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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

THERAPEUTIC GOODS LEGISLATION AMENDMENT (COPYRIGHT) BILL 2011

EXPLANATORY MEMORANDUM

(The Hon Catherine King, Parliamentary Secretary for Health and Ageing)

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OUTLINE

Generally, therapeutic goods are required to be approved for inclusion in the Australian Register of Therapeutic Goods (the Register) before they can be lawfully marketed and supplied in Australia. Inclusion of prescription and other higher risk medicines in the Register signifies they have undergone a high level of scrutiny before they are approved.

A draft Product Information document ("PI") is lodged as part of the application process for registration of these medicines under the *Therapeutic Goods Act 1989*. The PI is approved by a delegate of the Secretary to the Department of Health and Ageing as part of the registration process. Any subsequent variation to a PI must also be approved.

The purpose of the approved PI for a medicine is to assist medical practitioners, pharmacists and other health professionals to prescribe and dispense the medicine appropriately and safely and to assist them to provide patient education so as to support high quality and safe clinical care.

The PI contains technical information about the medicine such as the characteristics of the active ingredient, its indications and contraindications, a description of clinical trials that support the indications, precautions, possible adverse reactions, dosages and storage, and other information relating to the medicine's safe and effective use.

It has been a long-standing practice in the Therapeutic Goods Administration (TGA) for delegates to approve the text of the PI of generic versions of a prescription medicine that is essentially the same as the approved PI of the "original" medicine. It is important for the safe and effective use of the medicine that doctors, pharmacists and other health professionals receive the same information about a medicine regardless of the brand, thus avoiding any perception that differences in the text of the PIs reflect clinical and/or pharmacological differences.

Recently a number of pharmaceutical companies that have prescription medicines on the Register ("originator companies") have taken, or threatened to take, legal action on the basis that they own the copyright in the approved PI for their medicines.

In 2008, the Federal Court granted an interlocutory injunction to a pharmaceutical company sponsor of a registered medicine partly on the basis of an argument that copyright in the approved PI for that medicine would be infringed by a competitor's use of the approved PI for a generic version of the medicine.

The Federal Court hearing in this matter is scheduled for March 2011 and the issue of copyright in the approved PI of a registered medicine will be considered by an Australian court for the first time.

The Therapeutic Goods Legislation Amendment (Copyright) Bill 2011 (the Bill) provides an exemption to the infringement of copyright that may subsist under the *Copyright Act 1968* where a person uses the relevant text for the purposes of applying to register a medicine, or for the purpose of varying the approved PI of a medicine, or any incidental or ancillary acts. The exemption applies to these acts irrespective of when the PI was approved. The exemption will also apply to third parties supplying, reproducing, publishing, communicating or adapting an approved PI for a medicine where such acts are for purposes related to the safe and effective use of the medicine.

The amendments are intended to prevent companies commencing legal action asserting copyright in the text of an approved PI where it is used in the PI of another version of the same medicine. They will enable the sound public health objectives underlying the TGA's practice in relation to the approval of the PIs of generic medicines to continue to be met.

FINANCIAL IMPACT STATEMENT

This measure would ensure that the Commonwealth is not subject to additional costs resulting from any delays in generic medicines being listed under the Pharmaceutical Benefits Scheme (thus triggering a statutory price reduction) and ensure that generic medicines are not subject to unnecessary additional costs in gaining access to the Australian market. No additional administrative costs to the TGA will result as it operates on full cost recovery.

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NOTES ON CLAUSES

Clause 1: Short Title

Clause 1 is a formal provision specifying the short title of the Bill. Once enacted, its title will be the Therapeutic Goods Legislation Amendment (Copyright) Act 2011.

Clause 2: Commencement

This clause provides that the Act commences on the day after it receives Royal Assent.

Clause 3: Schedules

This clause provides that each Act specified in a Schedule to the Bill is amended or repealed as set out in the applicable items in the Schedule, and any other item in a Schedule to the Bill will, once enacted, have effect according to its terms.

Schedule 1 – Amendments

Copyright Act 1968

Item 1

This item inserts new section 44BA in Part III of the *Copyright Act 1968*.

Proposed section 44BA provides that certain acts are not an infringement of copyright subsisting in a work that is Product Information (PI) approved under the under the *Therapeutic Goods Act 1989* (the TG Act) in relation to particular medicines.

