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I N F O R M A T I O N A N D R E S E A R C H S E R V I C E S

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No. 115 2001-02

Therapeutic Goods Amendment Bill (No 1) 2002

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22 March 2002

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Therapeutic Goods Amendment Bill (No 1) 2002

Date Introduced: 20 February 2002

House: House of Representatives

Portfolio: Health and Ageing

Commencement: Royal Assent

Purpose

To amend the *Therapeutic Goods Act 1989* to allow the importation, manufacture and supply of unapproved therapeutic goods that are needed to treat large numbers of patients in a national emergency. Additionally to provide for strengthened offence provisions and record keeping and reporting requirements in relation to such unapproved therapeutic goods.

Background

The *Therapeutic Goods Act 1989* ('the Act') establishes a uniform national system of controls on the availability within Australia of therapeutic goods, administered by the Therapeutic Goods Administration: see further Bills Digest No 149 of 2000-01 (<http://www.aph.gov.au/library/pubs/bd/2000-01/01BD149.htm>).

The *Therapeutic Goods Amendment Bill (No 1) 2002* ('the Bill') aims to amend the Act to introduce provisions to allow for the supply within Australia of therapeutic goods, not otherwise approved under the Act, in the case of an actual or foreseen emergency which requires these goods to be available to treat mass casualties.

The *Explanatory Memorandum* to the Bill indicates the rationale for the Bill is to:¹

...[strengthen] the ability of the Commonwealth to plan for and be able to respond quickly to national emergencies, including acts of bioterrorism that involve the deliberate release of chemical, biological or radiological substances or the emergence of a new, highly contagious disease. Either of these circumstances may result in the need for emergency pharmaceutical treatment of large numbers of people to counteract the effect of such substances or diseases. The necessary therapeutic goods may not currently be available in Australia and may also be in short supply overseas.

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In her second reading speech on the Bill, the Parliamentary Secretary to the Minister for Health and Ageing amplified this stated rationale as follows:²

The recent bioterrorist activities in the United States have highlighted the need for nations to be prepared for chemical, biological and radiological disasters.

The government in its planning has placed a high priority on the availability of pharmaceutical treatments (antibiotics, vaccines and chemical antidotes) to counteract the effects of chemical and biological weapons.

There are two main issues that need to be addressed in relation to pharmaceuticals.

Firstly, the rarity of likely agents used in these terrorist activities is such that some of the recommended drugs for prevention and treatment are not registered and therefore not readily available in Australia. However, in the event of a chemical, biological or radiological disaster such treatments will need to be supplied to many casualties with minimum delay. Some of the other recommended treatments, particularly antibiotics, are marketed but not approved for indications associated with the pathogens that could be used for bioterrorism.

Secondly, as many countries round the world face the same problem, we have to be able to deal with the possibility of global shortages of antibiotic treatments and vaccines. It is therefore important that Australia has the capacity to stockpile the essential pharmaceutical agents that may be expected to meet a crisis.

The Bill accordingly forms part of the Government's legislative response to the post-'September 11' environment.

Main Provisions

Exemption in the 'national interest'

Division 2 of Part 3 of the Act regulates the registration and listing of therapeutic goods in Australia. **Proposed subsection 18A(1), inserted by item 1 of Schedule 1**, gives the Minister the power to exempt in writing from the provisions of Division 2 either specified therapeutic goods, or therapeutic goods in a specified class.

The Minister may only exempt the goods if he or she is satisfied that, in the 'national interest,' the exemption should be made either:

- 'so that the goods may be stockpiled as quickly as possible in order to create a preparedness to deal with a potential threat to public health that may be caused by a possible future emergency' (**proposed paragraph 18A(2)(a)**) ; or

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- ‘so that the goods can be made available urgently in Australia in order to deal with an actual threat to public health caused by an emergency that has occurred’ (**proposed paragraph 18A(2)(b)**).

The terms ‘national interest’, ‘threat to public health’ and ‘emergency’ are not defined for this purpose.

The Senate Standing Committee for the Scrutiny of Bills makes the following point of relevance:³

[The] registration and listing requirements were presumably included in the Act in the public interest. Where it is proposed that they be bypassed, that same public interest would normally require a cautious approach – for example, in the circumstances of emergency contemplated by the bill perhaps by including measures such as criteria to determine when exemptions should be granted.

