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Therapeutic Goods Amendment Bill (No. 2) 2005

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Contents

Therapeutic Goods Amendment Bill (No. 2) 2005

Date Introduced: 14 September 2005

House: House of Representatives

Portfolio: Health and Ageing

Commencement: Sections 1 to 3, the day on which this Act receives the Royal Assent; Schedule 1, a day to be fixed by Proclamation. If any of the provisions do not commence within 6 months after Royal Assent, the first day after the end of that period.

Purpose

The Therapeutic Goods Amendment Bill (No. 2) 2005 (the Bill) amends the *Therapeutic Goods Act 1989* (the Act) by creating an exemption to the current certification requirements for registering or listing therapeutic goods in the Australian Register of Therapeutic Goods (ARTG).

Background

Australia-United States Free Trade Agreement

As of 1 January 2005, all applicants seeking to register or list a product in the ARTG,[1] have been required to provide section 26B(1) certificates. A 26B(1) certificate declares that applicants will:

- not enter the market in a manner that would infringe a patent on the product; or,
- if they intend to enter the market before the expiry of any applicable patent, that they have notified the patent owner of their intention to do so.

This requirement was introduced in order to comply with Article 17.10.4 of the Australia-United States Free Trade Agreement (FTA) which relevantly provides:

> Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety or efficacy information, to rely on evidence or information concerning the safety or efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory:
>
> (a) that Party shall provide measures in its marketing approval process to prevent those other persons from:

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(i) marketing a product, where that product is claimed in a patent; or

(ii) marketing a product for an approved use, where that approved use is claimed in a patent,

during the term of that patent, unless by consent or acquiescence of the patent owner; and

(b) if the Party permits a third person to request marketing approval to enter the market with:

(i) a product during the term of a patent identified as claiming the product; or

(ii) a product for an approved use, during the term of a patent identified as claiming that approved use,

the Party shall provide for the patent owner to be notified of such request and the identity of any such other person.[2]

The main purpose of this Article was to prevent manufacturers of a generic version of a patented product from entering the market before the expiry of the patent covering that product. However, the Australian section 26B(1) certification requirement applies to *all* applicants, not only those wanting to market a generic product; and, as applicants may have to undertake expensive global patent searches and obtain legal advice in relation to the results of any search, this is considered unnecessarily bureaucratic and burdensome on industry.

Change in certification requirement

To address this criticism, the Bill restricts the certification requirement to only certain applicants:

- those required to submit safety and efficacy data when making their application, and
- who, when making their application, rely on data previously submitted to the Therapeutic Goods Administration by another person in relation to an approved product.

All other applicants may provide a notice to the Secretary of the Department of Health and Ageing (Secretary) that a section 26B(1) certificate is not required.

Effect on industry

The effect of the amendment is that the sponsors of generic medicines will still have to provide a certificate but the majority of complementary medicines, which rely on readily accessible data, and most originator medicines, which submit their own safety and efficacy data, will no longer be subject to the certification requirements and a notice will be sufficient.[3]

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The exemption will also cover the majority of over-the-counter medicines such as sunscreens and throat lozenges[4] as these contain active ingredients of which there is adequate knowledge available in the public domain. As 'low risk' therapeutic goods, the Act does not require the sponsors of such goods to submit safety or efficacy data on the product.[5] Therefore a notice will be sufficient for these products.

For prescription medicines which are considered 'high risk' registrable therapeutic goods, sponsors are required to submit both safety and efficacy data. As a result of the amendment, a certificate would only need to be provided if relying on safety or efficacy data previously submitted by another person.

The Bill and the FTA

Parliamentary Secretary for Health, Christopher Pyne MP, has described the Bill as simply correcting 'an unintended drafting error'[6] that adds considerable cost to the registration and listing process. However, as the change is related to a provision of the FTA, it may have wider repercussions.

For example, while some companies welcome the Government's initiative because it will reduce their costs, it has been reported that industry sources are critical of the Government's quiet approach to introducing the amendments 'for fear that other industry groups would lobby the government to make changes to the FTA.'[7]

Also, potential exists for the United States to challenge the legislation if it believes the amendments breach the FTA. It may do so under the Chapter 21 provisions which provide for dispute settlement by consultation (Article 21.5) or panel review (Article 21.7).

