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AUSTRALIA

Therapeutic Goods Amendment Regulations 2001 (No. 3)[1]

Statutory Rules 2001 No. 12

252

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 13 SEP 2001 2001

PETER HOLLINGWORTH Governor-General

By His Excellency's Command

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

1 Name of Regulations

These Regulations are the *Therapeutic Goods Amendment Regulations 2001 (No. 1)*.

2 Commencement

These Regulations commence on the commencement of the *Therapeutic Goods Amendment Act 2001*.

3 Amendment of *Therapeutic Goods Regulations 1990*

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

Schedule 1 Amendments

(regulation 3)

[1] Before regulation 10

insert

10A Characteristics that separate and distinguish certain medicines from other therapeutic goods

(1) For paragraph 16 (1A) (d) of the Act, different characteristics are:

(a) a different name; or

(b) different indications; or

(c) a different excipient; or

(d) for medicines that contain any restricted ingredients:

(i) a different quantity of a restricted ingredient that is an excipient; or

(ii) if the restriction on a restricted ingredient relates to its concentration in a relevant

medicine — a different concentration of the restricted ingredient; or

(iii) if the restriction on a restricted ingredient relates to its quantity in the recommended single or daily dose in a relevant medicine — different directions for use setting out a different recommended single or daily dose.

(2) A substance is a ***restricted ingredient*** if:

(a) it is an ingredient in a relevant medicine; and

(b) for that medicine to be, or to remain, eligible for listing, the permissible quantity or concentration of the substance in the medicine is restricted by operation of any of the following:

(i) Schedule 4;

(ii) the Poisons Standard;

(iii) a condition imposed under section 28 of the Act;

(iv) a standard under section 10 of the Act;

(v) any other provision in these Regulations or in the Act that deals with eligibility of medicines for listing.

(3) In this regulation:

relevant medicine means a medicine that is listable goods or listed goods and that is not an export only medicine.

[2] Regulation 23

omit

In this Part,

insert

(1) In this Part,

[3] Regulation 23

insert

(2) For this Part, a sample of therapeutic goods is appropriately fastened and sealed if the sample is fastened and sealed:

(a) in a vessel or package that is marked with the name and address of:

(i) the person from whom the sample was taken; or

(ii) for a sample delivered under subsection 28 (5A) of the Act -- the sponsor of the goods; and

(b) so as to prevent the opening of the vessel or package, and the removal of the name and address, without breaking the seal.

[4] Paragraphs 25 (3) (b) and (c)

omit

the sample

insert

a sample taken under paragraph (a) or delivered under subsection 28 (5A) of the Act

[5] Subregulation 26 (1)

omit

Where an authorised officer takes a sample of therapeutic goods,

insert

When an authorised officer takes a sample of therapeutic goods (other than a further sample taken under the circumstances described in subregulation 30 (6)),

[6] Subregulations 26 (2) and (3)

substitute

(2) An authorised officer must ensure that any sample of goods taken (including further samples taken under the circumstances described in subregulation 30 (6)) is:

(a) appropriately packaged, fastened and sealed; and

(b) stored and transported in accordance with the instructions (if any) specified on the label of the goods.

[7] After regulation 26

insert

26A Receiving samples for testing

(1) When a sample of a medicine is delivered under subsection 28 (5A) of the Act, the Secretary must as soon as practicable:

(a) determine whether the sample is appropriately packaged, fastened and sealed; and

(b) do either of the following:

(i) if the sample is appropriately packaged, fastened and sealed — send the sample, in the form in which it was received, to the relevant laboratory operated by the Department for analysis;

(ii) if the sample is not appropriately packaged, fastened and sealed — return the sample to the sponsor of the medicine, with a statement explaining in what way the sample is not appropriately packaged, fastened or sealed.

(2) In complying with subregulation (1), the Secretary must ensure that the sample is stored and transported in accordance with the instructions (if any) specified on the label of the medicine.

[8] Paragraph 29 (2) (b)

before

the person

insert

if the sample was taken under subregulation 25 (3) —

[9] After subregulation 31 (1)

insert

(1A) If a sample of a medicine delivered under subsection 28 (5A) of the Act is sent to a laboratory for analysis, the Commonwealth is liable to pay to the person in relation to whom the medicine is listed an amount equal to the value of the sample.

[10] Subregulation 31 (2)

omit

taken.

insert

taken by the authorised officer or delivered under subsection 28 (5A) of the Act.

[11] Schedule 2, Part 1, item 1, column 2

omit

about a disease, condition, ailment or defect specified in

insert

that is a prohibited representation under

[12] Schedule 2, Part 1, item 4, column 2

omit

paragraph 7.1 (a)

insert

paragraph 7.1.3 (a)

[13] Schedule 4, Part 2, column 1

after

Thiamine nitrate

insert

Thiamine phosphoric acid ester chloride

[14] Schedule 4, Part 3

after

Calcium lactate

insert

Calcium lactate gluconate

[15] Schedule 4, Part 3

omit

ferrous lactate

insert

Ferrous lactate

[16] Schedule 4, Part 5, Division 1

insert in appropriate alphabetical position

Chondroitin sulfate — bovine

Chondroitin sulfate — shark

Lycopene

Papain

Tocotrienols complex — palm

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[17] Schedule 4, Part 5, Division 2, Subdivision 2, table

substitute

Item	Substance	Maximum amount per dosage form	Maximum daily dose (all dosage forms)
1	Chromium nicotinate		50 µg of chromium
2	Chromium picolinate		50 µg of chromium
3	High chromium yeast		50 µg of chromium
4	Cupric citrate		750 µg of copper
5	High molybdenum yeast		62.5 µg of molybdenum
6	*Piper methysticum*	if in a tablet or capsule — 125 mg of kavalactones per tablet or capsule if in a tea bag — 3 g of dried rhizome per tea bag	250 mg of kavalactones
7	Sugar cane wax alcohols		12 mg
8	Ubidecarenone		150 mg

Note Certain substances mentioned in this Division are also mentioned in Division 3.

[18] Schedule 4, Part 5, Division 3, before item 1

insert

1A	Ademetionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts	Words to the following effect: Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner

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[19] Schedule 4, Part 5, Division 3, after item 5

insert

5A	(*S*)-S-Adenosylmethionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts	Words to the following effect: Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner

[20] Schedule 4, Part 5, Division 3, after item 6

insert

6A	Sugar cane wax alcohols	Words to the following effect: Not recommended for use by pregnant or lactating women

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 and 160.

2. Notified in the *Commonwealth of Australia Gazette* on / 2001. 20 September

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