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Consultation: Reforms to the generic medicine market authorisation process

Roche Products Ltd. (Roche) welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation: *Reforms to the generic medicine market authorisation process*. We have also provided input on this consultation as a member of Medicines Australia's Regulatory Affairs Working Group (RAWG).

The consultation proposes reforms that are intended to "*reduce regulatory barriers for applicants seeking to register generic prescription medicines, while maintaining existing safety, quality and efficacy standards*" and "*provide incentives for specific generic applications, where these would support a more robust supply of medicines*".

Roche supports the public health goal of providing a robust supply of medicines in Australia.

Evaluation Standards
Registration of novel and generic medicines requires an evaluation by TGA of the quality, safety and efficacy of the medicine under the Therapeutic Goods Act 1989 (The Act). Roche considers it critical that the regulatory evaluation standards to demonstrate safety, quality or efficacy for registration of generic products are not reduced or compromised as a consequence of proposed reduction of regulatory barriers for registration of generic medicines. This could lead to the possible unintended impact of increasing quantity but not quality of medicines available for Australian patients.

Biosimilars
The consultation proposes that there are similar opportunities to reform other registration processes, particularly those for biosimilar medicines. The complexity of the manufacturing process for biosimilar medicines is far greater than for traditional generic chemical entities. In addition, there is currently a paucity of real world data from biosimilar patient use in Australia. Roche considers any suggestions for reduction of regulatory barriers in relation to biosimilar registration to be premature and we do not support this proposal.

Incentives
The consultation proposes possible incentives to encourage applications for new generic medicines of special interest with the goal of providing a more robust supply of generic medicines where this may

be beneficial to patients and the Australian health system. As referenced earlier, Roche fully supports the public health goal of providing a robust supply of medicines in Australia.

We believe however that the proposals for incentives that could include reduced review time, reduced fees and reduced data requirements create an unjustified imbalance between approval standards for generic and innovator products.

There is an important distinction between the proposals for accelerated access options for generic medicines and accelerated pathways for novel medicines. In the latter case, accelerated pathways are available in the event of a potential or known clinical advantage over existing therapies and unmet patient needs whereas reductions in regulatory barriers for generics cannot be offset against potential clinical advantage.

In particular, we have concerns regarding Case Study 2 in the consultation which proposes a potential priority system for generic products that appears to be based on criteria relating to medicine expenditure and access regulated by the PBS and is questionable in the context of the TGA role.

Summary
Overall, while we fully support the public health goal of providing a robust supply of medicines in Australia, this must be carefully balanced against any real or unintended "trade-offs" that may be introduced if increasing access, rather than ensuring quality, safety and efficacy is the primary driver for changes. We strongly urge TGA to ensure the remit of regulating quality, safety and efficacy of therapeutic products available in Australia, remains at the forefront of any proposed changes to generic product registration.

We thank you for the opportunity to comment on this consultation.

Regards
Roche Products Pty. Limited

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