



Therapeutic Goods (Charges) Amendment Bill 2009

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Therapeutic Goods (Charges) Amendment Bill 2009

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House: House of Representatives

Portfolio: Health and Ageing

Commencement: Formal provisions: on Royal Assent

Schedule 1: on a day to be fixed by Proclamation

Links: The [relevant links](#) to the Bill, Explanatory Memorandum and second reading speech can be accessed via BillsNet, which is at <http://www.aph.gov.au/bills/>. When Bills have been passed they can be found at ComLaw, which is at <http://www.comlaw.gov.au/>.

Purpose

The Therapeutic Goods (Charges) Amendment Bill 2009 (the Bill) proposes to amend the *Therapeutic Goods (Charges) Act 1989* (the Charges Act) in relation to:

- the imposition of annual charges for the continued inclusion of biologicals in the Register, and
- the impact of suspension of therapeutic goods or biological on the imposition of charges.¹

Background

The Bill complements the Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009 (the TGA No. 3 Bill). In addition, the *Therapeutic Goods Act 1989* (the TGA Act) is incorporated and is to be read as one with the Charges Act.²

For background information, including the policy commitment behind both Bills, please refer to the Bills Digest for the TGA No. 3 Bill.³

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1. For the meaning of ‘biologicals’, see Therapeutic Goods Administration (2009 Measures No. 3) Bill **item 25 (proposed section 32A)**.
 2. *Therapeutic Goods Act 1989* subsection 3(1).
 3. R de Boer and S Scully, *Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009*, Bills digest, no. 83, 2009–10, Parliamentary Library, Canberra, 2009.

Warning:

This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.

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Committee consideration

As at 30 November 2009—the last day of sitting for Parliament in 2009, the Bill had not yet been referred to a parliamentary committee for review.

Financial implications

According to the Government, these proposed amendments would not impact financially on the Commonwealth as the Therapeutic Goods Administration operates on a cost recovery basis.⁴ Although it would be expected that these proposed amendments would have some financial impact on industry (which presumably—would be passed on to consumers), to date, there appears to have been no publicly available comment from the pharmaceutical industry. Arguably, any kind of change would result in some sort of financial impact but, at this stage, it remains obscure just what that impact would be.

Main provisions

Item 1 proposes to insert **new subsections 3(1A) and (1B)** into the Charges Act. These new subsections would mean that despite suspension of a therapeutic good or biological from the Australian Register of Therapeutic Goods (the Register), the therapeutic good or biological would be taken as being included in the Register for the purposes of the Charges Act.⁵

It is stated in the Explanatory Memorandum that:

This is to ensure that annual charges remain payable in respect of therapeutic goods that are suspended from the Register. This is necessary because suspension is temporary (not more than six months, unless it is extended) and does not result in a reduction to the usual regulatory work required to be undertaken by the Therapeutic Goods Administration (TGA) in relation to the good.⁶

This is consistent with the approach already taken regarding medical devices under subsection 3(2) of the Charges Act.

Item 3 proposes to insert **new subsection 4(1AA)** into the Charges Act. This means that an annual charge of a prescribed amount would be payable for the inclusion of a biological

4. Explanatory Memorandum, Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009 and Therapeutic Goods (Charges) Amendment Bill 2009, p. 2.

5. As to suspension of therapeutic goods or biologicals from the Register, see *Therapeutic Goods Act 1989* Part 3-2 (therapeutic goods) and **proposed section 32FA** in **item 25** of the Therapeutic Goods Administration (2009 Measures No. 3) Bill (biologicals).

6. Explanatory Memorandum, op. cit., p. 107.

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in the Register under Part 3-2A of the TGA Act, effective at any time during the financial year.

Subsection 6AAE of the TGA Act provides that where a State law confers either:

- the function of including therapeutic goods in the Register, or
- the power to include goods in the Register,

on a Commonwealth officer or authority, that officer or authority may include the goods in the Register according to the corresponding State law.

Item 4 proposes to insert **new subsection 4(4A)** into the Charges Act. This means that if a biological is included in the Register in the exercise of a function conferred on the Secretary by a corresponding State law, annual charges would apply to that biological as if it had been included in the Register under Part 3–2A of the TGA Act.

This approach is consistent with that taken regarding both listed and registered therapeutic goods, as well as medical devices.⁷

Concluding comments

These proposed amendments are consequential to and would complement the amendments proposed in the TGA No. 3 Bill. These amendments would also ensure consistency with the approach taken towards all therapeutic goods (including biologicals) and medical devices that are suspended under the Charges Act.

7. *Therapeutic Goods (Charges) Act 1989* subsections 4(3)–(5).

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