

Bills Digest
No. 75 2000–01

Therapeutic Goods Amendment Bill (No 4) 2000

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No. 75 2000–01

Therapeutic Goods Amendment Bill (No 4) 2000

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Contents

Purpose	1
Background	1
Listing therapeutic goods on the Register	2
Main Provisions	3
Definitions	3
Simplified self-assessment listing process for medicines	3
Power to request samples	4
Power to cancel listing	5
New offences	6
Concluding Comments	7
Endnotes	7

Therapeutic Goods Amendment Bill (No 4) 2000

Date Introduced: 7 December 2000

House: Senate

Portfolio: Health and Aged Care

Commencement: On Proclamation, or 6 months after Royal Assent, whichever is the earlier.

Purpose

To amend the simplified listing process for low risk medicines in the *Therapeutic Goods Act 1989*, to provide for complete self-assessment. This, it is claimed, is necessary to facilitate the introduction of a new refined system for electronically listing medicines on the Australian Register of Therapeutic Goods.

Background

The *Therapeutic Goods Act 1989* establishes a uniform national system of controls on the availability within Australia of therapeutic goods.¹ The system is administered by the Therapeutic Goods Administration (TGA), which is within the Department of Health and Aged Care. The Secretary of the Department exercises the powers of the TGA. Under the legislation, therapeutic goods may be supplied in, or exported from, Australia only if they fall into one of four categories:

- goods 'registered' on the Australian Register of Therapeutic Goods (the Register)
- goods 'listed' on the Register
- goods 'exempt' from the registration and listing process (generally, drugs requested by a medical practitioner to treat terminally ill patients,² or drugs imported for personal use under the Personal Import Scheme,³) or
- goods given a 'specific approval' by the Secretary of the Department, which do not have to undergo registration or listing.⁴

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The majority of therapeutic goods must either be registered or listed on the Register.⁵ Registered goods are those assessed as having a higher level of risk. They include goods, such as prescription drugs, which require rigorous and detailed examination and evaluation by the TGA for quality, safety and efficacy.⁶

Listed goods, by contrast, are generally lower risk products. They only contain well known established ingredients, usually with a long history of use, such as vitamin, herbal and mineral products or sunscreens, which are not scheduled poisons. Some over-the-counter medicines are also listed goods rather than registered goods. The majority of listed medicines are self-selected by consumers and used for self-treatment.⁷

Listing therapeutic goods on the Register

This Bill is concerned with the listing process. Currently, there are two separate processes by which therapeutic goods may be listed on the Register – a standard process and a simplified process. The simplified process is separated into one procedure for therapeutic devices and another procedure for other therapeutic goods.

Section 26AA contains the simplified listing process for therapeutic devices. The Secretary must list a therapeutic device on the Register if an application is made accompanied by a conformity assessment certificate, unless he or she considers that the therapeutic device may compromise the health and safety of users.

Section 26A contains the simplified listing process for therapeutic goods, other than therapeutic devices and export only medicines. Basically, the Secretary must list a therapeutic good on the Register if an application is made accompanied by a certificate stating that the therapeutic good meets certain criteria relating to quality, safety and manufacturing standards, and if the applicant has provided any information requested by the Secretary.

Section 26 sets out the standard listing process. This process may be followed in relation to any therapeutic goods or devices if the sponsors for some reason do not wish to undertake self-assessment under one of the simplified procedures, and must be followed in relation to export only medicines. Under this process, an application is made for the listing of a therapeutic good, and information is provided to the Secretary as requested. The Secretary then determines whether to list the good, based on whether it meets safety, manufacturing and quality control standards.

The Bill makes amendments to the simplified listing process for therapeutic goods (other than therapeutic devices) contained in section 26A. It confers greater responsibility for self-assessment of listable therapeutic goods on applicants. The Second Reading Speech explains that these amendments ‘are necessary to allow the introduction of a redeveloped and refined system for electronically listing medicines.’ Although there is currently an electronic lodgement system for listing medicines, a new refined listing system has been

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developed, which is claimed to achieve ‘a better balance of responsibilities for industry and the TGA under a co-regulatory framework.’⁸

The details of the current listing processes and the amendments made by the Bill are explained in the Main Provisions section.

Main Provisions

All references to items refer to items in **Schedule 1** of the Bill. Unless otherwise specified, all the amendments described below apply only to applications for listing made after the commencement of the Bill (**sub-item 36(1)**).

