency is one of GSK's core values, and GSK has made important commitments to champion transparency in clinical research and on medicines shortage reporting. Equitable reform to transparency of marketing authorisation applications for prescription medicines is required for both innovator and generic sponsors to maintain an environment with incentive for pharmaceutical research and development. Increased transparency across the industry, by publishing the acceptance of applications for both innovator medicines and generics/biosimilars, will help to build trust with stakeholders and confidence in the regulatory process.

New medicines have often been submitted to, or evaluated by, a comparable overseas regulator before they are submitted to the TGA. As tabulated in the consultation document, many overseas regulators publish when medicines are under evaluation and the information is within the public domain. Industry sponsors are often aware of this information, and transparency would ensure all stakeholders can easily access this information.

Transparency of generic medicine marketing authorisation applications would provide opportunity for sponsors to negotiate any potential patent injunctions in advance of approval, which could prevent delay in supply.

5. **What would be the impact of implementing Option 2 on you individually, or your organization (if affiliated)?**

GSK Comments

It would provide clarity on when generic medicines may join the market and help logistical planning to maintain robust supply of medicines as they approach the end data exclusivity periods.

6. **Do you support option 3?**

GSK Comments

No. This does not support transparency. Industry, sponsors, healthcare professionals and the public have an interest in potential marketing approval dates for all prescription medicines, including new medicines, generics and biosimilars. Providing information on generic/biosimilar medicines on approval of a medicine (rather than registration on the ARTG) would not support this demand and would make negligible difference to Option 4.

7. **What would be the impact of implementing Option 2 on you individually, or your organization (if affiliated)?**

GSK Comments

Implementing option 3 would remove the incentive for innovation of pharmaceutical research and development.

8. **Do you support option 4?**

GSK Comments

No. As for option 3.

9. **What would be the impact of implementing Option 4 on you individually, or your organization (if affiliated)?**

GSK Comments

As for option 3.