Newsletter
Stephens Lawyers & Consultants

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Therapeutic Goods Regulatory Reforms target false and misleading industry practices

In Brief:

The Federal Government is currently implementing a three-stage reform program to update the therapeutic goods regulatory framework in Australia. Amendments to the *Therapeutic Goods Act 1989* (Cth), (" **the *Therapeutic Goods Act"***) will have significant consequences for the pharmaceutical industry, particularly in relation to:

1. Penalties for providing false or misleading patent certificates:

- Companies relying on third party data of registered drugs to establish safety and efficacy of their product as a part of the Therapeutic Goods Administration (**"TGA")** approval process, must provide the TGA with a patent certificate under section 26(B) of the *Therapeutic Goods Act* as to whether the marketing of the drug will infringe an existing Australian patent. The *Therapeutic Goods Act* imposes penalties where patent certificates contain false or misleading information. [1] Recent amendments to the *Therapeutic Goods Act* remove the Court's discretion in imposing a maximum penalty for an offence. The penalty is now fixed at 1,000 units. This penalty equates to $110,000 for individuals and $550,000 for companies. [2]
- The penalty for providing false or misleading information in relation to a patent infringement certificate under section 26C of the *Therapeutic Goods Act* remains unchanged, with the maximum set at $10 million. Where a patent certificate has been provided under section 26B, patent owners must lodge a patent infringement certificate before instituting infringement proceedings, stating that the proceedings will be commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay.
- To avoid penalties, companies providing certificates must exercise extreme caution to ensure that adequate searches are undertaken and a legal opinion is obtained before certificates are issued.

2. Stricter advertising regulation:

- Under new provisions in the *Therapeutic Goods Act*, the Secretary of the Department of Health and Ageing now has power to prevent the publication of advertisements in non-mainstream media which make false or misleading representations. The penalty for this offence is set at 60 penalty units. Previously, the *Therapeutic Goods Act* only required that business obtain pre-approval of advertisements in mainstream media.
- The Senate Community Affairs Legislation Committee has also recommended that the Government introduce further amendments to deter sponsors from recruiting other persons to inappropriately advertise a product on their behalf. This will mean that offence provisions will be applied to any person found to be inappropriately advertising a therapeutic good, not just sponsors as is the current situation. [3]

Therapeutic Goods Regulation & Patent Certificates

The import, export, manufacture or supply of drugs and medical devices in Australia require regulatory approval by the TGA. The process can be complex and lengthy.

Patent Certificates under s 26B

In 2005, the Australia-US Trade Agreement resulted in a number of changes to the application and registration process. Companies relying on third party data of a registered drug to establish safety or efficacy of their product as a part of the TGA approval process, must provide the TGA with a certificate in accordance with sections 26B(1A) [4] and 26B(1), [5] as to whether the marketing of the product will infringe an existing Australian patent.

Applicants face penalties under this section if they provide false or misleading material in the patent certificate. [6] Reform of the penalty provisions in s 26B(2) aims at aligning all offence provisions in the *Therapeutic Goods Act* with current policy on the expression of such provisions. [7] Previously, the penalty imposed on a person who provides a false or misleading patent certificate was discretionary, with a possible maximum of 1,000 penalty units. By removing the word "maximum", under the new provisions anyone found to have provided false or misleading patent certificates will face a set penalty of 1,000 penalty units. [8]

Patent Infringement Certificates under s 26 C

Businesses should also be aware that they can face substantial penalties for providing false or misleading material in relation to patent infringement certificates under s 26C.

Where a party provides a certificate in accordance with s 26B(1), the patent owner cannot commence legal proceedings for infringement until it lodges an infringement certificate with the TGA stating that the proceedings will be commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay. [9]

Penalties for providing false or misleading material in relation to a patent infringement certificate are severe, but remain unchanged under the new amendments. The maximum penalty that can be imposed by the Court is $10 million. [10] In determining this pecuniary penalty, Courts will take into account any profit obtained by the patent owner and any loss or damage suffered by third parties as a consequence of the patent owner's exploitation of the patent during the infringement proceedings. [11]

Regulation of Advertising

Reform of the advertising provisions in the *Therapeutic Goods Act*, seek to ensure that controls over restricted representations and prohibited representations apply to advertisements in all media. [12] Previously, the *Therapeutic Goods Act* required pre-approval of advertisements of therapeutic goods only in "mainstream" media. [13] New provisions under Division 3A [14] of the *Therapeutic Goods Act* allow the TGA to prevent the publication of advertisements in non-mainstream media which make false or misleading representations about a therapeutic good. [15] The penalty for this offence is 60 penalty units. [16]