Definitions

Items 1, 2 and 3 of the Bill insert three new definitions into subsection 3(1).

An ‘*export only medicine*’ is one that is manufactured in or imported into Australia solely for export, and is required to be listed on the Register only because it is manufactured or imported for export. These medicines will not be eligible for listing after self-assessment under section 26A.

‘*Listable goods*’ means goods which are required to be listed on the Register.⁹ Listable goods will be taken to be separate from other listable goods if they have different active ingredients, different quantities of active ingredients or a different dosage form. Other different characteristics may be set out in the regulations (**item 5**). This definition will apply to all listed goods, whether listed before or after the commencement of this Bill (**sub-item 36(2)**).

‘*Working day*’ means any day except Saturday, Sunday or a public holiday.

Simplified self-assessment listing process for medicines

Section 26A currently applies to ‘*therapeutic goods*’ other than therapeutic devices. The Bill amends the terminology to refer instead to ‘*medicines*’ (**items 8, 10, 11, 13, 15-17, 19-25, 28, 30 and 32**). This appears to be a change in language only. Therapeutic devices will continue to be covered by the simplified process in section 26AA, and medicines intended solely for export will continue to be excluded from the simplified listing process.

Presently, the applicant for self-assessment listing must certify that:¹⁰

- the goods are eligible for listing

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- the goods comply with all prescribed quality or safety criteria and are safe for the purposes for which they are to be used
- the presentation of the goods is acceptable
- the goods have been made in accordance with acceptable manufacturing and quality control procedures, whether within or outside Australia¹¹
- the goods conform to any advertising requirements applicable under the regulations
- the goods do not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*, and
- the information included in or with the application is correct.

These quality control requirements will continue under the provision as amended by the Bill. In addition, the applicant will be required to certify (**item 12**) that:

- the application contains the names of all manufacturers of the medicine,
- written agreements are in place with prescribed manufacturers, and
- the applicant holds information or evidence to support any claim that the applicant makes relating to the medicine.

These additional requirements strengthen the accountability of the applicant for the quality of listed medicines. If the applicant incorrectly certifies as to any of these additional matters, the Secretary will have power to cancel the listing of the medicine (**item 33**).

Currently, a person applying for listing of a therapeutic good must, prior to listing, provide any information or documents required by the Secretary in relation to the composition, quality, safety and manufacture of the product. This requirement is repealed by the Bill (**item 9**). The *Explanatory Memorandum* explains that the requirement ‘is redundant because entry onto the Register will be largely automatic once an application has been submitted by an applicant using the electronic lodgement facility’.¹² Instead, the Secretary or an authorised person may request information as part of the TGA’s post-listing monitoring.¹³

The existing obligation of the Secretary to notify the applicant of a decision whether or not to list a medicine is also repealed (**items 26 and 27**), because listing will be automatic after a certified self-assessment application is lodged.

Power to request samples

Although the listing process will be based completely on self-assessment by the sponsor of medicines, the Secretary will have two new means to control the safety and quality of

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listed medicines: the power to request samples for testing, and the power to cancel a listing.

The Secretary already has power to impose conditions on listed medicines and other therapeutic goods, on a case-by-case basis.¹⁴ In addition, there are two existing statutory conditions that apply to all listed therapeutic goods. These are:

- that the sponsor will allow authorised people (such as TGA officers) and officers of the Australian Federal Police to enter premises where listed medicines are manufactured or sold, and will permit those persons to inspect the premises or medicines, or to take samples,¹⁵ and
- that the sponsor will keep information and evidence to support any claims made in relation to the listed medicines and will produce the information and evidence if required.¹⁶

Item 29 of the Bill inserts a third statutory condition that a person who sponsors the listing of medicines under the self-assessment process will deliver samples to the Secretary if requested. This will enable the TGA to conduct laboratory testing and monitoring of listed medicines to determine their composition and quality. The *Explanatory Memorandum* states that this amendment ‘will strengthen the post-market monitoring system for listed medicines.’¹⁷

Power to cancel listing

The Secretary already has power to cancel the listing of any medicines or therapeutic devices for a number of reasons, including:

- to avoid imminent risk of death, serious illness or injury,
- if the quality, safety or efficacy of the goods is unacceptable,
- if the sponsor fails to comply with a direction given in relation to advertising the goods in accordance with the Therapeutic Goods Advertising Code,
- if the sponsor fails to comply with a condition applicable to the listing of the goods, or
- if the goods are exempt from registration or listing.

