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Therapeutic Goods Amendment (2011 Measures No. 1) Bill 2011

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Therapeutic Goods Amendment (2011 Measures No. 1) Bill 2011

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Commencement: the day after receiving Royal Assent

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

Purpose

The Therapeutic Goods Amendment (2011 Measures No. 1) Bill 2011 (the Bill) makes minor technical amendments to the *Therapeutic Goods Act 1989* (the Act) in relation to: processes for the application and evaluation of changes to the entry of a prescription medicine on the Australian Register of Therapeutic Goods (ARTG); the collection of evaluation fees; and standard conditions for the registration or listing of therapeutic goods.

Background

The Therapeutic Goods Administration (TGA) regulates medicines, medical devices and blood and tissue products in Australia. Therapeutic goods cannot be sold in Australia without being registered or listed on the ARTG.

In 2008, the Government commenced consultation on the proposed regulatory reform program intended to update and streamline the existing regulatory framework for therapeutic goods in Australia. This culminated in five Acts, amendments to the regulations and the current Bill. The substantive policy and regulatory issues were considered in the five Acts and canvassed in each Bill Digest.[1]

1. See R de Boer and S Scully, *Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008*, Bills Digest, no. 84, 2008-09, Parliamentary Library, Canberra, 2008; R de Boer and S Scully, *Therapeutic Goods Amendment (2009 Measures No. 1) Bill 2009*, Bills Digest, no. 122, 2008-09, Parliamentary Library, Canberra; R de Boer and S Scully, *Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009*, Bills Digest, no. 8, 2009-10, Parliamentary Library, Canberra; R de Boer and S Scully, *Therapeutic Goods Amendment (2009 Measures No. 3) Bill*

This Bill makes minor amendments to the operation of the Act to streamline the submission and registration process for prescription medicines.[2] It is intended to support the revised procedures, a number of which have already been introduced by the *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010* (the Amendment Act).[3]

The Bill addresses three issues, which will be discussed in the 'Key provisions' section of this Digest:

- administrative changes to the process for amending the listing of products on the ARTG
- the collection of evaluation fees, and
- clarity around 'standard' conditions prescribed by the Minister in relation to therapeutic goods.

Committee consideration

This Bill was debated by the Main Committee of the House of Representatives on 12 May 2011. It was ordered that the Bill be reported to the House without amendment.[4]

The Senate Standing Committee for the Scrutiny of Bills had no comment on this Bill.[5]

Stakeholder commentary

There has been no stakeholder commentary in relation to the Bill.

Financial implications

The TGA operates on principles of cost recovery and this Bill will have nil financial impact.

2009, Bills Digest, no. 83, 2009-10, Parliamentary Library, Canberra; R de Boer and S Scully, *Therapeutic Goods Amendment (2010 Measures No 1) Bill 2010*, Bills Digest, no. 33, 2010-11, Parliamentary Library, Canberra.

2. C King, 'Second reading speech: Therapeutic Goods Amendment (2011 Measures No. 1) Bill 2011', House of Representatives, *Debates*, 23 March 2011, p. 2873. For example, the amendment proposed in **item 1** of the Bill reflects provisions already in place in relation to the application for new entries in the ARTG for prescription medicines: Explanatory Memorandum, Therapeutic Goods Amendment (2011 Measures No. 1) Bill 2011, p. 2.
3. See C King, op. cit.; Explanatory Memorandum, op. cit.
4. Australia, House of Representatives, *Votes and proceedings,* 12 May 2011, p. 104, viewed 13 May 2011, http://www.aph.gov.au/hansard/reps/dailys/dr120511.pdf
5. Senate Standing Committee for the Scrutiny of Bills, *Alert Digest No. 4 of 2011,* 11 May 2011, p. 67, viewed 13 May 2011, http://www.aph.gov.au/Senate/committee/scrutiny/alerts/2011/d04.pdf

Key provisions

Administrative changes to amending entries of prescription medicines listed on the ARTG

The current arrangements for the evaluation of changes to the registration of existing products on the ARTG by the TGA permit applicants to submit further documentation and information during the evaluation process. This often adds considerable additional time to the evaluation process.

Item 1 of the Bill proposes to amend **subsections 9D(6)–(8)** of the Act to the effect that, in general, when an applicant makes a particular type of request to change an entry in the ARTG in relation to a therapeutic good which is incorrect or incomplete, the applicant must lodge a request in the required form and manner, submit all relevant information and pay the prescribed fee.[6]

This is designed to ensure that the necessary information is supplied at the time of lodgement and the evaluation is completed within the agreed timeframes.[7] According to the Explanatory Memorandum:

> This amendment will assist in eliminating unnecessary delays by requiring that requests to which these requirements apply contain all the information necessary in order for a decision to be made on the request in a timely manner. It reflects provisions already in place under section 23 of the Act in relation to applications for new entries in the Register for prescription medicines.[8]

The proposed amendment will ensure that there is consistency between the arrangements for new entries on the ARTG for prescription medicines and changes to existing entries on the ARTG for prescription medicines.

