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20th March 2019

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

Dear Sir/Madam,

Re: Reforms to the generic medicine marketing authorisation process

ASMI welcomes the opportunity to comment on the consultation paper seeking stakeholder comments regarding possible reforms to the generic medicine marketing authorisation process.

About ASMI

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. More information about ASMI and our membership is available on our website.

Scope of the consultation

ASMI notes that the consultation paper focuses on proposed reforms to market authorisation processes for generic prescription medicines, and that "*future opportunities may exist for similar changes to other prescription and non-prescription medicines*" (page 4).

The Australian Regulatory Guidelines for OTC Medicines (ARGOM) section on safety and efficacy includes information on requirements for bioequivalence studies, or for a justification that a bioequivalence study is not needed. For certain medicines that are not included in the ARGOM list of medicines that do not require bioequivalence data, sponsors must then provide either a bioequivalence study, or a justification that a bioequivalence study is not needed. ASMI notes that these data requirements are the same as those currently in place for prescription medicines, so the data requirements are comparable:

- Requirements for biopharmaceutic studies[1] refers to Guidance 15 Biopharmaceutic studies [previously Australian Regulatory Guidelines for Prescription medicines (ARGPM)]
- ARGOM refers to the EU Guideline on the investigation of bioequivalence[2]
- The summary of a bioavailability or bioequivalence study[3] is common to prescription and non-prescription medicines

[1] https://www.tga.gov.au/guidance-15-biopharmaceutic-studies
[2] https://www.tga.gov.au/clinical-efficacy-and-safety-guidelines#clinical
[3] https://www.tga.gov.au/form/summary-bioavailability-or-bioequivalence-study

- The sponsor must demonstrate bioequivalence against the corresponding strength of the originator medicine as marketed in Australia; this is the same requirement as for both prescription and non-prescription medicines
- Alternatively, the sponsor must provide a biowaiver or justification for not providing a bioequivalence study, the requirements and forms for which are the same as prescription medicines.

ASMI believes that any TGA reforms that seek to reduce regulatory barriers for prescription medicines, should automatically be applied to the non-prescription medicine requirements, and it is not reasonable that the current regulatory requirements be retained for non-prescription medicines and reduced for prescription medicines.

Any regulatory reforms to the regulatory requirements for generic medicines ought to be applied to both classes of medicines.

Further comments on improvement of the generic medicines market authorisation process

From a practical point of view, issues concerning the marketing authorisation process for generic medicines may be less pressing for OTC products than it is for prescription medicines since many OTC medicines are older molecules, that are included in the TGA's list of non-prescription medicines that do not require bioequivalence data. There are also several OTC medicine monographs that can be used to register OTC medicines through the N2 pathway.

There are however certain newer OTC medicines that are not included in this list, and for which the N2 pathway is also not available. For these medicines, bioequivalence data may be required for reformulations, or for new OTC generic medicine applications. On this basis, ASMI is interested in any future reforms to the regulatory requirements around bioequivalence data.

Although ASMI members did not at this point provide detailed responses to some questions asked throughout the consultation, we would like to provide the following general comments on some aspects of the consultation paper.

Australia-specific requirements

As a general principle, ASMI is supportive of international alignment and consistency of requirements across markets with similar regulatory standards.

ASMI believes that there may be advantages in reviewing how "identicality" is defined, and we would be keen to examine the practices of other comparable agencies such as Switzerland and Singapore in this regard. We support the TGA undertaking further detailed consultation on any proposed changes in this area.

In relation to the question of changing data requirements to allow for use of overseas reference product, ASMI believes that any proposed changes be carefully assessed for impact on potential new products as well as existing products, and that any changes should not be at the expense of Australia's high standards in quality, safety and efficacy of medicines.

Early advice on biowaiver justifications

The current ARGOM includes a list of substances which do not generally require bioequivalence data. Bioequivalence data or a justification for not providing bioequivalence data must otherwise be provided.

However, under the OTC Business Processes, there are serious consequences for sponsors who include a justification for not providing bioequivalence if that justification is found to be unacceptable by the TGA. These sponsors risk rejection at screening or subsequent failure of their application and loss of fees.

ASMI is supportive of any TGA proposals to provide more transparency and certainty for sponsors developing new products, which may require a biowaiver. In this way sponsors will know with certainty and in advance of lodging a submission with the TGA, whether expensive scientific justifications (or even more expensive bioequivalence studies) will be required to support their new product applications.

Supporting work sharing

Given that OTC medicines are generally well known, older substances, there may not be the need to undertake work sharing on submissions as applications may not necessarily have been lodged in multiple markets concurrently.

ASMI members are supportive of international work sharing by the TGA in principle, however this should be conducted only at the sponsor's request and where relevant for a specific application.

International templates

ASMI supports the TGA's involvement in the International Pharmaceutical Regulators' Program (IPRP) Bioequivalence Working Group for Generics (BEWGG), and we are keen to understand more of the detail around possible future adoption of international templates whether for joint submission to other agencies or for TGA-only submissions. We would also like more detail on whether these international templates are used for both prescription and OTC medicines.

If international agencies do not use these templates for OTC medicines, then ASMI believes that a careful examination of the differences between the international templates and the TGA's own templates should be conducted, in order to ensure that there is no increase in regulatory requirement for lower risk OTC medicines.

Conclusion

ASMI understands that this consultation is preliminary in nature, and that the TGA will review feedback and initiate further consultation with interested parties.

ASMI is keen to be involved in any proposals to make changes to the requirements concerning bioequivalence, as these requirements apply by default to certain OTC medicines. Any reduction of regulatory barriers should align between prescription and non-prescription medicines.

There should be no increase in regulatory requirements or unintended impact on bioequivalence requirements for OTC medicines, and any amendments should achieve increased clarity and certainty for sponsors.

ASMI would be pleased to assist in any analysis of potential impact on OTC medicines. Please feel free to contact me if you have any further questions or comment.

Yours sincerely,

[redacted]