The Senate Community Affairs Legislation Committee, in reviewing the newly proposed *Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009*, has also recommended that the Government introduce further amendments to deter sponsors from recruiting other persons to inappropriately advertise a product on their behalf. This will mean that offence provisions will be applied to any person found to be inappropriately advertising a therapeutic good, not just sponsors as is the current situation. The Committee has also called for a specific review of all provisions and procedures in relation to therapeutic goods advertising. [17]

Reform Framework

In recent months, three pieces of amending legislation have been introduced into Parliament to bring into effect the Government's regulatory changes.

Stage 1: Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009.

The initial amendments came into effect on 18 June 2009 under the *Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009*. This legislation forms the first stage of the Government's three part regulatory reform program. [18]

In addition to the altered penalty and advertising provisions, other amendments which are now in operation, include:

- introducing provisions to exempt medical devices from the operation of the *Therapeutic Goods Act* so that they can be made available for use in a health emergency;
- reformulating the test of whether a person is a "fit and proper person" to hold a manufacturing licence or a medical device conformity assessment certificate;
- adopting the European Pharmacopeia and United States Pharmacopeia as additional default standard to the British Pharmacopeia under the *Therapeutic Goods Act*; and
- amending the information release provisions to support public access to an increased range of information held by the TGA. [19]

Stage 2: Therapeutic Goods Amendment (2009 Measures No. 1) Bill 2009

On 13 August 2009, the second amending Bill was passed by the Senate and the Act will come into effect on receiving royal assent. These amendments aim to [20] :

- enable medicines to be temporarily suspended from the Australian Register of Therapeutic Goods where there are safety concerns that can be corrected during the period of the suspension;
- require manufacturing licences for therapeutic goods (other than medical devices) to cover only one manufacturing site, except in limited circumstances (such as where two sites are next to one another and are jointly involved in the manufacture of a therapeutic good). Licence holders will be able to apply to have a detail on their manufacturing licence varied or to transfer the licence to another manufacturer;
- enhance the current monitoring powers under the *Therapeutic Goods Act* for all therapeutic goods to enable authorised officers inspecting a site to take, for example, samples of ingredients used to make a medicine and to take a video or other recording, not just still photographs;
- provide a regulatory framework for homoeopathic and anthroposophic medicines to apply from July 2011. Further consultations will occur with interested parties before this time to develop supporting elements of the framework in regulations under the *Therapeutic Goods Act*;
- enable lists of permitted and prohibited ingredients to be made as legislative instruments and require medicines seeking listing to comply with the lists; and
- make other amendments including to clarify the arrangements for setting conditions on medicines so these are more transparent and also to enable sponsors who have asked for the registration or listing of a medicine to be cancelled to apply for this to be revoked to keep the medicine on the Register. [21]

Stage 3: Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009 & Senate Committee Review

On 24 June 2009, the third stage of amending legislation was introduced to Parliament, which aims to:

- implement new separate scheduling arrangements for medicines and chemicals;
- enable the Secretary of the Department of Health and Ageing (under which the TGA, operates) to declare purposes for which a kind of medical device cannot be included in the Australian Register of Therapeutic Goods and thus made available;
- extend the circumstances in which consultation can occur with the Gene Technology Regulator to therapeutic goods that are or contain genetically modified organisms (in addition to genetically modified products currently provided for under the *Therapeutic Goods Act*);
- amend the advertising provisions to provide that it is an offence for any person to advertise a therapeutic good inappropriately for a purpose that has not been accepted in relation to the product;
- amend the delegation provisions to enable the regulations to specify a relevant person for the purposes of exercising delegation under section 19A of the *Therapeutic Goods Act*; and
- introduce provisions to enable the Minister to specify, by legislative instrument, advisory statements required to be included on the labels of specified medicines. [22]

The issues raised under the Bill were referred to the Senate Community Affairs Legislation Committee for inquiry, which tabled its report on 7 August 2009. In addition to the recommendations relating to advertising, the report proposed significant changes to scheduling arrangements for medicines and chemicals. [23] The Bill passed through the Lower House on 19 August, and is awaiting approval in the Senate.

Stephens Lawyers & Consultants' intellectual property lawyers have extensive experience and represent leading pharmaceutical and biotech companies in both commercial and litigious matters.

We assist our clients with the regulatory process including advice with respect to patent infringement or invalidity.

