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Therapeutic Goods Legislation Amendment (Copyright) Bill 2011

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Contents

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Therapeutic Goods Legislation Amendment (Copyright) Bill 2011

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Links: The links to the Bill, its Explanatory Memorandum and second reading speech can be found on the Bills home page, or through http://www.aph.gov.au/bills/. When Bills have been passed they can be found at the ComLaw website, which is at http://www.comlaw.gov.au/.

Purpose

The Therapeutic Goods Legislation Amendment (Copyright) Bill 2011 (the Bill) amends the *Copyright Act 1968* in order to ensure that the Product Information document issued for generic versions of prescription medicines can be identical to the approved Product Information document of the original medicine.

Background

Generic medicines

When the patent of an innovator drug expires, other manufacturers can make generic versions. A generic drug contains the same active ingredient as another product, but is marketed under a different name. In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC)[1] recognises the interchangeability of different brands containing the same active ingredient, providing these brands are proven to be bioequivalent.[2]

Generic medicines have an important place in health care. Consumers see generic medicines as an opportunity to access cheaper medicines, while government sees the opportunity to achieve the

1. The PBAC assesses applications for listing of medicines on the PBS to ensure that all products listed as benefits meet the criteria specified in the *National Health Act 1953*.
2. Two products are bioequivalent when they produce such similar plasma concentrations of the active ingredient that their clinical effects can be expected to be the same. Bioequivalent products are marked with a superscript a or b in the Schedule of Pharmaceutical Benefits. 'Frequently asked questions about generic medicines', *Australian Prescriber,* April 2007, viewed 21 March 2011, http://www.australianprescriber.com/magazine/30/2/41/3

same health outcomes for patients at a lower cost.[3] The pricing and purchasing of generic medicines in Australia is a significant policy challenge with prices for generic medicines considered still to be high by international standards. The Further Reforms of the Pharmaceutical Benefits Scheme implemented under the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010* has attempted to address these issues. Amongst other things, it introduced price reductions so that the first listing of a generic version of a medicine now triggers a 16 per cent reduction[4] in the price the Commonwealth pays for the medicine.[5]

Product Information

As a condition of registration, certain medicines, mainly those prescribed by a doctor, are required to have a Product Information (PI) document which provides information relating to the safe and effective use of the medicine, including information regarding the medicine's usefulness and limitations. PI documents are agreed with the Therapeutic Goods Administration (TGA) as part of the medicine's approval process before it can be made available in Australia.

As the Explanatory Memorandum notes, the information in these documents assists doctors, pharmacists and other health professionals in prescribing and dispensing medicines and also in their consultations with patients, such as to better educate a patient on the medicine they are being given.[6]

PI is defined in the *Therapeutic Goods Act 1989* to mean information relating to 'the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods'.[7] Details about what should be in the PI document are contained in the *Australian regulatory guidelines for prescription medicines.*[8] It includes 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.[9]

In relation to PI for generic medicines, the Explanatory Memorandum notes that it has been a long-standing practice in the TGA for delegates to approve the text of the PI of generic versions of a

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3. A McLachlan, 'Editorials: Generic medicines literacy—minimising the potential for patient confusion', *Medical Journal of Australia*, vol. 192, no. 7, 2010, pp. 368-369, viewed 21 March 2011, http://www.mja.com.au/public/issues/192_07_050410/mcl11419_fm.html
4. Prior to 1 February 2011 this figure was 12.5 per cent.
5. For further information, the reader is referred to: R de Boer, 'PBS reform—a missed opportunity', *Australian Health Review*, vol. 33, no. 2, May 2009; and R de Boer and S Scully, *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*, Bills Digest, no. 13, 2010–11, Parliamentary Library, Canberra, 2010, viewed 21 March 2010, http://parlinfo.aph.gov.au/parlInfo/download/legislation/billsdgs/289006/upload_binary/289006.pdf;fileType=application/pdf#search=%22de%20boer%20scully%20therapeutic%22
6. Explanatory Memorandum, Therapeutic Goods Legislation Amendment (Copyright) Bill 2011, p. 1.
7. Section 3 of the Therapeutic Goods Act.
8. Therapeutic Goods Administration, *Australian regulatory guidelines for prescription medicines*, viewed 21 March 2011, http://www.tga.gov.au/pmeds/argpm.htm
9. Explanatory Memorandum, p. 1.

prescription medicine that is essentially the same as the approved PI of the 'original' medicine. The rationale is that 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.[10]

Committee consideration

The Bill has not been referred to committee for inquiry.

Position of major interest groups

Generic Medicines Industry Association (GMiA) is reported as welcoming the Bill saying the changes are necessary to ensure generic medicines can continue to be supplied in Australia'.[11]

Other than GMiA, there is little reported comment on the Bill.

Financial implications

The Explanatory Memorandum states that the Bill has no additional financial costs.[12]

Main issues

The Bill proposes only one significant amendment—it amends the Copyright Act in order to ensure that the PI document issued for generic versions of prescription medicines can be identical to the approved PI document of the original medicine.