When an exemption takes (or ceases to take) effect

Proposed subsection 18A(3) provides that an exemption takes effect on the day on which the exemption is made, or on a later day that is specified in the exemption.

Proposed subsection 18A(4) provides that an exemption will cease to have effect upon the expiry of the period specified in the exemption, or when it is revoked. Further, **proposed subsection 18A(5)** provides that an exemption will cease to have effect in relation to particular therapeutic goods when they become registered or listed under the Act, or when the Minister varies the exemption to remove those particular goods. **Proposed subsection 18A(6)** prescribes when a revocation to or variation of an exemption takes effect.

Conditions of an exemption

Proposed subsection 18A(7) provides that conditions may be imposed on the grant of any exemption, and itemises a list of the kinds of conditions that are likely to be imposed. That list is non-exhaustive. Any such conditions may be revoked or varied by the Minister, in writing (**proposed subsections 18A(8) and (9)**). Breach of any condition does not affect the status of the goods as exempt (**proposed subsection 18A(7)**).

Notification and tabling of exemptions

Proposed subsection 18A(10) obliges the Secretary of the Department to set out particulars of any exemption, or variation or revocation of an exemption, to be published in the *Gazette* within five working days after the day on which the Minister makes the exemption, variation or revocation. Failure to comply with this obligation does not of itself invalidate the exemption, revocation or variation.

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Proposed subsection 18A(11) obliges the Minister to set out particulars of any exemption, or variation or revocation of an exemption, to be tabled before each House of the Parliament within 5 sitting days of that House after the day on which the Minister makes the exemption, variation or revocation. Failure to comply with this obligation does not of itself invalidate the exemption, revocation or variation.

In both cases, it is only ‘particulars’ of the exemption, or revocation or variation of an exemption, that must be gazetted and tabled; rather than the Minister’s exemption, variation or revocation itself. On this question, the Senate Standing Committee for the Scrutiny of Bills notes that:⁴

... the Explanatory Memorandum states that the declaration itself need not be either gazetted or tabled, because ‘it would not be in the interests of public safety to release every detail of some conditions, such as the location where specific goods are being stored.’

The Committee notes that these Ministerial declarations, which allow for the granting of exemptions from the legislation, and which are therefore apparently legislative in character, are not disallowable instruments. The Committee, therefore, seeks the Minister’s advice as to why these declarations are not subject to Parliamentary scrutiny, and whether any guidelines will be produced to determine when s 18A exemptions are to be granted.

Pending the Minister’s response, the Committee draws Senators’ attention to these provisions as they may be considered to insufficiently subject the exercise of delegated legislative power to Parliamentary scrutiny, in breach of principle 1(a)(v) of the Committee’s terms of reference.

Offences

Proposed subsection 18A(12) confers immunity on the Commonwealth, the Minister or any Ministerial delegate for liability to any person for loss, damage or injury of any kind suffered by that person, resulting from the use of exempt therapeutic goods by that person or by another person. Presumably the rationale for this provision is that decisions about exempting therapeutic goods would be likely to be made as a matter of urgency, and in response to an actual or foreseen emergency, and additionally could involve the use of goods that may in the event prove to have damaging impacts on users, not least because they are exempt from the normal processes of assessing therapeutic goods for quality, safety and efficacy.

Item 2 inserts **proposed subparagraph 20(1)(b)(iia)**, so that it is not an offence to import, export, manufacture or supply therapeutic goods that are exempt under proposed section 18A. **Item 3** inserts a note at the end of subsection 20(1) of the Act which points out that an offence may nonetheless be committed in respect of good exempt under proposed section 18A, under **proposed subsections 20(2)(2A) and (2C)**. These proposed offences are inserted by **item 4**:

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- importing goods that are exempt under proposed section 18A, but in breach of a condition of the exemption (**proposed subsection 20(2A)**), and where there has been intent or recklessness in relation to the act of importing these goods (**proposed subsection 20(2B)**). The offence is punishable by a maximum of 4 years' imprisonment or a fine of 240 penalty units, or both;
- importing goods that are exempt under proposed section 18A, but in breach of a condition of the exemption (**proposed subsection 20(2C)**). Strict liability applies to the entire offence (**proposed subsection 20(2D)**); this means where 'the requisite level of intent or recklessness cannot be established to ensure a successful prosecution under subsection (2A), but mistake of fact will still be available under section 9.2 of the Criminal Code.'⁵ The offence is punishable by a maximum fine of 60 penalty units. The Senate Standing Committee for the Scrutiny of Bills has raised the following concern in relation to this strict liability provision⁶ -

