APOTEX
Innovating for
patient affordability

Scientific Operations Management Section
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Therapeutic Goods Administration
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Dear [redacted]

Response to the consultation on *Reforms to the generic medicine market authorisation process*

Apotex Pty Ltd (Apotex) would like to take this opportunity to thank the Therapeutic Goods Administration (TGA), part of the Department of Health of the Australian Government, on inviting the Australian public to comment on the consultation paper regarding possible future reforms to the generic medicine market authorisation process.

The importance of generic medicines to the health of Australians is indicated by this consultation, which is looking at improving the speed by which a generic medicine can be made available to Australian patients. This in turn would assist the Australian government to reinvest funds to subsidising newer medicines, as generic medicines are often cheaper to both the patient and the government.

Apotex – a generic medicines provider to Australian patients
Improved patient outcomes and easing the burden on healthcare systems worldwide is what drives us in everything we do.

Apotex Pty Ltd is the Australian subsidiary of the Apotex Group of Companies. Apotex's commitment to improving access to quality, affordable medicines has meant Australians have been able to access generic versions of essential medicines such as rosuvastatin, clopidogrel, perindopril, leflunomide and mometasone sooner.

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Comments on the TGA reforms that seek to reduce regulatory barriers for generic medicines

Apotex is a member company of both GBMA (Generics and Biosimilar Medicines Association) and ASMI (Australian Self-Medication Industry) due to the wide range of products it offers to Australian patients.

Apotex supports in principle the responses provided by both GBMA and ASMI on this important initiative.

In particular, Apotex supports:

- the overall drive to improve and maintain continuity of supply of medicines to Australian patients,
- the fact that this is a preliminary consultation and that further consultations will occur following a review of the feedback received,
- international alignment and consistency of requirements across markets with similar regulatory standards, which in turn would allow for faster availability of generic medicines to Australian patients,
- consideration of work-sharing opportunities with other recognised regulators to avoid duplication of effort,
- more transparency on evaluation timelines and clarity on regulatory requirements.

Yours sincerely

Roger Millichamp
Managing Director | Asia Pacific

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