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F.R.L.I.

1996B00412

Statutory Rules 1992 No. 1

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Therapeutic Goods Regulations² (Amendment)

I, THE 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 20 October 1992.

BILL HAYDEN

Governor-General

By His Excellency's Command,

Peter Staples

Minister of State for Aged, Family and Health Services

1. Amendment

1.1 The Therapeutic Goods Regulations are amended as set out in these Regulations.

[NOTE: These Regulations commence on gazettal: see *Acts Interpretation Act 1901*, s.48.]

2. Regulation 2 (Interpretation)**2.1 Definition of “drugs”, paragraph (a):**

Omit the paragraph, substitute:

“(a) therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a person or an animal; and”.

3. Regulation 46 (Release of information)**3.1 Add at the end:**

“(3) For the purposes of subsection 61 (6) of the Act, the Secretary may release therapeutic goods information of a kind that relates to the evaluation of therapeutic goods by the Australian Drug Evaluation Committee by publishing the information in the *Gazette*.”.

4. New regulation 46A**4.1 Before regulation 46, insert in Part 8:****Delegation under the Act**

“46A. The appointment of National Manager, Therapeutic Goods Administration is declared for the purposes of paragraph 57 (1) (c) of the Act to be an appointment the holder of which may be a delegate of the Minister or the Secretary under section 57 of the Act.”.

5. Regulation 47 (Delegation—powers and functions of the Secretary)**5.1 Subregulation 47 (1):**

Omit the subregulation, substitute:

“(1) The Secretary may delegate a power or function of the Secretary under these Regulations to:

- (a) an officer of the Department; or
- (b) the National Manager, Therapeutic Goods Administration.”.

6. Review of decisions

6.1 Subregulation 48 (1) (definition of “initial decision”):
After “9,” insert “paragraph 11 (2) (d),”.

6.2 Subregulation 48 (1A):
Omit the subregulation, substitute:

“(1A) The Minister may, by signed instrument, delegate a power or function of the Minister under this regulation to:

- (a) an officer of the Department; or
- (b) the National Manager, Therapeutic Goods Administration.”.

7. Schedule 1 (Part 2 does not apply to members of an Australian Branch of one of these bodies)

7.1 Item 23 (second occurring):
Omit “23”, substitute “24”.

7.2 Item 24:
Omit “24”, substitute “25”.

7.3 Add at the end:

“26 The Acupuncture Association of Australia, New Zealand and Asia

27 The New South Wales Research Association of Traditional Chinese Medicine”.

8. Schedule 5 (Therapeutic goods exempt from the operation of Part 3 of the Act)

8.1 Item 7, paragraph (j):
Omit the paragraph, substitute:

- “(j) protective clothing for patients or health workers, except:
- (i) clothing supplied in a sterile state; or
 - (ii) surgeon’s gloves, patient examination gloves and other protective gloves for the prevention of contact with body fluids or body tissue; or
 - (iii) patient nuclear radiation shields and radiation shielding apparel; or”.

8.2 Item 7, subparagraph (m) (ii):
Omit "and", substitute "or".

8.3 Item 7, paragraphs (n) and (o):
Add at the end "or".

9. Schedule 10

9.1 Omit the heading, substitute:

"SCHEDULE 10
PRESCRIPTION DRUGS".

Subregulations 16C (1),
16D (1) and 16F (1)

NOTES

1. Notified in the *Commonwealth of Australia Gazette* on 1992. 27 October /
2. Statutory Rules 1990 No. 88 amended by 1990 No. ^{394 as} 394; 1991 Nos. 84 and 485; 1992 Nos. 19, 89, and 109.