Item 31 inserts **proposed subsections 30(1A), (1B) and (1C)**, which contain new grounds for the cancellation of the listing of medicines listed under the self-assessment process in section 26A. This amendment permits the cancellation of the listing of medicines, whether they were listed on the Register before or after the commencement of this Bill (**sub-item 36(3)**). The new grounds for cancellation are:

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- if the medicine is not eligible for listing (for example because it contains a substance of higher risk, or because it makes a claim in relation to a serious disease, in which cases it should be evaluated for registration, not listed)
- if the medicine is exempt from registration or listing
- if there is a serious breach of the advertising requirements which apply to the medicine under the regulations, which is misleading to a significant extent,¹⁸ or
- if the sponsor fails within 20 working days to provide information or documents relating to whether the medicine should have been listed, when requested by the Secretary.

These expanded powers also form part of the post-market monitoring of medicines listed after self-assessment.

New offences

The Bill creates two new offences, both relating to the provision of false or misleading information.

It is currently an offence to intentionally or recklessly make a false or misleading statement in or in connection with an application for listing of a therapeutic good. The maximum penalty is \$6,600.¹⁹

Item 6 inserts **proposed subsection 22(2A)**. This makes it an offence to intentionally or recklessly make a false or misleading statement in or in connection with a certification that a medicine is eligible for automatic listing under section 26A. The maximum penalty is \$44,000.

Item 35 inserts **proposed subsection 31(6)**. This makes it an offence to intentionally or recklessly provide false or misleading information if, after self-assessment under section 26A, the Secretary requests information under section 31 relating to a listed medicine. The maximum penalty is also \$44,000.

The maximum penalties for breaching these provisions are significantly higher than the maximum penalty for the existing offence of making a false or misleading statement in an application for listing. The *Explanatory Memorandum* explains that this is justified because the self-assessment process relies heavily on information provided by applicants, therefore significant penalties are required 'to discourage the provision of inaccurate information that could have serious public health consequences.'²⁰ Similarly, the post-listing monitoring of medicines by the TGA depends in part on the sponsor providing information, and the high penalty for providing false or misleading information is intended to act as a deterrent to sponsors.

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Concluding Comments

In regulating therapeutic goods, a balance needs to be maintained between regulatory control to ensure the safety and quality of medicines, and streamlining regulatory procedures, thus expediting consumer access to low-risk therapeutic goods. This Bill aims to slightly alter this balance in favour of streamlined market access. It does this by permitting self-assessment of medicines that are eligible for listing on the Register. Although the current simplified listing process is already largely based on self-assessment, the Secretary retains some residual role in approving medicines for listing. The Bill facilitates the introduction of an electronic listing system which will be automatic, and will require no involvement from the TGA prior to listing.

To counter this increased autonomy, the TGA intends to maintain current standards of safety and quality of medicines by requiring sponsors to certify additional matters, enhancing post-listing monitoring of medicines by the TGA, imposing stringent penalties for the provision of inaccurate information, and requiring sponsors to certify that they hold evidence to support any claims made in relation to listed medicines.

In introducing the Bill, Senator Ian Campbell stated that the 'new listing system has been developed by the TGA in co-operation with industry and consumer representatives and is supported by the key stakeholder groups.'²¹ Although the stakeholders who were consulted are not identified by the Senator, this statement appears to indicate that both medicine manufacturers and consumers are in favour of the balance struck by the Bill.

Endnotes

- 1 Therapeutic goods are divided broadly into two classes - drugs and devices. Therapeutic products are defined broadly to include items such as prescription medicines and vaccines, non-prescription medicines including vitamins and sunscreens, and traditional or alternative medicines such as herbal products, aromatherapy and homeopathic products. Therapeutic devices include devices such as pacemakers, heart valves, bandages and certain contraceptives.
- 2 Section 18 of the *Therapeutic Goods Act 1989* permits therapeutic goods specified in the Therapeutic Goods Regulations 1990 to be exempt from registration or listing. For example, drugs to treat a Category A patient (a patient who is seriously ill and likely to die within months) are exempt if the treating medical practitioner signs a statement and sends it to the Secretary: regulation 12A of the Therapeutic Goods Regulations 1990. This is because in a life-threatening situation it is often impractical to wait months or years until the drug can be evaluated and entered on the Register.
- 3 Under the Personal Import Scheme, individuals can legally import most therapeutic goods for personal use, subject to restrictions on the quantity that can be imported in any twelve-month period, without the goods being entered on the Register. Drugs prohibited by Customs legislation or injectable drugs that contain material of human or animal origin cannot be

