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**Therapeutic Goods (Charges) Amendment Bill  
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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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Therapeutic Goods (Charges) Amendment Bill 2002

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12 March 2002

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# Therapeutic Goods (Charges) Amendment Bill 2002

**Date Introduced:** 14 February 2002

**House:** House of Representatives

**Portfolio:** Health and Ageing

**Commencement:** When Schedule 1 of the *Therapeutic Goods Amendment (Medical Devices) Act 2002* commences.

## Purpose

To amend the *Therapeutic Goods (Charges) Act 1989* to allow annual charges to be levied in respect of the inclusion of medical devices on the Australian Register of Therapeutic Goods.

## Background

The Therapeutic Goods (Charges) Amendment Bill 2002 (the 2002 Bill) is identical to the Therapeutic Goods (Charges) Amendment Bill 2001 (the 2001 Bill). The 2001 Bill lapsed at the time Parliament was prorogued prior to the recent Federal election.

The 2001 Bill was discussed in [Bills Digest](#) No. 150 of 2000-01. See also [Bills Digest](#) No 149 of 2000-01.

## Main provisions

Bills Digest No 150 of 2000-01 explains the relevant provisions. The provisions (and numbering) of the 2002 Bill are identical to those of the 2001 Bill.

Currently, under the *Therapeutic Goods (Charges) Act 1989*, annual charges are payable in respect of the 'listing' or 'registration' of therapeutic goods. If the Therapeutic Goods Amendment (Medical Devices) Bill 2001 is passed, medical devices will be 'included' on the Register rather than 'listed' or 'registered'.

### **Warning:**

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

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

**Item 3 of Schedule 1** of the Bill amends the *Therapeutic Goods (Charges) Act 1989* so that annual charges will be payable also for medical devices that are 'included' on the Register. Under **item 5**, this extends to medical devices which are 'included' on the Register pursuant to a corresponding State law.

Charges will be payable even if a particular medical device or class of medical devices is suspended from the Register (**item 2**).

The regulations may prescribe different charges for different classes of therapeutic goods, including different classes of medical devices (**item 7**). The exemption from annual charges for low volume manufacturers of therapeutic goods is also extended to medical devices (**items 8 and 9**).

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