Refund of evaluation fees

The TGA charges a fee for the evaluation of products to be listed or registered on the ARTG. Currently, at the time of lodgement, 75 per cent of the fee is required with the final 25 per cent to be paid if the TGA completes the evaluation within the timeframes specified in the Regulations.

The proposed amendments in **item 4** of the Bill, which propose to amend **subsection 24D(2)-(6)** in the Act, generally seek to change this approach, with the full fee being paid at the time of lodgement and 25 per cent being refunded if the TGA fails to complete the evaluation on time.

6. According to the Explanatory Memorandum, the proposed provision relates to circumstances where such requests also require the evaluation of clinical, pre-clinical and bioequivalence data: Explanatory Memorandum, op. cit., p. 2.
7. C King, op. cit., p. 2873. See also Explanatory Memorandum, op. cit., p. 2.
8. Ibid.

The rationale for this approach is that the TGA has only failed to complete evaluations on time on about 15 occasions since 1992.[9] It is argued that the proposed amendment provides for a more efficient way of recovering monies from the Commonwealth and for reducing administrative costs.[10] This is expected to be of benefit to the industry as the TGA operates on a cost recovery basis.[11]

Note, however, that the Explanatory Memorandum points out that:

> An applicant will not be entitled to a refund in cases where the applicant withdraws the application before the evaluation is completed even if the prescribed period is passed.[12]

This raises the question of whether an applicant should be automatically entitled to a refund once the timeframe for completing the evaluation has passed.

It is also noted that **item 4** is silent as to an expressed timeframe in which the refund is to be made.

Standard conditions

The *Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009* (the Amendment Act), which commenced on 25 January 2010, amended **section 28** of the Act in relation to the imposition of conditions on the registration and listing of therapeutic goods. These conditions are imposed by legislative instrument and relate to such matters as the manufacture, supply, use custody or disposal of goods on the ARTG.[13]

The Explanatory Memorandum states that:

> Subsection 28(1) provides that the registration or listing of therapeutic goods is subject to the conditions set out in a determination made under subsection 28(2). Subsection 28(2) allows the Minister, by legislative instrument, to make a determination setting out various kinds of conditions that apply generally to therapeutic goods or classes of therapeutic goods. In addition to the conditions contained in the instrument made under subsection 28(2), the Secretary has the power to impose, on a case-by-case basis, further conditions on the registration or listing of goods under subsection 28(2B). The Secretary may also, under subsection 28(3) impose new conditions or vary or remove conditions imposed under subsection 28(2B).
>
> The effect of item 57 in Schedule 7 of that Act is that any legislative instrument made under the new subsection 28(2) and imposed under the new subsection 28(1) (the "new" standard conditions) will apply to the registration or listing of therapeutic goods occurring before, on or after the commencement of the item. The item also preserves the conditions applying to goods already on the Register when the instrument takes effect and treats them as if they had been

9. C King, op. cit., p. 2873.
10. Ibid. See also Explanatory Memorandum, op. cit., p. 2.
11. C King, op. cit., p. 2873.
12. Explanatory Memorandum, op. cit., p. 5.
13. C King, op. cit., p. 2874.

> imposed under subsection 28(2B) thus allowing the Secretary to vary or remove them on a case-by-case basis.
>
> ...
>
> The intention is that the new standard conditions imposed by the Minister will apply to all registered and listed goods, including those on the Register at the time that the instrument comes into effect. In order to prevent an overlap with standard conditions already in place ("old" standard conditions), the Secretary would, by notice in writing given to the person in relation to whom the goods are registered or listed, remove the old standard conditions on a case-by-case basis using subsection 28(3).[14]

Item 8 is a transitional provision applying to old standard conditions that were either:

- taken to have been made under subsection 28(2B)of the Act by the operation of **subitem 57(3)** of **Schedule 7** of the Amendment Act, or
- imposed by the Secretary under subsection 28(2B) of the Act.

In general, **subitem 8(1)** of the Bill amends the operation of **item 57** of **Schedule 7** of the Amendment Act so that any old standard conditions would cease when the new standard condition takes effect.

However, under **subitem 8(2)** of the Bill, an instrument made under **subsection 28(2)** of the Act may provide that specified conditions apply only to a specified class of therapeutic goods that are registered or listed on or after that instrument takes effect.

According to the Explanatory Memorandum:

> This amendment will ensure that the Minister has the power to determine that specified conditions only apply to the registration or listing of a class goods after the relevant instrument takes effect where it is appropriate to do so.[15]

It is expected that these amendments would ensure that there is no overlap or inconsistency between the conditions.

Concluding comments

This Bill is largely administrative in nature and seeks to enhance the operation of the Act. It makes some minor amendments to legislation which have been previously debated by the Parliament. Given the nature of these amendments, it is not surprising that the introduction of this Bill has failed to generate any significant stakeholder commentary and the Opposition has already stated that it

14. Explanatory Memorandum, op. cit., p. 6.
15. Ibid., p. 7.

will not be opposing the Bill.[16]

16. *Votes and proceedings,* 12 May 2011, op. cit., p. 100.

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