The Government's rationale for the Bill, stated in both the Explanatory Memorandum and the Minister's second reading speech, is 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.[13]

The Explanatory Memorandum notes that recently a number of pharmaceutical companies that have prescription medicines on the Australian Register of Therapeutic Goods ('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.[14] In particular, 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

10. Ibid.
11. 'Generics back copyright reform', *Pharmain Focus*, 23 February, 2011, viewed 14 February 2011.
12. Explanatory Memorandum, p. 2.
13. ibid.
14. Ibid, p. 1.

competitor's use of the approved PI for a generic version of the medicine. The Explanatory Memorandum further notes that 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.[15]

The Government states that such actions involving a claim of copyright in PI could have the effect of delaying the listing of generic medicines under the Pharmaceutical Benefits Scheme thus resulting in subjecting the Commonwealth to additional costs as well as artificially prolonging any market exclusivity that the originator company may have under patent law.[16]

It is of note that the Government's explanatory materials do not identify the pharmaceutical companies involved in Federal court proceedings. However a report by Pharmain Focus notes that copyright issues affecting PI arose in July 2010 in a case between Apotex (a generic drug company) and Sanofi-Aventis over the drug Leflunomide in which, amongst other things, Apotex was denied permission to reproduce a PI document on the grounds of copyright infringement.[17] The details of this 2010 case would appear to be *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd* [2010] FCA 601 (8 June 2010)[18] in which Jagot J denies a request to vary the interlocutory orders granted by Lindgren J on 30 October 2008.[19] This matter would appear to be the one referred to in the Explanatory Memorandum, although it is unclear why the details of this particular case are not provided.

As the history of the Copyright Act shows, introducing exceptions to copyright infringement is not done lightly and usually has to be in accordance with quite onerous treaty obligations. The need to defer to international copyright law may be the reason why the Minister's second reading speech notes that if implemented, the changes will bring Australian law substantially into line with the 'same labelling requirements' for medicines in the United States.[20]

In this context, it is also of note that such an amendment of the Copyright Act is not unique and that a similar exception was introduced in 1994 in respect of chemical product labelling approved under the Agricultural and Veterinary Chemical Code ("AGVET Code").[21]

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15. Ibid.
16. Ibid, p. 2; C King (Parliamentary Secretary for Health and Ageing), 'Second reading speech: Therapeutic Goods Legislation Amendment (Copyright) Bill 2011', House of Representatives, *Debates,* 24 February 2011, p. 1364, viewed 21 March 2011, http://parlinfo.aph.gov.au/parlInfo/genpdf/chamber/hansardr/2011-02-24/0025/hansard_frag.pdf;fileType=application%2Fpdf
17. PharmainFocus, *News: Generics back copyright reform*, op. cit.
18. http://www.austlii.edu.au/au/cases/cth/FCA/2010/601.html
19. The 2008 orders can be found at: https://www.comcourts.gov.au/file/Federal/P/NSD1664/2008/3553081/event/25679953/document/147167
20. C King (Parliamentary Secretary for Health and Ageing), 'Second reading speech', op. cit.
21. A 'chemical product' is defined in the AGVET Code to include chemical products that are designed to have an effect on plants or animals (e.g. fertilisers and veterinary medicine).

Key provisions

There is only one major amendment— **item 1** which inserts **proposed section 44BA** in Part III of the Copyright Act.

Part III of the Copyright Act and exceptions to infringement

Copyright is designed to prevent the unauthorised use by others of original works. Copyright in Australia exists in works of specified types, including literary and artistic works, by virtue of the Copyright Act.[22] Copyright gives copyright owners a number of exclusive economic rights, such as the right to: reproduce the work in a material form; publish the work; perform the work in public; communicate the work to the public, and make an adaptation of the work.[23]

There are exceptions to the exclusive rights of copyright owners that enable the exercise of certain rights without constituting a copyright infringement. Some of these are set out in sections 40 to 44F of the Copyright Act and include, for example, exceptions that permit fair dealing for certain specified purposes[24] and reproduction of writing on approved labels for containers for chemical product.[25]

Proposed section 44BA—exception to copyright infringement relating to product information for certain medicines

The Bill proposes an additional copyright exception as set out in **proposed section 44BA**.

Proposed subsection 44BA(1) provides that actions under the Therapeutic Goods Act for the purposes of approving PI for certain medicines or approving variations to the PI will not be an infringement of any copyright subsisting in the PI previously approved by the TGA.[26] The effect is to enable, for instance, an applicant for the registration of a generic version of a registered medicine to lodge similar PI to that previously approved by the TGA without infringing copyright.

In addition **proposed subsection 44BA(2)** provides that the supplying, reproducing, publishing, communicating or adapting, in Australia, of any PI approved under the Therapeutic Goods Act in relation to particular medicines is not an infringement of copyright, providing that any such act is undertaken for a purpose related to the safe and effective use of the medicine.

22. See Part III of the Copyright Act that deals with copyright in original literary, dramatic, musical and artistic works.
23. Section 31.
24. Such as research or study and reporting of news. Fair dealing exceptions are set out in sections 40 to 42.
25. Division 3 of Part III—Acts not constituting infringements of copyright in works, section 44B.
26. The requirements for lodging a PI in relation to the registration of a medicine under section 25 of the Therapeutic Goods Act are set out in paragraph 23(2)(ba) and subparagraph 25(1)(da)(ii) of the Act.

Application of the amendments

Item 2 provides that the new infringement exemption provision will apply to acts done on or after commencement. However these acts may relate to PI approved before as well as after the commencement of these provisions.

Compensation for acquisition of property

Item 3 provides for compensation for acquisition of property. This provision follows a standard format which responds to a constitutional requirement that Commonwealth acquisitions of property be compensated for if they have not been undertaken on just terms. Note that the section is not to be inserted into the Copyright Act itself but will remain an item in the Schedule of the Act resulting from passage of this Bill.

Members, Senators and Parliamentary staff can obtain further information from the Parliamentary Library on (02) 6277 2438.