Therapeutic Goods Amendment Regulations 1999 (No. 3) 1999 No. 324

EXPLANATORY STATEMENT

Statutory Rules 1999 No. 324

Issued by the Authority of the Minister for Health and Aged Care

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulations 1999 (No. 3)

Subsection 63(1) of the Therapeutic Goods Act 1989 (the Act) provides that the GovernorGeneral may make regulations prescribing matters required or permitted to be prescribed, or necessary or convenient for carrying out or giving effect to the Act.

The objects of the Act include the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia. To this end, the Governor-General may: make regulations, under paragraph 63(2)(c) of the Act, that prescribe requirements for the advertising of therapeutic goods; prescribe, pursuant to subsection 17(4) of the Act, therapeutic goods or classes of therapeutic goods that may be included in each part of the Australian Register for Therapeutic Goods (the Register); prescribe, for the purposes of paragraphs 26(1)(g) and (k) of the Act, listable therapeutic devices that are required to meet acceptable standards and the standards themselves.

The purpose of the amendments to the principal Regulations is to:

(a) include further organisations in Schedule 1 of the Regulations, for the purpose of permitting members of such organisations to receive unregulated advertisements for therapeutic goods. Advertisements directed at the general public are subject to restrictions under the Therapeutic Goods Advertising Code;

(b) prescribe what warning statements must appear on labels for vitamins that are supplied or exported;

(c) include, and describe, additional substances that may be included in the Register as "listable therapeutic goods". Listable goods may be included in the Register without undergoing the same level of scrutiny required for "registrable therapeutic goods", such as prescription medicines and certain implantable devices;

(d) clarify the requirements relating to standards that apply to non sterile bandages, whether these are imported or manufactured in Australia;

(e) clarify the safety and quality requirements that apply to listable therapeutic goods;

(f) permit the manufacture of bulk hamamelis water without a manufacturing licence where this substance is manufactured only for use as a starting material by other licensed manufacturers to make other therapeutic goods; and

(g) increase the fees that may be charged by the bodies delegated the function of pre-clearing advertisements published in mainstream print media. Pre clearance is required to ensure that advertisements published in mainstream print media meet the requirements of the Therapeutic Goods Advertising Code. The Secretary of the Department of Health and Aged Care has delegated this function to 2 peak industry bodies, in accordance with subregulations 5Q(3) and (4) of the Regulations. The increases were sought by the 2 bodies.

The amendments have been made following consultations with peak industry bodies whose members may be affected by these changes.

Further details of the regulations are set out in the Attachment.

The regulations commence on gazettal.

ATTACHMENT

DETAILS OF THE THERAPEUTIC GOODS AMENDMENT REGULATIONS 1999 (No. 3)

Regulation 1

This is a formal provision that specifies the title of the Regulations as the Therapeutic Goods Amendment Regulations 1999 (No. 3).

Regulation 2 (Commencement)

This provision provides that the Regulations will commence on gazettal.

Regulation 3 (Amendment of Therapeutic Goods Regulations 1990)

This provision provides that Schedule 1 amends the Therapeutic Goods Regulations 1990.

SCHEDULE 1 AMENDMENTS

Items 1 and 2

These Items insert 2 new definitions to clarify the meaning of 2 words used in Schedule 11 of the Regulations, as amended by Item 40 below. The 2 new words are "expiry date" and "open shelf life". "Expiry date" refers to the date after which the therapeutic goods, in relation to which the words are used, are no longer suitable for use, whether this is because of deterioration, contamination of the goods following the passage of time or for any other reason. "Open shelf life" refers to the period, after breaking the seal or removal of packaging of therapeutic goods for the purpose of using the goods, within which the goods in question may still be safely used.

Items 3, 4 and 5

These Items have the effect of amending Regulations 5F and 5G so that an applicant seeking approval for the publication of an advertisement about therapeutic goods can be notified of the fees payable for clearing the advertisement before the applicant has to pay. Advertisements about therapeutic goods intended for publication in mainstream print media are required to be pre-cleared by the Secretary, or the Secretary's delegate, before they may be published. For this purpose the delegate will be either the Complementary Healthcare Council of Australia or the Proprietary Medicines Association of Australia. Once the applicant is informed about the amount payable under Item 17, Schedule 9 of the Regulations, the applicant must pay these fees before the application is determined in accordance with regulation 5G.

Item 6

This amendment replaces the previous name of the organisation with its new name.

Items 7, 8 and 9

These Items insert 3 new professional organisations, whose members may receive advertisements about therapeutic goods that are not subject to any restrictions under the Therapeutic Goods Advertising Code. The Code restricts the kind of claims that may be made in advertisements for therapeutic goods that are published for members of the public. In general, these claims relate to the prevention or cure of major medical conditions, which generally should be diagnosed by health care professionals to ensure appropriate and proper treatment for individual patients.

