



TRIPPLICATE C

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# Therapeutic Goods Amendment Regulations 2002 (No. 2)<sup>1</sup>

Statutory Rules 2002 No. 42

114

I, PETER JOHN HOLLINGWORTH, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Therapeutic Goods Act 1989*.

Dated - 6 JUN 2002 2002

**PETER HOLLINGWORTH**

Governor-General

By His Excellency's Command

TRISH WORTH

Parliamentary Secretary to the Minister for Health and Ageing

**1 Name of Regulations**

These Regulations are the *Therapeutic Goods Amendment Regulations 2002* (No.   ).

2

**2 Commencement**

These Regulations commence on gazettal.

**3 Amendment of *Therapeutic Goods Regulations 1990***

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

**Schedule 1 Amendments**

(regulation 3)

**[1] Schedule 3, Part 1, item 4**

*omit*

active implantable medical devices,

*insert*

active implantable therapeutic devices,

**[2] Schedule 3, Part 1, after item 4**

*insert*

**5 implantable therapeutic devices that:**

(a) incorporate an ancillary medicinal substance; or

(b) are designed to incorporate an ancillary medicinal substance;

if the purpose of the incorporation is to enhance the function of the device

**[3] Schedule 4, Part 1, item 2, paragraph (a)***omit*

item 3 or 4 of Part 1

*insert*

item 3, 4 or 5 of Part 1

**Notes**

1. These Regulations amend Statutory Rules 1990 No. 394, as amended by 1991 Nos. 84 and 485; 1992 Nos. 19, 89, 109, 332, 370 and 430; 1993 No. 141; 1994 Nos. 150, 222 and 364; 1995 Nos. 33, 111, 192, 208, 253, 320 and 328; 1996 Nos. 9, 25 (disallowed by the House of Representatives on 10 September 1996), 131, 200 and 208; 1997 Nos. 162, 398, 399, 400 and 401 (disallowed by the Senate on 31 March 1998); 1998 Nos. 227, 247 and 369; 1999 Nos. 62, 209 and 324; 2000 Nos. 29, 48, 70, 123, 124, 267 and 358; 2001 Nos. 159, 160, 252 and 343; 2002 Nos. 9 and 84.

2. Notified in the *Commonwealth of Australia Gazette* on 2002.

7 June