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- imported under the scheme, unless an import permit has been obtained: Therapeutic Goods Regulations 1990, Schedule 5.
- 4 Approval may be granted to import, export or supply a particular drug for use in the treatment of an individual (*special treatment approval*) or for use in experiments in humans (*clinical trial approval*): subsection 19(1) of the *Therapeutic Goods Act 1989*. Approval may also be granted where similar registered goods are in short supply or are unavailable (*substitute product approval*): section 19A of the *Therapeutic Goods Act 1989*. Where a particular medical practitioner is likely to treat a significant number of patients with the same condition with the same drug, he or she may apply to the Secretary for approval to supply a specified drug or drugs to a specified class of patients (*authorised prescriber authority*): subsection 19(5) of the *Therapeutic Goods Act 1989*. This removes the need for the medical practitioner to obtain a separate approval for every patient.
 - 5 Registration occurs under subsection 25(3) and listing under subsection 26(1) of the *Therapeutic Goods Act 1989*. Schedule 3 of the Therapeutic Goods Regulations includes the types of substances required to be registered on the Register while Schedule 4 of the Regulations contains goods required to be listable goods.
 - 6 Subsection 25(1) of the *Therapeutic Goods Act 1989*.
 - 7 See further the TGA publication *Medicines Regulation and the TGA* (December 1999), <http://www.health.gov.au/tga/docs/html/medregs.htm> (12 January 2001).
 - 8 Senator Ian Campbell, Second Reading Speech on the Therapeutic Goods Amendment Bill (No 4) 2000, Senate *Hansard*, p. 21031, 7 December 2000.
 - 9 The regulations or a notice issued by the Minister and published in the *Gazette* may require certain types of therapeutic goods to be listed on the Register.
 - 10 Subsection 26A(2) of the *Therapeutic Goods Act 1989*.
 - 11 If the goods are manufactured in Australia, each step must be carried out by a licensed manufacturer: paragraph 26A(2)(e). If any step in the manufacture of the goods has been carried out outside Australia, then (unless the goods are exempted by regulations from the manufacturing standards in Part 4 of the *Therapeutic Goods Act 1989*: subsection 26A(7)) the Secretary must have certified, prior to the application being made, that the manufacturing and quality control procedures used in each such step are acceptable: subsection 26A(3). This may require the applicant providing a conformity assessment certificate if the step in the manufacture was carried out in a country that is a member of the European Community or a member of the European Free Trade Association, or alternatively providing evidence from the relevant services authority as to the standard of the manufacture, or even paying for officials from the Department of Health to inspect the manufacturing procedures: subsection 26A(4). Additionally, the Bill provides that an application may have to provide information related to a medicine's manufacture or preparation, before the Secretary will certify that a foreign manufacturing process is acceptable (**item 18**).
 - 12 *Explanatory Memorandum*, p. 3.
 - 13 Under provisions such as paragraphs 28(5)(b), 28(6)(e) and subsection 31(2) of the *Therapeutic Goods Act 1989*.

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- 14 Section 28 of the *Therapeutic Goods Act 1989*.
- 15 Subsection 28(5) of the *Therapeutic Goods Act 1989*.
- 16 Subsection 28(6) of the *Therapeutic Goods Act 1989*.
- 17 *Explanatory Memorandum*, p. 4.
- 18 This ground of cancellation does not apply to export only medicines, **proposed subsection 30(1B)** of the *Therapeutic Goods Act 1989*.
- 19 Subsection 22(2). The current value of a penalty unit is \$110: subsection 4AA(1) of the *Crimes Act 1914* (Cth).
- 20 *Explanatory Memorandum*, p. 3.
- 21 Senator Ian Campbell, Second Reading Speech on the Therapeutic Goods Amendment Bill (No 4) 2000, Senate *Hansard*, p. 21031, 7 December 2000.

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