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[1] For more information on patent certificates under s 26B(1), please see "Australia-US Free Trade Agreement" at http://www.tga.gov.au/international/usfta.htm .

[2] "Australia-US Free Trade Agreement" at http://www.tga.gov.au/international/usfta.htm .

[3] The Senate Community Affairs Legislation Committee, *'Therapeutic Goods Amendment (2009) Measures No. 2) Bill 2009 [Provisions]'*, 2 August 2009, 15; at http://www.aph.gov.au/Senate/committee/clac_ctte/therapeutic_goods_09/report/index.htm .

[4] **Section 26B Certificates required in relation to patents**

(1A): *A certificate is required under subsection (1) in relation to an application for registration or listing of therapeutic goods only if:*

(a) the applicant is required to submit evidence or information to establish the safety or efficacy of the goods as part of the process of applying for registration or listing; and

(b) in order to satisfy that requirement, the applicant relies (in whole or in part) on evidence or information that another person submitted to the Secretary:

(i) to establish the safety or efficacy of other therapeutic goods that have already been registered or listed; and

(ii) as part of the process of applying for the registration or listing of those other goods.

5] **Section 26B(1)** *:*

The certificate required under this subsection is either:

(a) a certificate to the effect that the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods; or

(b) a certificate to the effect that:

(i) a patent has been granted in relation to the therapeutic goods; and

(ii) the applicant proposes to market the therapeutic goods before the end of the term of the patent; and

(iii) the applicant has given the patentee notice of the application for registration or listing of the therapeutic goods under section 23.

The certificate must be signed by, or on behalf of, the applicant and must be in a form approved by the Secretary.

[6] **Section 26B(2)**

A person is guilty of 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.

[7] Explanatory Memorandum, *Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008*, Senate, pg 2.

[8] Under section 4AA of *Crimes Act1914* (Cth) 1 penalty unit means $110 .

[9] The infringement certificate must be in accordance with **Section 26C(3):**

The certificate required by this subsection is a certificate to the effect that the proceedings:

(a) are to be commenced in good faith; and

(b) have reasonable prospects of success; and

(c) will be conducted without unreasonable delay.

[10] Section 26C(5A).

[11] For more information on patent infringement certificates, please see "Australia-US Free Trade Agreement" at http://www.tga.gov.au/international/usfta.htm .

[12] For more information, please see "Regulatory Reform" at: www.tga.gov.au/regreform/index.htm .

[13] Under section 42B, "mainstream media" is defined as *'any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions.'*

[14] **Division 3A-Therapeutic goods advertisements for which an approval is not required**

42DKA Application of Division

This Division applies to advertisements about therapeutic goods other than advertisements for which an approval is required under Part 2 of the Therapeutic Goods Regulations 1990.

42DKB Certain representations not to be published or broadcast

(1) If a representation in an advertisement about therapeutic goods is false or misleading, the Secretary may, by notice given to the person apparently responsible for publishing or broadcasting the advertisement, prevent that person from publishing or broadcasting, or causing to be published or broadcast, an advertisement containing that representation (whether express or implied) about those goods.

[15] These provisions were introduced under the *Therapeutic Goods Amendment (Medical Devices and Other Measures) Act2009.*

[16] Section 42DL.

[17] The Senate Community Affairs Legislation Committee, *'Therapeutic Goods Amendment (2009) Measures No. 2) Bill 2009 [Provisions]*', 2 August 2009, 15; at http://www.aph.gov.au/Senate/committee/clac_ctte/therapeutic_goods_09/report/index.htm .

[18] For more information, please see "Regulatory Reform" at: www.tga.gov.au/regreform/index.htm .

[19] For more information, please see "Regulatory Reform" at: www.tga.gov.au/regreform/index.htm .

[20] The commencement date for each provision of the Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009 is contained in the table which forms part of Section 2 of the Act.

[21] For more information, please see "Regulatory Reform" at: www.tga.gov.au/regreform/index.htm .

[22] For more information, please see "Regulatory Reform" at: www.tga.gov.au/regreform/index.htm .

[23] The proposed changes to the scheduling of medicines under the Act will not be discussed in this newsletter. For more information on these recommendations, please see: The Senate Community Affairs Legislation Committee, *'Therapeutic Goods Amendment (2009) Measures No. 2) Bill 2009 [Provisions]*', 2 August 2009, at http://www.aph.gov.au/Senate/committee/clac_ctte/therapeutic_goods_09/report/index.htm .