GSK Comments on TGA Consultation: Reforms to the generic medicine market authorisation process (March 2019)

Overall Comment

GlaxoSmithKline (GSK) welcomes the opportunity to comment on the TGA consultation *Reforms to the generic medicine market authorisation process.*

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. As an innovative company, although GSK is an innovative company, we appreciate that generic medicines comprise a significant portion of the pharmaceutical market, and as such constitute a critical part of the Australian healthcare system.

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.

Questions about how to reduce barriers through international alignment

1. **Would changes to our requirements for demonstrating that Australian and overseas reference products are identical reduce barriers for applicants seeking to register new generic medicines?**

GSK Comments

Yes. The consultation paper outlined examples where it may be difficult to access a reference product or identify the formulation or complex products to demonstrate 'identicality'.

2. **Are there any potential unintended consequences of changing the data requirements when using an overseas reference product in a bioequivalence study submitted to the TGA?**

GSK Comments

Yes. Adjusting requirements so bioequivalence can be demonstrated with an overseas reference product (with less emphasis placed on confirming identicality with the Australian reference product) may permit wider parameters for deviation, particularly for 'complex generics'.

Requirements to demonstrate 'identicality' need careful consideration if non-Australian reference products are permitted, to avoid 'drift' in pharmacokinetic parameters through serial comparisons (e.g. if a and b are bioequivalent, and b and c are bioequivalent, that does not mean a and c are necessarily bioequivalent). CMC assessment requirements for comparable overseas reference products may vary and could lead to further deviation.

Acceptance and approval of a generic medicine where bioequivalence has been demonstrated with an overseas reference product would heavily depend on the reference product and which regulatory agency had evaluated the product. The consultation paper outlines that various

jurisdictions have different requirements for demonstrating bioequivalence, and acceptable jurisdictions should be clarified.

GSK is concerned that changing the requirements for generic evaluations may lead to confusion, given HCP and patient use of generics is based on current understanding of TGA requirements, particularly for 'complex generics'; such a change would need to be supported by education to the healthcare community.

GSK notes that data exclusivity periods and patent requirements may differ between jurisdictions and any reform to overseas reference product data should align with the data exclusivity periods applicable in Australia. Reliance on overseas regulatory data should not be permitted during the data exclusivity periods applicable in Australia in order to provide incentives for pharmaceutical research and development

3. **Are there any other ways that we could reduce barriers through increased international alignment in the processes for obtaining market authorisation for generic medicines?**

GSK Comments

The TGA reform to introduce the Comparable Overseas Regulator (COR) report-based process and work sharing for both innovator and generic medicines has introduced opportunities for efficiencies of prescription medicines registration applications.

International cooperation through activities such as the Australia-Canada-Singapore-Switzerland (ACSS) Consortium and International Generic Drug Regulators Programme (IGDRP) have promoted collaboration and alignment in generic drug regulatory programs for regulatory agencies across several different countries.

The ICH Reflection Paper: *Further Opportunities for Harmonisation of Standard for Generic Drugs (November 2018)* outlines scientific and technical areas where guidance would help to enhance and develop ICH guidelines for complex and non-complex dosage forms. Such guidelines would be valuable across multiple regulatory pathways and can be drawn upon in future to optimise local legal and regulatory requirements.

Questions on how to increase transparency of regulatory requirements

4. **Would early advice from the TGA on biowaiver justifications be useful in compiling a dossier?**

GSK Comments

Yes. Earlier consultation on a biowaiver before an application is submitted seems appropriate.

5. **In what other ways can we increase transparency and clarity of regulatory requirements for generic medicine applications?**

GSK Comments

GSK expects that the TGA will be most familiar with problems encountered with generic medicine market authorisation applications and where efficiencies can be found. GSK suggests that problems encountered are regularly shared with industry sponsors to provide more education and guidance to improve the quality and success of generic applications.

GSK endorses the current activity of TGA publishing the registration and approval timeframe of new generic medicines and biosimilar medicines on the TGA website. Historically, the timeframe for generic medicine approval is much shorter than the legislated timeframe of 255

working days, and this is reflected in other jurisdictions such as the UK. We understand that the approval timeframe of generic medicine marketing applications could be reduced if the quality of generic medicine applications was improved.

Questions on how to support work sharing opportunities

6. **Will adopting these international templates improve opportunities for joint submissions to multiple agencies and hence work sharing?**

GSK Comments

Yes.

7. **Are there other ways of improving the generic medicines market authorisation process to support work sharing?**

GSK Comments

GSK has no further suggestions.

Questions on how to support a robust supply of medicines

8. **Is it appropriate to offer incentives to medicine sponsors to bring more generic medicines to Australia?**

GSK Comments

No. GSK does not support such incentives. It is in the Australian public's interest to have TGA evaluate medicines on their merit and prioritise those which will have the most impact to their lives.

9. **Should we offer incentives to medicine sponsors to address medicine shortages and medicine expenditure?**

GSK Comments

No, there are current mechanisms to help source and provide alternative medicines. Medicine shortages are often unexpected and due to global manufacturing issues. Bringing medicines into Australia on short notice and potentially for short periods of time is logistically difficult. Responsible Sponsors who are aware of impending shortages usually are aware of alternatives and can work with the TGA to identify them.

10. **Are there any other examples where a more robust supply of generic medicines may be beneficial to patients and the Australian health system?**

GSK Comments

GSK in unaware of further examples.

11. **What incentives should we pursue in order to create a more robust supply of medicines?**

GSK Comments

The TGA has implemented reforms to improve management of medicine shortages in Australia, including improving communication and increasing transparency. This is a positive step to enable sponsors to share supply problems and adjust supply where possible. GSK suggests that TGA analyses the efficiency and effectiveness of the initiative, and what gaps remain to create a

more robust supply of medicines. Robust and timely review of the TGA Medical Watch List is crucial to ensuring medicines of high medical need are fully available.

General feedback

12. Are there any other options for improvements to generic medicines market authorisation processes that would:

- **reduce regulatory barriers through greater international alignment with comparable overseas regulators**
- **increase clarity and transparency of regulatory requirements**
- **support international work sharing for generic medicines**
- **support a more robust supply of medicines?**

GSK Comments

No further comments.