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GBMA Summary Response

Reforms to the generic medicine market authorisation process, version 1.0, February 2019

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GBMA Response | Reforms to the generic medicine market authorisation process, version 1.0, February 2019

The GBMA and its members welcome the opportunity to provide input to the consultation on the Reforms to the generic medicine market authorisation process, version 1.0, February 2019.

Overview

The Generic and Biosimilar Medicines Association (GBMA) represents the manufacturers and suppliers of generic and biosimilar medicines in Australia. As a representative body, GBMA is making this submission on behalf of its members and it is our intention to provide a balanced assessment of the reform proposals with specific comments on the commercial and operation implications for Australian sponsors and potential impacts to patients and broader health outcomes.

Acknowledgement

The GBMA and its members would like to acknowledge the TGA's exploration of the reduction of barriers to obtaining market authorisation for generic medicines, through opportunities including international alignment and potential reduction in Australian specific requirements.

The GBMA also acknowledges that opportunity for reform focuses on the end-patient through the potential alleviation of medicine shortages.

The GBMA is completely aligned with the TGA in ensuring that Australian patients receive products that are of equivalent quality, safety and efficacy to that of the originator (branded) products.

The GBMA is further aligned with the TGA in the aim of increasing access to generic medicines so that Australian patients have better choice, convenience, continuity of supply and where possible, better value for money, for their medicines.

Key themes have been considered in the consultation document and they are provided below.

The GBMA welcomes the TGA's consideration of opportunities to improve the generic medicines market authorisation process and access to generic medicines by Australian patients via various means which we shall discuss further when addressing questions posed by TGA in this Consultation Paper.

Opportunities to Improve the Generic Medicines Market Authorisation Process

1. Reducing barriers to approval through international alignment

Bioequivalence studies are carried out to show that generic medicines are bioequivalent to reference products from the US and/or EU. These studies compare the rates that the medicines are absorbed and metabolised in the body and there is a clinical impact if the rate of absorption of the generic medicine is different to the reference product.

Australia has the additional requirement that, to be supplied locally, the generic medicine has be shown to be bioequivalent to the Australian reference product. This requirement sometimes results in products not being available for Australian patients.

The GBMA appreciates that the TGA is questioning whether bioequivalence studies need to be carried out with, or bridged to, Australian reference (innovator) products. The TGA is aligning with Comparable Overseas Regulators (CORs) in terms of acceptability of data supporting medicines applications and so use of overseas reference products to support Australian generic medicine applications is a natural extension of this.

GBMA POSITION

GBMA welcomes the proposal to reduce barriers through international alignment, along with consideration of best practice demonstrated by other regulators that have considerable experience in evaluating submissions for generic medicines.

2. Increased clarity and transparency of regulatory requirements

In specific cases, bioequivalence studies performed in humans can be replaced by *in vitro* testing for example drug substances which exhibit high solubility and high permeability characteristics. In these cases, the generic medicine dosage form can be shown to dissolve and release active ingredient at the same rate as the reference product without having to undertake studies in humans.

The TGA has previously been responsive to applicants seeking scientific advice on a number of issues relating to Australian applications, including the design of bioequivalence studies and the acceptability of biowaivers.

GBMA POSITION

GBMA fully supports the move to increase clarity and transparency that permits sponsors to seek timely and consistent advice from the TGA on data requirements in general and the appropriateness a of biowaiver strategy in particular.

A pre-submission request for formal advice from the TGA on the requirements, acceptability of BA/BE studies or biowaiver justifications, in conjunction with a robust interpretation of the relevant guidelines and scientific literature could be assessed prior to the full dossier submission. This would potentially increase the efficiency of the evaluation process and minimise the rejection of applications if critical components of the application are considered and agreed upfront.

The pre-submission process and timelines for feedback would need to be clearly defined to ensure Sponsors can efficiently plan their activities. The outcome of this advice would need

to be binding on the TGA as well as on the sponsor, in particular given the significant investment a sponsor would make to conduct studies and/or commit to a regulatory strategy.

It is recognised that the formal pre-submission advice would also be applicable to other types of therapeutic goods.

3. Supporting work sharing opportunities

The TGA's initiative to engage in Work Sharing with recognised regulators is considered a very positive step toward international harmonisation and is welcomed.

The Comparable Overseas Regulators (CORs) e.g. US FDA, European EMA, ICH have developed stringent standards and guidelines for the development and testing of medicines to ensure the quality characteristics. Generic medicines supplied to patients in these regions with comparable regulatory standards undergo extensive evaluation of supporting data prior to approval. Many of the international guidelines and standards used by the CORs are recognised and adopted by the TGA.

The TGA has additional Australian-specific requirements for prescription medicines, such as Therapeutic Goods Orders and the *Mandatory requirements for an effective application* which often requires supplementation and revision of a global dossier prior to submission in Australia. For example, more stringent finished product specifications for Australia may have implications for the continuity of medicine supply. Reduction of the burden placed by these requirements and increased international harmonisation would increase access to affordable generic medicines.

International work sharing provides the industry and the TGA with an opportunity to avoid duplication of effort and leverage the work conducted by international counterparts. This could potentially enhance the decision-making process and reduce market authorisation timelines.

GBMA POSITION

The use of international templates has the potential to improve opportunities for joint submissions and provide clarity around the information required. The GBMA encourages the adoption of these templates, without the additional requirement for Australian specific information.

Work sharing with recognised, experienced and comparable regulators has been the aim of sponsors over many years in discussions with TGA, and the acknowledgement of this in the consultation paper is welcomed.

GBMA would appreciate if the TGA could reconsider whether Australian specific requirements, in addition to the international requirements, enhance the safety and efficacy of generic medicines.

Generic medicines of special interest

1. Need for a robust supply of medicines in Australia

Medicines shortages are caused by many factors, including manufacturing issues, difficulties in procurement, manufacturing merger and acquisitions, the lead time for GMP clearance and subsequent variation approvals for supply chain changes, along with the challenges associated with smaller populations, compared to major global regions.

It is clear from the consultation document that an important issue for the TGA is securing and maintaining a reliable supply of medicines to the market. The TGA document provides a good overview of the purpose of the consultation, seeking feedback to address these concerns by proposing streamlined authorisation and maintenance models.

The thoughts presented by TGA in regard to drug access and supply in Australia, reflect concern by not only the TGA but the sponsors/manufacturers of drugs on the ARTG, to ensure continuous supply to the public. A number of the suggestions mentioned in this response document apply to originator and generic medicines alike.

2. Options for incentives

Incentives highlighted by the TGA, including evaluation timelines, associated fees, data and administrative requirements have the potential to encourage activity that promotes a robust supply of medicines in Australia.

Further exploration of all the key areas is outlined in the GBMA technical response to the Consultation Paper – Reforms to the generic medicine market authorisation process, version 1.0, February 2019. This document is intended for review by the TGA in conjunction with this response.

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