.. it seems that there might be a danger of criminalising conduct which might otherwise have an innocent explanation (*ie* importing therapeutic goods while unaware that they are subject to an exemption). If the mischief here is the risk to public health as a result of the possible return to an importer of unapproved therapeutic goods then, arguably, the bill might address this by amending requirements elsewhere in the Act (for example, by providing for the retention of unapproved goods subject to an exemption until approval had been granted).

- and accordingly drew Senators' attention to this provision as '[it] may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.'⁷

Item 5 inserts **proposed paragraph 21(ba)**, so that it is not an offence to engage in wholesale supply within Australia of therapeutic goods that are exempt under proposed section 18A.

Item 6 inserts **proposed subparagraph 22(4)(ba)**, to establish an offence where a person intentionally or recklessly misrepresents therapeutic goods to be exempt under proposed section 18A.

Item 7 amends subsection 22(6) to include goods that are exempt under proposed section 18A, in the general exemption in that subsection from the prohibition on claiming that unregistered or unlisted therapeutic goods can be supplied.

Item 8 introduces **proposed subsections 22(7AB) and 22(7AD)** to create two new offences for breaching a condition of an exemption under section 18A:

- breaching a condition of an exemption where the behaviour in question is likely to cause a 'serious risk to public health' (**proposed subsection 22(7AB)**). 'Serious risk to public health' is not defined for this purpose. The maximum penalty is 5 years' imprisonment, a fine of 300 penalty units, or both;

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- breaching a condition of an exemption (**proposed subsection 22(7AD)**). The maximum penalty is 4 years' imprisonment or 240 penalty units, or both.

Item 9 amends subsection 22(8) to include goods that are exempt under proposed section 18A, in the general exemption in that subsection from the prohibition on using unlisted or unregistered (or otherwise not exempt) therapeutic goods for the treatment of another person, or for experimental purposes in humans.

Item 10 amends paragraph 30A(1)(b) to include goods that are exempt under proposed section 18A, in the general exemption in that subsection from the Secretary's power to require the sponsor of goods that are unlisted or unregistered (or not otherwise exempt) to inform the public that goods have been wrongly supplied and/or recall the goods.

Recovery, disposal and recording of goods exempt under section 18A

Item 11 inserts provision relating to the recovery, disposal and recording of goods exempt under section 18A.

Proposed section 30F empowers the Secretary of the Department to require, by written notice, the supplier of goods exempt under section 18A to take steps to recover those goods, where the Secretary is satisfied that the goods do not conform to an applicable standard or are otherwise unfit for their intended purpose (**proposed subsections 30F(1)-(4)**). Failure to comply with the requirements of such a notice will amount to an offence punishable by a maximum of 12 months' imprisonment or 60 penalty units, or both; strict liability applies to elements of the offence (**proposed subsections 30F(5) and (6)**).

Proposed section 30G empowers the Secretary of the Department to arrange, according to regulations, for the disposal of goods that have been the subject of an exemption under section 18A, but which have not been used before the exemption ceases to have effect (and which have not become registered or listed goods).

Proposed section 30H establishes offences where it is a condition of the exemption of goods under section 18A that appropriate records are kept in relation to those goods, and such records are not kept.

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Endnotes

- 1 *Explanatory Memorandum*, p. 1.
- 2 The Hon. Ms T. Worth, *House Hansard*, 20 February 2002, p. 512.
- 3 Senate Standing Committee for the Scrutiny of Bills, *Alert Digest No 2 of 2002*, 13 March 2002, p. 16.
- 4 Senate Standing Committee for the Scrutiny of Bills, *Alert Digest No 2 of 2002*, 13 March 2002, p. 17.
- 5 *Explanatory Memorandum*.
- 6 Senate Standing Committee for the Scrutiny of Bills, *Alert Digest No 2 of 2002*, 13 March 2002, p. 18.
- 7 *ibid*, p. 19.

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