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Therapeutic Goods Amendment Regulations 1999 (No.3)

Statutory Rules 1999 No. /

324

I, WILLIAM PATRICK DEANE, 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 15 DEC 1999 1999.

WILLIAM DEANE

Governor-General

By His Excellency's Command,

GRANT TAMBLING
Parliamentary Secretary to the Minister for Health
and Aged Care
for the Minister for Health and Aged Care



Therapeutic Goods Amendment Regulations 1999 (No. 4)¹

3

Statutory Rules 1999 No. 4²

324

made under the

Therapeutic Goods Act 1989

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1999, 4

Therapeutic Goods Amendment Regulations 1999 (No. 4)

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Regulation 1

1 Name of Regulations

These Regulations are the *Therapeutic Goods Amendment Regulations 1999 (No. 4)*.

3

2 Commencement

These Regulations commence on gazettal.

3 Amendment of *Therapeutic Goods Regulations 1990*

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

2 *Therapeutic Goods Amendment Regulations 1999 (No. 4)* 1999, 4

3 324

Schedule 1 Amendments

(regulation 3)

[1] Regulation 2, after definition of *ethics committee*

insert

expiry date, for therapeutic goods, means the date (expressed as the month and year) after which the goods should not be used.

[2] Regulation 2, after definition of *official analyst*

insert

open shelf life, for therapeutic goods, means the time, after the container holding the goods is opened, after which the goods should not be used.

Note For *container*, see Act, subs 3 (1).

[3] Paragraph 5F (b)

omit

applicant; and

insert

applicant.

[4] Paragraph 5F (c)

omit

[5] Subregulations 5G (1) and (2)

substitute

- (1) If an application for approval of an advertisement is made and the prescribed fee is paid, the Secretary must approve the advertisement if the Secretary is satisfied that it:
- (a) complies with the Therapeutic Goods Advertising Code; and
 - (b) does not contain a prohibited representation (whether in express terms or by necessary implication) about the goods; and
 - (c) contains a required representation about the goods; and
 - (d) does not contain an unacceptable presentation of the goods within the meaning of regulation 6A.

[6] Schedule 1, item 3

substitute

3 Association of Traditional Health Practitioners
Incorporated

[7] Schedule 1, after item 3A

insert

3B Australasian Federation of Natural Therapists Inc.

[8] Schedule 1, after item 5

insert

5A Australian Association of Exercise and Sports
Scientists

[9] Schedule 1, after item 26A

insert

26B The Australian Podiatry Association (NSW)

[10] Schedule 2, Part 2, item 1

substitute, in column 2

if the advertisement is in the form of a
label on the retail container — a
statement that:

- (a) vitamins can only be of assistance
to a person if the person's dietary
vitamin intake is inadequate; or
- (b) vitamin supplements should not
replace a balanced diet

[11] Schedule 4, Part 1, item 3

omit

substances or other substances specified

insert

substances, a substance mentioned

[12] Schedule 4, Part 1, item 3, paragraph (d)*substitute*

- (d) the preparation:
 - (i) does not include a herbal substance derived from plant material mentioned in Division 1 of Part 4 of this Schedule; and
 - (ii) if it includes a herbal substance derived from plant material mentioned in Division 2 of that Part:
 - (A) does not include the substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1 mg of the dry herbal starting material; or
 - (B) is not inconsistent with the qualification mentioned, in relation to the substance, in column 1 of the table in that Division; and

[13] Schedule 4, Part 1, item 3, subparagraph (f) (ii)*omit*

substance;

insert

substance; and

[14] Schedule 4, Part 1, item 3, after paragraph (f)*insert*

- (g) if a substance mentioned in Division 3 of Part 5 is an ingredient — the preparation is supplied:
 - (i) in accordance with the qualification (if any) mentioned, in relation to the substance, in column 2 of the table in that Division; and

- (ii) with a label showing the warning (or warnings) mentioned, in relation to the substance, in column 3 of the table in that Division;

[15] Schedule 4, Part 4, item 1 (except the table)

substitute

Division 1 Herbal substances that must not be an ingredient in listed therapeutic goods

[16] Schedule 4, Part 4, item 2 (except the table)

substitute

Division 2 Herbal substances that may be an ingredient in listed therapeutic goods only in minute doses or if other specified conditions are met

[17] Schedule 4, Part 4, item 2

after

Lithospermum (all or any species)

insert, in columns 1 and 2

<i>Medicago sativa</i> , if the L-canavanine level is not more than that of dried leaf of the plant	Alfalfa
---	---------

[18] Schedule 4, Part 4, item 2*after**Oenanthe* (all or any species)*insert, in columns 1 and 2*

<i>Paullina cupana</i> , if the label on the goods states:	Guarana
--	---------

- (a) that the goods contain caffeine; and
- (b) the quantity of caffeine per dosage unit

[19] Schedule 4, Part 5, Division 1, heading*substitute*

Division 1	Substances, not mentioned in Division 2 or 3, that may be ingredients of preparations
-------------------	--

[20] Schedule 4, Part 5, Division 1*omit*

Bacterial strains of the genera *Lactobacillus* and *Bifidobacterium* (other than *Bifidobacterium dentium*) present in registered goods on 31 July 1998

insert

Alfalfa (*Medicago sativa*) — fresh leaf extract, having a concentration ratio between 34:1 and 46:1 and L-canavanine level not more than fresh alfalfa leaf

