Scientific Operations Management Section
Scientific Evaluation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

29 March 2019

Dear Sir/Madam,

Consultation: Reforms to the generic medicine market authorisation process

Medicines Australia welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation on reforms to the generic medicine market authorisation process.

Our submission has been prepared with the expert input of Medicines Australia member companies as well as the Medicines Australia's Regulatory Affairs Working Group (RAWG). RAWG members are selected for their regulatory experience and industry knowledge and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact our sector.

Medicines Australia recognises there is an important place for generic medicines in Australia, and that their availability supports a sustainable PBS. Whilst Medicines Australia does not object to any proposed reforms which improve administrative or process aspects of generic medicine registration, it cautions that the TGA should be cautious in potentially reducing the extent of required evidence for the registration of new generic medicines. Reducing the amount of data that a sponsor of a new generic medicine needs to submit could potentially lead to a reduction in safety standards and subsequently result in unintended safety consequences. It is critical that any changes to the regulatory process ensure the safety and efficacy of medicines being registered is maintained. In addition, in the context of the role of the TGA, we question a potential priority system for generic products that appears to be based on criteria relating to medicine expenditure and access regulated by the PBS.

Additionally, it would be useful to understand if the provision of any TGA advice would be binding on either TGA or the Sponsor as if this was so it would represent a policy shift of the TGA. It would be helpful to understand if this would apply to other meetings where advice is solicited (e.g. pre-submission meetings for NCEs/EoIs) and whether the TGA is considering scientific advice services for other types of medicine/sectors of the pharmaceutical industry.

Medicines Australia seeks clarification as to whether biosimilar medicines are included in the scope of these reforms and are not considered a type of generic medicine, and that any such proposal would be the subject of a separate consultation. Medicines Australia does note that the consultation document states the following: "This consultation paper focuses on proposed reforms to market authorisation processes for generic medicines. Future opportunities may exist for similar changes to other prescription and non-prescription medicine processes, particularly those for biosimilar medicines." In view of the complexity of biosimilar molecules compared to generics and the lack of patient experience in Australia, Medicines Australia believes it is premature for the proposals in this consultation to be extended to biosimilar medicines. In addition, other alternative pathways may also be required to

provide transparency and clarity in the assessment of complex medicines to ensure that appropriate and harmonised science-based approvals exist.

With regard to the specific questions in the paper:

Q1. 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?

Whilst it is likely that barriers will be reduced due to a reduction in the amount of required data, there is concern that this may lead to a reduction in quality and safety standards. An appropriate, robust registration process must be maintained to ensure the safety and efficacy of all medicines.

Q2. 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?

Concern has been expressed to Medicines Australia that reducing barriers to generic medicine market entry could make it commercially unviable for small innovator companies to register and launch in Australia and potentially deter them from entering the Australian market.

Q4. Would early advice from the TGA on biowaiver justifications be useful in compiling a dossier?

Yes. Medicines Australia contends that for the TGA to be consistent in achieving its objective of increased transparency, and to not disadvantage innovator companies, innovator and generic medicines should be treated equally, and the advisory service implemented for all medicines at the same time. Early advice would give the sponsor a better basis for a go/no go decision, which would also potentially reduce TGA workload.

Medicines Australia understands that medicines Sponsors already currently seek advice from the TGA on biowaivers and suggests that one way to promote submissions with better prospects for success would be to provide clearer guidance for industry. Where the TGA are providing this service, a cost recovery fee may be appropriate in order to ensure that it is not cross-subsidised from other revenue/fees.

Q6. Will adopting these international templates improve opportunities for joint submissions to multiple agencies and hence work sharing?

Medicines Australia supports the proposal for adopting the international templates 'Bioequivalence trial information form' and 'Biowaiver justification'.

Consultation issue 4: Need for a robust supply of medicines in Australia

Medicines Australia has previously stated that, as the peak body representing innovative pharmaceutical companies in Australia, we take medicines shortages seriously and put patient care at the centre of everything we do. Unfortunately, medicines shortages occur despite the best efforts of sponsors, manufacturers, distributors, pharmacies and government. Increasing the number of brands registered for a particular medicine will not necessarily result in supply certainty. Medicines shortages occur for various reasons including the increasingly globalised nature of the supply chain for medicines and the small Australian market for prescription medicines. However, there are other reasons for medicines shortages including Federal/state/territory procurement models, quality use of medicines

and pricing policies. A comprehensive analysis of the causes of medicines shortages, recognising that government plays a role through signals to industry about the value of medicines in the Australian health system, is imperative to mitigate the immediate and long-term risk of medicines shortages.

Therefore, medicine supply alone should not be a reason to lower the bar of data requirements for registration. As noted in the consultation document, the TGA acknowledges that it cannot unilaterally solve weaknesses in the supply of medicines. In acute situations of a particular medicine shortage, Section 19 of the Therapeutic Goods Act is in place to provide a pathway for registered supply of alternative medicines.

Medicines Australia cautions that providing incentives to increase the number of generic medicines in Australia may not solve issues around a robust supply of medicines in Australia, and may in fact lead to unintended consequences by further creating an unlevel playing field with regard to medicines registration and exacerbating the impact of existing pricing policies. To avoid inequity within the industry, and to avoid creating a disincentive for innovator medicine companies to register their products and invest in the R&D in Australia, which would bring new treatment options to Australians, equivalent benefits should be considered for Sponsors of innovative medicines.

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.

Please feel free to contact [redacted] if you would like further clarification on any aspect of our submission [redacted]

Yours sincerely

[redacted]

Dr Vicki Gardiner
Director, Policy and Research
Medicines Australia