Consumers Health Forum of Australia

SUBMISSION

CONSULTATION: REFORMS TO THE GENERIC MEDICINE MARKET AUTHORISATION PROCESS

February 2019

Consumers Health Forum of Australia 2019
Submission: *Reforms to the generic medicine market authorisation process consultation*
Canberra, Australia

P: 02 6273 5444
E: info@chf.org.au

twitter.com/CHFofAustralia
facebook.com/CHFofAustralia

Office Address
7B/17 Napier Close
Deakin ACT 2600

Postal Address
PO Box 73
Deakin West ACT 2600

Consumers Health Forum of Australia is funded by the Australian Government as the peak healthcare consumer organisation under the Health Peak and Advisory Bodies Programme

CONTENTS

Contents

Summary

Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health care consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF appreciates the oppourtunity to provide input into your consultation on potential reforms to the generic medicine market authorisation process.

The CHF is generally supportive of improving the availability and accessibility of generic medicines to Australian consumers. Doing so makes more healthcare options affordable to consumers, empowering them to make decisions that improve their heath. However it must be done is such a way that does not risk the lowering of quality, safety and efficacy standards or delay other critical medicine evaluations.

At the heart of CHF's policy agenda is patient-centred care. Our responses to the TGA's consultation questions have been formed with a patient-centred approach in mind.

Consultation Questions

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? (Page 7)

We believe the primary unintended consequence of changing data requirements is the risk of potentially reducing standards of quality, efficacy and safety. This can be prevented by introducing rigorous regulations alongside this proposed change that ensure any overseas reference products, are at a minimum, the same standard as an Australian reference product.

We would additionally suggest that the TGA publish and maintain a list of approved overseas regulators/standard authorities and the areas for which they are approved to provide a substitute reference product.

Additionally, we would note there is a risk of inconsistencies between international regulations in regard to safety warnings and labels resulting in warnings required in overseas jurisdictions not being applied to products made available in Australia e.g. "Boxed Warnings". We would advocate for further work to occur to ensure that if a product is approved based on an overseas reference product, Australian consumers are given at least the same level and type of warnings as their overseas counterparts.

Q8. Is it appropriate to offer incentives to medicine sponsors to bring more generic medicines to Australia? (Page 11)

The CHF does not have any in-principle opposition to the TGA offering incentives to medicine sponsors to increase the availability of generic medicines to Australian consumers.

However we do not support the suggested incentive of reducing data requirements for approval. Doing so may lead to lower standards of safety, efficacy and quality of generic medicines and expose consumers to unnecessary risks.

Additionally caution must be applied in terms of the proposed incentive reducing the "Time taken to evaluate, make a decision and register a medicine on the ARTG". The CHF supports reaching this incentive through methods such as increased TGA staff resourcing to accelerate the process. However we would not necessarily support methods such as prioritising generic medicine applications over other medicine applications. The CHF would strongly oppose simply mandating faster processing times without increasing staff resources, increasing the risk of errors occurring through applications being "rushed" through the system.

Q9. Should we offer incentives to medicine sponsors to address medicine shortages and medicine expenditure? (Page 11)

The CHF does not have any in-principle opposition to the TGA offering incentives to medicine sponsors to address medicine shortages and medicine expenditure.

However we do not support the suggested incentive of reducing data requirements for approval. Doing so may lead to lower standards of safety, efficacy and quality of medicines and expose consumers to unnecessary risks.

Additionally caution must be applied in terms of the proposed incentive reducing the "Time taken to evaluate, make a decision and register a medicine on the ARTG". The CHF supports reaching this incentive through methods such as increased TGA staff resourcing to accelerate the process. However we would not necessarily support methods such as prioritising generic medicine applications over other medicine applications. The CHF would strongly oppose simply mandating faster processing times without increasing staff resources, increasing the risk of errors occurring through applications being "rushed" through the system.

Q10. Are there any other examples where a more robust supply of generic medicines may be beneficial to patients and the Australian health system? (Page 11)

The CHF believes that the primary benefit of increasing the availability of generic medicines in Australia, to both consumers and the larger healthcare system, is reducing the costs of medicines via increased competition in the market.

Q11. What incentives should we pursue in order to create a more robust supply of medicines? (Page 11)

The CHF believe that the fee structure improvements are a good suggestion for potential incentives, noting that lowering fees may have a further benefit of reducing the cost of the market product to consumers.

The CHF supports shortening the time taken to approve medicines by increasing the staffing capacity/TGA resources dedicated to processing generic medicine applications, ensuring that the quality of review isn't impacted by the reduced time although we note that lowering fees would be counterproductive to increasing TGA resources allocated to this task.

Prioritising evaluations of generic medicines or medicines that address current shortages that will reduce prices/increase accessibility is an option CHF could potentially support. However it would need to be balanced with the "importance" of other medicines applications waiting to be evaluated. Delaying a critical life-saving new medicine in order to prioritise a generic medicine would be less than ideal.

The CHF has no position on the other questions posed in the consultation paper as they relate solely to industry concerns.

Once again, thank you for the ability to feedback into this consultation. If you require further input further into the process, please do not hesitate to contact us on [redacted]