Proposed subsection 44BA(1) provides that the following acts are not an infringement of any copyright subsisting under Part III of the Copyright Act (copyright in original literary, dramatic, musical and artistic works) in a work that is approved PI under section 25AA of the TG Act:

(a) acts done under the TG Act in respect of PI for any restricted medicine, for any other medicine in respect of which the Secretary has, under subparagraph 25(1)(da)(ii) of the TG Act, required a PI document to be provided, and for any medicine in respect of which the Secretary has otherwise approved PI under section 25(4) of the TG Act; and

(b) acts ancillary or incidental to an act referred to in paragraph (a).

PI approved under section 25AA of the TG Act is the following:

(a) PI approved by the Secretary in relation to a medicine included in the Register under subparagrapah 25(4)(d)(ii) after the legislative instrument made under subsection 3(2A) and 3(2B) of the TG Act comes into effect (subsections 25AA(1) and (3) of the TG Act);

(b) PI in relation to a medicine included in the Register before the commencement of that legislative instrument, that was approved by the Secretary in a notice

given under subsection 25(4) of the TG Act, including that PI as varied before that time (subsection 25AA(2) of the TG Act); and

(c) PI approved in relation to a medicine before or after the commencement of section 44BA, and subsequently varied under section 25AA of the TG Act (subsections 25AA(4) and (5) of the TG Act).

The exemption in proposed subsection (1) will only apply to acts done after the commencement of the amendments.

The effect of proposed subsection (1) is to enable any person applying to register a medicine who is required to lodge a PI for approval as part of the registration process, or a sponsor of a registered medicine seeking to vary an approved PI, to lodge PI without infringing any copyright if the lodged PI contains text in PI previously approved by the TGA under section 25AA of the TG Act (as described above).

The requirements for lodging a PI in relation to the registration of a medicine under section 25 of the TG Act are set out in paragraph 23(2)(ba) and subparagraph 25(1)(da)(ii) of the TG Act.

If the application is made under section 23 of the TG Act to register a restricted medicine in the Register, the application is required to be accompanied by PI for that medicine using a form approved by the Secretary. A restricted medicine is a medicine, or class of medicines, specified by the Minister in a legislative instrument made under the TG Act. Restricted medicines include medicines that must be prescribed by a medical practitioner and medicines that are "pharmacist only" medicines (substances the safe use of which requires professional advice and are available from a pharmacist without a prescription).

The requirement for PI to be provided in relation to an application to register a medicine that is not a restricted medicine applies where the Secretary notifies the applicant for the registration of a medicine to give to the Secretary, in an approved form, PI for that medicine (refer to subparagraph 25(1)(da)(ii) of the TG Act).

Variations to approved PI can be made by the Secretary under section 25AA of the TG Act, including as a result of a request under section 9D of the TG Act for a variation to the entry of a registered medicine.

Proposed subsection 44BA(2) provides that the supplying, reproducing, publishing, communicating or adapting in Australia of any, or any part of, PI that has been approved under section 25AA of the TG Act in relation to medicine is not an infringement of any copyright subsisting under Part III of the Copyright Act in a work that is PI approved under section 25AA of the TG Act, providing that any such act is undertaken for a purpose related to the safe and effective use of the medicine.

The use by pharmaceutical companies and their employees and agents of approved PI in presentations about the relevant medicine and the making available online of approved PI for the use of health professionals are instances of acts that would be covered by the exemption set out in proposed subsection (2).

Proposed subsection 44BA(3) provides that any act that is ancillary or incidental to an act set out under proposed subsection (2) is not an infringement of any copyright subsisting in the relevant work.

Proposed subsection 44BA(4) provides that for the purposes of the section, ***medicine***, ***approved product information*** and ***restricted medicine***, have the same meaning as in the TG Act.

Item 2
This item provides that new subsections 44BA(1), (2) and (3) inserted by item 1 apply in relation to acts done on or after the day on which the provisions commence.

The acts done after commencement may relate to PI approved under section 25AA after the commencement of these provisions but also to PI approved by the Secretary before that commencement, that is, approved or taken to be approved under section 25AA as described above.

Item 3
Sub-item (1) provides that where the operation of the amendments set out in Schedule 1 to the Bill result in an acquisition of property from a person otherwise than on just terms, the Commonwealth is liable to pay a reasonable amount of compensation to the person. The inclusion of this provision ensures the constitutional validity of the proposed amendments.

Sub-item (2) provides that if the Commonwealth and the person claiming compensation do not agree on the amount of the compensation the person may institute legal proceedings in a court of competent jurisdiction for the recovery from the Commonwealth of a reasonable amount of compensation as determined by the court.

Sub-item (3) provides that for the purposes of this item the terms ***acquisition of property*** and ***just terms*** are to have the same meaning as in paragraph 51(xxxi) of the Constitution.