Australian Government
Department of Health
Therapeutic Goods Administration

Prescription medicines transparency measures

Implementation of generic medicines early notification to innovators of an application and publication of innovator applications

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TGA Health Safety Regulation

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Overview

The Australian Government has given approval to proceed with implementation of enhanced transparency measures for prescription medicines, in response to public demand for more information on prescription medicines that are under evaluation.

The purpose of this paper is to canvass implementation options for these measures to obtain feedback from industry stakeholders. We are seeking your input in particular on whether the preferred option is efficient.

Background

Consumers, their carers and families, together with healthcare professionals have said they are frustrated in not being able to know whether new treatments are likely to be available in Australia as they are not aware that an application has been made to the TGA. Presently, the TGA can only state that it can "neither confirm nor deny" receipt of an application for registration for commercial-in-confidence reasons.

In February 2019, the TGA released a public consultation paper on whether or not the TGA should publish that a prescription medicine is under evaluation and what types of prescription medicine application should be published.

Proposed approach to implement new transparency measures for prescription medicine applications

The Australian Government is proposing to increase transparency for applications under evaluation in a way that balances availability of information to the public, while recognising that this information could have commercial value to the applicant by:

- only publishing information with the greatest public impact on public health (applications for innovative medicines such as new chemical entities and extensions of indications and new combination medicines); and
- respecting the commercial value of information on generic medicines applications prior to registration by not making this information publically available; and
- respecting the need for timeliness in resolution of issues with the innovator patent holder by providing the innovator company with confidential earlier notification of a generic application that has passed preliminary assessment.

Amendments to the *Therapeutic Goods Act 1989* (the Act) and regulatory changes would be required to implement these measures. The proposed implementation arrangements are described below.

Measure 1: Early publication of major innovator medicine applications

This measure will introduce earlier publication of major innovator prescription medicines that have been accepted for evaluation under section 25 of the Act. Information on potential

availability of new medicines or new uses for medicines is considered to be of the greatest value to consumers and healthcare professionals.

Implementation arrangements

The mechanism of publication is a new legislative instrument supporting the release of information under the current section 61 of the Act.

Publication of the following details is intended:

- product sponsor; and
- product name; and
- active ingredient(s); and
- proposed indications; and
- application type.

Publication will occur for the following application types:

- new medicines (type A); and
- new combinations of medicines (type B); and
- new indications for an existing medicine (type C).

What the applicant will start doing

No additional actions are required by the applicant for registration of the medicine.

What the TGA will start doing

This measure could commence from June 2020. The TGA will publish information within one month of the date that an affected application has passed preliminary assessment.

Measure 2: Earlier notification of generic medicine applications to the innovator

It is expected that there would be less public interest in the notifications of generic prescription medicine evaluations as many follow-on from previously registered generic medicines that are already on the market.

Section 26B of the Act requires a generic applicant to certify to the TGA that it is either:

1. not infringing a valid patent; or
2. proposes to market a product before the expiry of a patent and has given the patentee notice of its application.

In practice, generic applicants, do not notify innovator companies of their anticipated entry into the market. Innovators become aware of market authorisation of a generic competitor only on the inclusion of the generic medicine in the Register.

Notification under the current system after entry of first generic medicines on the Register leaves little time for an innovator to appropriately consider whether its pharmaceutical patent is infringed by the generic medicine and consequently, to prepare for ‘patent infringement’

litigation. The result has been that in certain cases an innovator applies to the Federal Court for an interlocutory injunction to restrain the marketing of the generic after entry onto the register, pending resolution of the dispute over the existence of a valid patent.

Implementation arrangements

This measure will introduce earlier notification of generic medicine applications to the innovator. Implementation is planned from early 2021.

This is intended to address the flaw (whether there is notification prior to registration of the generic is at the sole discretion of the generic) in the existing notification scheme which has caused significant cost to the generic, the innovator and the community as manifested in the expensive patent dispute litigation.

The new notification scheme will apply in the following circumstances:

- a person has made an application for registration of a medicine under section 23 of the Act;
- the medicine is a prescription medicine;
- the medicine has passed preliminary assessment, in accordance with subsection 23B(1) of the Act; and
- the person has submitted evidence to establish the safety or efficacy of the medicine as part of the registration application, relying on evidence that another person has previously submitted for another medicine (whether or not that medicine is entered on the Register).

There are **two options** for implementing an early notification scheme for new generic medicines.

Option 1 – requires early notification *in addition* to the existing scheme, only where a patent *has not* expired

What the applicant would start doing under this option

Where an applicant has a reasonable belief that a patent has not expired, it would be required to provide a confidential notification to the patentee that **the application has passed preliminary assessment**.

