

Therapeutic Goods Amendment Regulations 2009 (No. 2)¹

Select Legislative Instrument 2009 No. 140

I, QUENTIN BRYCE, 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 24 June 2009

QUENTIN BRYCE Governor-General

By Her Excellency's Command

MARK BUTLER
Parliamentary Secretary for Health

1 Name of Regulations

These Regulations are the *Therapeutic Goods Amendment* Regulations 2009 (No. 2).

2 Commencement

These Regulations commence on the day after they are registered.

3 Amendment of Therapeutic Goods Regulations 1990

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

Schedule 1 **Amendments**

(regulation 3)

[1] After subregulation 10F (4)

insert

- (4A) If a person for whom a kind of medical device is included in the Register under Chapter 4 of the Act transfers or assigns, in whole or in part, the business to which the kind of medical device relates or the person's interest in the kind of medical device, the person to whom the business or interest is transferred or assigned:
 - is taken, to the extent of the business or interest transferred or assigned, to be the person for whom the medical device is included in the Register under Chapter 4 of the Act; and
 - (b) must, within 3 months after the transfer or assignment, notify the Secretary in writing of the transfer or assignment.

[2] Subregulation 10F (5)

omit

$$(2)$$
 (b) or (3) (b),

insert

$$(2)$$
 (b) , (3) (b) or $(4A)$ (b) ,

[3] Regulation 46A

substitute

46A Delegation under the Act

For paragraph 57 (1) (c) of the Act, the following appointments are appointments the occupant or holder of which may be a delegate under section 57 of the Act:

- (a) the appointment of National Manager, Therapeutic Goods Administration;
- (b) the secondment of a person employed by a national therapeutic goods regulatory authority of another country to a position in the Therapeutic Goods Administration.

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See http://www.frli.gov.au.