AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

[redacted]

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TGA consultation - Transparency reforms for prescription medicines under evaluation

Response from the Australian Commission on Safety and Quality in Health Care

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Summary

The Therapeutic Goods Administration (TGA) proposes transparency reforms for prescription medicines under evaluation. The Australian Commission on Safety and Quality in Health Care (the Commission) strongly supports transparent communication of information about medicines to support quality use of medicines for Australian consumers.

Introduction

In February 2019, the TGA published a public consultation paper concerning whether the TGA should publish that a prescription medicine is under evaluation (**Appendix A**).

The Commission supports Option 3 where the TGA lists all applications at two different time points

- new chemical entities (including biological medicines) and extensions of indication on acceptance of application for evaluation;
- generic/biosimilar medicines on approval of an application..

Options 2, 3 and 4 all offer improved transparency for new chemical entities and extensions of indication. Options 2 and 4 appear to favour innovator and generic sponsors respectively.

The Commission suggests Option 3 appropriately encourages transparency whilst supporting both innovator and generic industry sectors in provision of medicines in Australia.

Transparency around generic or biosimilar applications should be considered alongside the TGA consultation on reforms to the generic medicines market authorisation process[1].

Context

Access to medicines information is fundamental to the safe and quality use of medicines. Information on availability and forthcoming availability impacts the shared decision making between the consumer and health professionals. The TGA describes the recent case study of Spinraza (nusinersen) registration to highlight the importance of communicating potential availability of an innovator product. Nusinersen is used in spinal muscular atrophy where until previously there were no specific treatment options in Australia. The potentially imminent registration would have contributed to better informed communications between patients, families, carers and health care teams.

Medicine shortages are a global issue. In Australia, this is exacerbated by the high percentage of imported, rather than locally manufactured, prescription medicines (90%). Limiting options for alternative medicines may lead to the introduction of medication errors with potentially serious outcomes. Forward notice of generic products may prompt a sponsor to cease production of the innovator medicine.

The improvements in communication of information about medicines ahead of registration will inform communications between consumers, carers, families and health professionals. These improvements should support accessibility to medicines and alleviate the number of medicines in short supply. Transparency around prescription medicines and the continued availability of both innovator and generic medicines is fundamental to quality use of medicines and the delivery of safer consumer care in Australia.

Background

Shared decision making involves the integration of consumer values, goals and concerns with the best available evidence about benefits, risks and uncertainties of treatment, in order to achieve appropriate health care decisions. It involves clinicians and consumers discussing all relevant healthcare options and making decisions together, including those related to medication management.

The Commission has a program of work to support engagement of consumers in care planning and decision making. This is an integral part of delivering person-centred care, and links with the Commission's efforts to reduce unwarranted healthcare variation and ensure the appropriateness of care.

The worldwide issue of medicine shortages is worsening with time[2]. The association between medicine shortages and harmful medication errors is well documented. An Institute for Safe Medication Practices (ISMP) survey recorded approximately one in three (35%) respondents experienced a near miss during the past year due to a medicine shortage. One in five reported adverse patient outcomes over the year due to medicine shortages[3].

The Commission welcomes the introduction of the Medicines Watch List with guidance on the management and communication of medicine shortages and discontinuations in Australia. Measures to proactively avoid shortages and negate the processes for managing these shortages will further minimise the potential for medication error and patient harm. This includes proposed reforms to the generic medicines market authorisation process and the impact of any transparency reforms should align with this consultation[1].

Feedback

Support for publication of a prescription medicine application

Feedback on **Appendix A (Consultation paper)** is provided with consideration of the four options proposed by the TGA.

The Commission supports Option 3: list all applications at two different time points

1. new chemical entities (including biological medicines) and extensions of indication on acceptance of application for evaluation;

2. generic/biosimilar medicines on approval of an application.

The Commission strongly supports the listing of all new chemical entities (including biological medicines) and extensions of indication on acceptance of application for evaluation as proposed in Options 2, 3 and 4. These options all provide greater opportunity for consumers to be aware of potential changes to the availability of new and different treatment options.

Option 3 appears to allow for greater provision of information to consumers whilst representing an equitable approach that favours neither innovator nor generic sponsors.

Option 3 offers improvements to current arrangements and should assist patient safety through:

- Facilitation of shared decision making by providing access to information and early knowledge about potential availability of treatments
- Preparation by health services to introduce medicines which may already be available overseas
- Consideration of medicine names during the application process. Identifying and preventing look-alike, sound-alike (LASA) medicine names at the earliest opportunity. So reducing the potential for LASA medicine name selection errors
- Consolidation of Australian Medicines Terminology (AMT) codes. The generation and allocation of temporary AMT codes which differ from those used post marketing could be avoided.

The Commission encourages transparency on all levels. Indeed, information on prescription medicines is already published in specific circumstances. For example, the Pharmaceutical Benefits Advisory Committee (PBAC) agenda includes information on new listings with sponsor and therapeutic area[4]. This is necessarily published ahead of listings and represents a precedent for preregistration publication.

However, Option 2, where the TGA would publish all applications on acceptance, could favour innovator medicine sponsors. This could prevent applications for generic products and which could impact medicines availability and costs for alternatives[5]. Option 4, where the TGA would not publish any advance information on generic or biosimilar products, could be unfairly bias towards the generic sponsors.

The decision should consider and align with outcomes from the consultation on the generic medicine market authorisation process. This focuses on maintaining safety, quality and efficacy of medicines to protect the Australian public whilst driving greater accessibility to medicines.

Discussion

Improving information on medicines in the application process, prior to their approval and potential availability should improve shared decision making and other measures impacting on medication safety.

Improving access to medicines should actively reduce the number of medicines in shortage and the health service resources involved in responding to the quality and safety challenges of the medicine shortage.

The TGA has proposed reforms to the generic medicines market authorisation process. This is anticipated to imnprove availability of generic medicines in Australia. The forward communication of generic medicine applications should be considered in light of any changes to the process so that the number of applications is not adversely impacted.

The Commission supports the increased transparency in relation to medicines undergoing evaluation in Australia. The Commission welcomes further opportunities to review any revisions to the TGA's consultation and offers support with discussion on any impact to quality and safe medicines use.

Appendices

A: Therapeutic Goods Administration. Consultation: Whether the TGA should publish that a prescription medicine is under evaluation. Transparency reforms Version 1.0, February 2019 www.tga.gov.au/sites/default/files/consultation-whether-tga-should-publish-prescription-medicine-under-evaluation.pdf

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3. Institute for Safe Medication Practices. Drug shortages: national survey reveals high level of frustration, low level of safety. ISMP. Med Saf Alert; 2010 www.ismp.org/Newsletters/acutecare/articles/20100923.asp

4. The Pharmaceutical Benefits Scheme Meeting agendas. Australian Government Department of Health www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/agenda

5. Pharmaceutical Patents Review. Australian Government. November 2012 www.ipaustralia.gov.au/about-us/public-consultations/archive-ip-reviews/pharmaceutical-patents-review