The notification would be required regardless of whether the applicant considers that it would, by the marketing of the applicant medicine, infringe the patent. It would be required to inform the patentee that the applicant proposes the use of the evidence or information relying on the evidence or information for which there is a patent.

The applicant would further be required to notify the TGA (in law, the Secretary of the Department of Health) providing either:

- evidence that they have notified the other person, and to provide a copy of the notification; or
- a declaration that they have a reasonable belief that no related patent exists

The option to notify the Secretary under subparagraph 25AB(3)(c)(ii) of the Act that a certificate to inform the patentee is *not* required (prior to entry of the approved medicine onto the Register) would no longer be available for applicants where it has a reasonable belief that a relevant patent(s) has not expired. However, it would continue to be available where the applicant has a reasonable belief that a patent(s) has expired. In this way the applicant is required at least at one point in the registration process to notify the Secretary as to its

reasonable belief about the existence of a patent regardless of whether the proposed marketing would infringe a patent, if it exists.

The purpose of this option is to **remove the assessment of whether the marketing of the generic (should its application for registration be approved) would infringe a valid claim of a patent from being at the sole discretion of the applicant**.

The obligation on the applicant is reduced to apply only in circumstances in which it has a reasonable belief about the existence of a valid patent. In effect, whether the marketing would so infringe the patent would be for the applicant and the patentee to resolve.

What the TGA would start doing under this option

Evaluation of the applicant's medicine would not commence unless and until the applicant gives to the Secretary, following passing of preliminary assessment, either:

- evidence that they have notified the other person, and to provide a copy of the notification; or
- a declaration that they have a reasonable belief that no patent exists.

Benefits

- Where the applicant is aware that a patent has not expired, this option provides innovators with an opportunity to resolve any potential infringement of the patent by the proposed marketing of the medicine before that marketing commences, and therefore reduces costs of potential litigation to the originator, generic and Commonwealth.
- Provides greater protection for the confidentiality and commercial value for a generic application under evaluation than with full public disclosure as was proposed in public consultation paper, since the generic application would only be disclosed to the innovator, but not to other generic competitors.
- This option would preserve the current late notification scheme (prior to registration) to applicants submitting applications, introducing the least amount of change compared to status quo.

Risks

- Relies on an applicant having a reasonable belief as to the existence of a patent so a patent holder may not always be notified of a generic application.
- Removes the option for applicants to avoid notification of the patent holder by declaring they are not infringing a valid patent, for example because marketing of the generic medicine is not intended until after the patent expires, which may impact availability of generic applications.
- Will require applicants relying on information where a patent has not expired to provide an early notification following preliminary assessment and a late certification, duplicating the process at different points in time.

Option 2 - requires early notification regardless of belief of the existence of a patent

What the applicant would start doing under this option

This option would apply to all applicants for the registration of a prescription medicine where it is proposed that the application rely on information of another to support that application.

The current requirement under paragraph 25AB (3)(c) of the Act (for applicants to provide a patent certificate or a notification that such a certificate is not required) would move from the point in time **where the evaluation has been completed** (prior to entry of the approved medicine onto the Register) to the point in time **after an application for registration passes preliminary assessment** (prior to the commencement of evaluation of the medicine).

All **applicants would be required to provide a notification to the innovator**, and a copy of the notification to TGA (i.e. the Secretary).

This option would, in addition to moving the current certification or notification requirements to the earlier point in the process **also** require the applicant to provide notification to the innovator where the applicant determines that a valid patent is not infringed. Option 3 would require early notification for both innovators (to the Secretary only) and generics (to the innovator and the Secretary) regardless of whether the patent term has ended.

What the TGA would start doing under this option

Evaluation of the applicant medicine would not commence unless and until the applicant gives to the Secretary a copy of the notification given to the patentee.

Benefits

- As above, this option would provide early notification to innovators but also provide greater protection for the confidentiality and commercial value for a generic application under evaluation than with full public disclosure.
- Provides applicants the option to notify the innovator that relevant patent(s) has not expired or notify the innovator that the applicant is not infringing a valid patent, for example because the product will not be marketed before the patent expires.
- This option has the advantage of providing a single point of notification for all registration applications.
- The innovator would receive notification of all applications that rely on its information regardless of whether there is a patent or a relevant patent has expired, so the risk of an innovator not being notified is removed.