Mr Pyne reportedly disputed that this would occur because the Australian legislation at present covered a far broader group of products than United States legislation and the amendments, in rectifying this anomaly, would not warrant United States approval.[8]

A reading of the relevant provisions in the United States *Federal Food, Drug and Cosmetic Act* does suggest that the U.S. legislation is more narrowly focused than its Australian equivalent. It requires similar certification but only in those circumstances where an applicant relies on safety and efficacy investigations which were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.[9] It is therefore unlikely that the United States would challenge the proposed amendments as they essentially mirrors the U.S. legislation.

More importantly, the Bill also appears to be consistent with the FTA as the measures proposed in Article 17.10.4 are directed at the marketing approval process for pharmaceutical products that 'rely on evidence or information concerning the safety or efficacy of a product that was previously approved'.

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Main Provisions

Schedule 1, Item 1 repeals the current paragraph 25(4)(d) and replaces it with a provision allowing applicants seeking to register therapeutic goods to provide either:

- a notification that a subsection 26B(1) certificate is not required for the purposes of registration; or
- a subsection 26B(1) certificate.

After the Secretary has notified the applicant that the therapeutic goods are eligible for registration and the goods will be included in the ARTG, either of these (a notice or certificate) must be provided to the Secretary.

Item 2 clarifies that once a notice or certificate is provided to the Secretary by an applicant, the Secretary must include the goods in the Register without inquiring into the correctness of the certificate or the notice.

Items 3 and 7 provide that civil proceedings cannot be bought against the Secretary where the Secretary includes or lists respectively, therapeutic goods in the ARTG in reliance upon a notice (as is the case with a certificate).

Items 8, 9, and **10** make similar amendments to the above to effect the introduction of 26B(1) notices with respect to the approval process for including listable medicines in the ARTG.

Item 11 provides that civil proceedings cannot be bought against the Secretary where the Secretary lists a medicine in the ARTG in reliance upon a notice.

Item 12 inserts the new subsection 26B(1A). Under this new provision, a certificate is required under 26B(1) only if the applicant is required:

- to submit evidence or information to establish the safety or efficacy of the goods as part of the registration process or listing; and
- in order to satisfy that requirement, the applicant relies to any extent, on evidence or information that another person submitted to the Secretary to establish the safety or efficacy of other therapeutic goods that have already been registered or listed, and this was done as part of the process of applying for registration or listing of those goods.

Item 14 inserts a new section 26BA as to the approved form for notices.

Item 15 provides that the amendments in the Bill apply to applications for registration or listing of therapeutic goods that are made on or after the day on which Schedule 1 commences.

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Concluding Comments

The Bill, in narrowing the category of applicants to whom the certification requirements apply, should achieve its purpose of making the registration process less onerous for the majority of applicants.

It is unlikely, especially in light of the comparable U.S. legislation, that the amendments breach the FTA.

Endnotes

1 Except those seeking to register or list therapeutic and medical devices.

2 http://www.dfat.gov.au/trade/negotiations/us_fta/final-text/index.html

3 *Explanatory Memorandum*, p. 1.

4 The Hon. Chris Pyne, MP, House of Representatives, *Debates*, 14 September 2005, p. 2.

5 The ARTG is divided into two parts: registered goods which are evaluated for quality, safety and efficacy; and listed goods, such as vitamins and herbal medicines, which are not evaluated for efficacy and assumed to be safe. See *Therapeutic Goods Act 1989* (Cth) Pt 3, and Therapeutic Goods Regulations (Cth), regs 10-12, 15.

6 Quoted by Lisa Allen, 'Free-trade drafting error fixed', *Australian Financial Review*, 20 September 2005, p. 5.

7 Ibid.

8 Ibid.

9 See *Federal Food, Drug and Cosmetic Act* (US) [21 U.S.C. 321], Sec. 201 for the definition of the term "drug" available at: http://www.fda.gov/opacom/laws/fdcact/fdcact1.htm.

See Sec. 505 [21 U.S.C. 355] for the application approval process for new drugs, specifically subsection (2)(A) which provides that applications relying on safety and efficacy investigations which were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from those who did conduct the investigations, must include certification that, in the opinion of the applicant and to the best of his knowledge, that a patent to which those investigations relate, if not filed or expired, is invalid or will not be infringed. The applicant must give notice to the patent owner whose patent is allegedly not infringed or not valid, and in that notice provide details of the patent application sought and the factual and legal basis for alleging invalidity or non-infringement. Available at: http://www.fda.gov/opacom/laws/fdcact/fdcact5a.htm

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