Bacterial strains from the genera *Lactobacillus* and *Bifidobacterium*, other than strains of *Lactobacillus cateniformis*, *Lactobacillus uli* and *Bifidobacterium dentium*

[21] Schedule 4, Part 5, Division 1

before

Bioflavonoids (except quercetin)

insert

Beta-hydroxy-beta-methylbutyric acid

[22] Schedule 4, Part 5, Division 1

after

Bioflavonoids (except quercetin)

insert

Calcium beta-hydroxy-beta-methylbutyrate

Calcium hydroxycitrate

[23] Schedule 4, Part 5, Division 1

after

Fructose

insert

Green lipped mussel (*Perna canaliculus*) — oil extract or dried flesh

[24] Schedule 4, Part 5, Division 1

after

Glucose

insert

Honey (except honey intended to be administered orally)

[25] Schedule 4, Part 5, Division 1*after*

Hydroxyapatite

insert

Hydroxycitric acid

[26] Schedule 4, Part 5, Division 1*after*

Pectin

insert

Potassium hydroxycitrate

[27] Schedule 4, Part 5, Division 1*after*

Shark cartilage

insert

Sodium beta-hydroxy-beta-methylbutyrate

Sodium hydroxycitrate

Squalene

[28] Schedule 4, Part 5, Division 2, heading*substitute***Division 2 Substances subject to
dosage limit****[29] Schedule 4, Part 5, Division 2***omit*

creatine

creatine monohydrate

creatine phosphate

[30] Schedule 4, Part 5, Division 2*after**Piper methysticum**insert, in columns 1 and 3*

Ubidecarenone

150 mg

[31] Schedule 4, Part 5, after Division 2*insert***Division 3 Substances requiring a
warning label**

Item	Substance	Warning
1	Creatine	Seek professional advice before long term use
2	Creatine monohydrate	Seek professional advice before long term use

Item	Substance	Warning
3	Creatine phosphate	Seek professional advice before long term use
4	Honey (for oral administration)	Not suitable for infants under 12 months
5	<i>Kunzea ambigua</i> (essential oil) (supplied in a container with a restrictive flow insert)	For external use only Keep out of the reach of children Not be applied undiluted to the skin except on the advice of a healthcare professional
6	Sodium selenite, selenomethionine, selenocysteine, high selenium yeast	Selenium is toxic in high doses Selenium in dietary supplements should not exceed a daily dose of 100 µg Not suitable for use by children under 15
7	Ubidecarenone	Not to be taken, if on warfarin therapy, without medical advice

[32] Schedule 6, after item 3

insert

3A non-sterile preserved multi-use gel wound dressings (*hydrogels*)

[33] Schedule 7, item 2, paragraph (b)

omit

or oils extracted from herbs,

insert

bulk hamamelis water or oils extracted from herbs,

[34] Schedule 7, item 4, paragraph (c)*omit***[35] Schedule 9, item 17***substitute*

17	Fee for an application for approval of an advertisement under regulation 5F:	
	(a) if the time taken for processing an application is an hour or less — for an advertisement:	
	(i) of not more than 100 words	120
	(ii) of more than 100 words	150
	(iii) of more than 300 words (including an advertorial)	270
	(iv) that consists of a minor change to an approved advertisement	60
	(v) that is designed for publication in the classified advertisement columns of a newspaper or other publication	60
	(b) for each additional hour or part of an hour	100

[36] Schedule 11, Part 1, heading*substitute*

**Part 1 Therapeutic goods for which
 quality or safety criteria are
 prescribed**

[37] Schedule 11, Part 1, after item 2

insert

2A non-sterile preserved multi-use gel wound dressings
(*hydrogels*)

[38] Schedule 11, Part 2, heading

substitute

Part 2 Quality and safety criteria

[39] Schedule 11, Part 2, item 1

omit

Unless item 2 applies — the

insert

Except as provided by another item, the

[40] Schedule 11, Part 2, after item 2*insert*

- 3 For non-sterile preserved multi-use gel wound dressings (*hydrogels*), the following criteria apply:
- (a) the total aerobic microbial count (TAMC) must not exceed 10 CFU per gm or per mL and the goods must be free of *Pseudomonas*, *S. aureus* and gram negative organisms;
 - (b) compliance with paragraph (a) must be shown by a certificate signed by an appropriately qualified analyst stating in English:
 - (i) the test method; and
 - (ii) if the test method is not a recognised pharmacopeial test method — full details of the test method; and
 - (iii) the date of testing (which must be not earlier than 6 months before retail supply);
 - (c) the labelling on the primary pack must include a statement that, after a dressing has been used by a patient, it must not be used by another patient, or words to that effect;

Note For *label* and *primary pack*, see Act, subs 3 (1).

- (d) the labelling must state an expiry date and an open shelf life for the goods, both of which must be supported by data about the efficacy of preservatives used in the goods;

Note For *expiry date* and *open shelf life*, see r 2.

- (e) the goods must not be represented:
- (i) for use in the treatment of third degree burns; or
 - (ii) as having an accelerating effect on the rate of wound healing or epithelisation; or
 - (iii) as long term, permanent or no-change dressings or as an artificial (synthetic) skin.

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 and 209.
2. Made by the Governor-General on *L* 1999, and notified in the *Commonwealth of Australia Gazette* on *L* 1999.

15 December
16 December