Risks

- Removes the option for the applicants to avoid notification of the patent holder by declaring they are not infringing a valid patent, for example because marketing is not intended until the patent expires, which may impact availability of generic applications.
- Would require innovator and generic applicants to provide early notification to the patentee that they are, or are not infringing a patent, where they rely on the patentees information.
- Would not reflect that some medicines may not be entered in the Register as a result of the evaluation process (rejection), and in those circumstances the early notification could be considered an unnecessary burden.

We are seeking your feedback:

Question 1: What is your preferred notification option?

Question 2: What is the predicted impact, financial and otherwise?

Provide an assessment of how the proposed change will impact on you, and what you see as the likely benefits or costs to you (financial or non-financial). If possible, please attempt to quantify these costs and benefits.

Question 3: Noting that early publication for innovator medicines and an early notification scheme for new generic medicines have government approval, what changes would you propose to minimise burden on industry?

Question 4: What other requirements for information should the notification include?

Attachment 1 - Detailed options for notification of generic medicine applications to the innovator

Option 1 – early notification applies in addition to the existing scheme, only where a patent *has not* expired

A patent has been granted in relation to another medicine for which evidence or information has been submitted to the Secretary, and the term of the patent has not expired (the new measure is only intended to apply where a valid patent is in place for the other medicine, and not where such a patent has already expired)

The applicant is required to notify the patent holder that its application has passed preliminary assessment and, as part of that notification, the applicant would be required to inform the patent holder that the application for registration of the new medicine intends to rely (in whole or in part) on the patentee's evidence or information (note that, in notifying the innovator under this proposal, the generic applicant would not have, as currently under subparagraph 25AB(3)(c)(ii), the option of declaring that a certificate to inform the innovator is not required).

As part of the new notification, inform the patentee that an application has passed preliminary assessment regardless of whether the applicant considers that it would, by the marketing of the applicant medicine, infringe the patent. It would be required to inform the patentee that the applicant proposes the use of the evidence or information relying on the evidence or information for which there is a patent.

The notification would state that:

- the generic medicine applicant is acting in good faith and if their medicine is registered in the Register after being evaluated, the applicant does not propose to market their medicine in a manner, or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the other person's medicine (i.e. an adaption of the current paragraph 26B(1)(a) of the Act); or
- a patent has been granted in relation to the other person's medicine, and inform the other person that the person (i.e. the generic medicine applicant) proposes to market their medicine before the end of the term of the patent (i.e. an adaption of the current paragraph 26B(1)(b) of the Act

The new provision (or a related new provision) would also require such a person to notify the Secretary that they have notified the other person, and provide a copy of the notification.

A new power would be provided for the Secretary to require the innovator to provide information or documents in relation to verifying that the person has done so.

A requirement would be included for the patentee to treat the information that an application has passed preliminary assessment as confidential.

A mechanism, in similar terms to paragraphs 24(2)(b) and (c) of the Act, would also be included under which the application for the medicine will lapse if the notification or copy contains information that is inaccurate or misleading in a material particular, or if information given to the Secretary in connection with the notification or copy is inaccurate or misleading in a material particular.

An offence, the nature of the offence is along similar lines to subsection 26B(2) as follows:

A person commits an offence if:

(a) the person gives a certificate required under subsection (1); and

(b) the certificate is false or misleading in a material particular.

Penalty: 1,000 penalty units

An amendment would be included to subsection 25A(1) of the Act to make it clear that the Secretary will not be obliged to evaluate the medicine for registration unless and until the person gives the Secretary the notification and copy.

Paragraph 25AB(3)(c) of the Act would remain unchanged - i.e. with generics in effect providing the new notification after passing preliminary assessment, and the existing certification requirements after the completion of the evaluation (this involves duplication for the generic applicant).

In relation to the timing of the notification, the scheme could operate in addition to the existing scheme: generics would provide the new notification after passing preliminary assessment, and the existing certification requirements (under 26B) later, commonly this is done after the completion of the evaluation.

Option 2 - requires early notification instead of the existing scheme where a patent has, and has not, expired

The option would move the current requirement under paragraph 25AB (3)(c) of the Act for applicants to provide a patent certificate or a notification that such a certificate is not required from the point in time where it occurs currently (i.e. when the evaluation has been completed, prior to entry of the approved medicine onto the Register) to the point in time after an application for registration passes preliminary assessment (prior to the commencement of evaluation of the applicant medicine).

In addition to moving the current certification or notification requirements to the earlier point in the process, this option would also require the applicant to provide a notification to the innovator where the applicant determines that a valid patent is not infringed. Option 2 would require early notification for both innovators (to the Secretary only) and generics (to the innovator and the Secretary) regardless of whether the patent term has ended.

Other aspects would operate similar to Option 1.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Application and Advisory Management / Prescription Medicine Authorisation Branch	27/03/2020

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