Item 10

This amendment enables a sponsor of therapeutic goods, being vitamins, to use an alternative mandatory warning statement on the labels for the vitamins. The alternative warning statement is that "vitamin supplements should not replace a balanced diet".

Item 11

The effect of this amendment is to clarify that the active ingredients set out in Part 5 of Schedule 4 are other substances, apart from vitamins, minerals or herbal substances, that may be included in listable therapeutic goods in accordance with Item 3, Part 1 Schedule 4.

Item 12

This item clarifies the operation of Item 3(d) of Part 1, Schedule 4, which sets out what therapeutic goods are eligible to be listed in the Register. The effect of this amendment is to clarify what herbal substances may be listed in the Register. The herbal substance must not be derived from plant material listed in Division 1 of Part 4 of Schedule 4, and there are certain herbal substances that can only be listed in the Register if they meet certain requirements, such as those relating to the strength of the substance, or other matters listed in Column 1 of Division 2 of Part 4, Schedule 4.

Items 13 and 14

The purpose of this amendment is to add a further qualification, where applicable, that must be met by the therapeutic preparations listed in Item 3 before the relevant preparation may be listed in the Register. Thus, if the preparation contains any ingredient that is listed in Division 3 of Part 5, Schedule 4, then the preparation must bear a label showing a warning that is required to be included, as set out in Column 3 of the table in that same Division.

Items 15 and 16

These Items amend the headings to the different Divisions of Part 4 of Schedule 4. To reflect the changes made at Item 12 above, the 2 new Divisions to be included in Part 4 of Schedule 4 will now be:

* "Division 1 - Herbal substances that must not be an ingredient in listed therapeutic goods"; and

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

Items 17 and 18

These Items add 2 other herbal substances that may be included in the Register as listed goods. These are Alfalfa with low levels of an undesirable component and Guarana accompanied by a label that states whether it contains caffeine and the quantity of caffeine per dosage unit.

Items 19, 28 and 31

Items 19 and 28 change the headings of 2 Divisions in Part 5, Schedule 4, and Item 31 inserts a new Division 3 to Part 5 of Schedule 4 of the Regulations. Part 5 of Schedule 4 sets out what other preparations, apart from goods containing as their active ingredients herbal substances,

vitamins and minerals, that may qualify as listable goods, eligible for inclusion in the Register as listed therapeutic goods. The new headings for the 3 Divisions are:

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

* "Division 2 - Substances subject to dosage limit"; and

* "Division 3 - Substances requiring a warning label".

Item 20

This item clarifies what bacterial strains from the genera Lactobacillus and Bifidobacterium may be listed in the Register, providing they also meet the requirements of Item 3, Part 1 of Schedule 4. The Item also inserts Alfalfa (medicago saliva) as an active ingredient that may be included in listable therapeutic goods.

Items 21, 22, 23, 24, 25, 26 and 27

These items have the effect of including the following substances in Schedule 4, so they qualify as listable therapeutic goods that may be listed in the Register:

- Beta-hydroxy-beta-methylbutyric acid;

- Calcium beta-hydroxy-beta-methylbutyrate,

- Calcium hydroxycitrate;

- Green lipped mussel (Perna canaliculus) - dried flesh or oil extract;

- Honey;

- Hydroxycitric acid;

- Potassium hydroxycitrate;

- Sodium beta-hydroxy-beta-methylbutyrate;

- Sodium hydroxycitrate; and

- Squalene

Items 29, 30 and 31

These Items insert the substance "Ubidecarenone" as a listable therapeutic good providing the maximum daily dose limit for this substance is 150 mg. Three other substances:

- creatine;

- creatine monohydrate; and

- creatine phosphate,

have been removed from Division 2, Part 5 and placed in Division 3, Part 5, so that these 3 substances will continue to be eligible to be included in the Register as listed goods where they have an appropriate warning statement set out in Column 3 of Division 3, Part 5 Schedule 4. The warning statement requires users to seek professional advice before long term use, and replaces the previous restrictions relating to the maximum daily dose for these substances. Item 31 also inserts a number of substances in new Division 3, Part 5, Schedule 4 which permits these substances to be included in the Register as listed goods providing they bear the relevant warning statements provided for in Column 3 of the Table.

Item 32

This Item will require non-sterile preserved multi-use gel wound dressings (hydrogels) manufactured overseas to meet acceptable manufacturing and quality control procedures before they are permitted to be imported and supplied for use in Australia.

Item 33

This Item clarifies Item 2(b) of Schedule 7 of the Regulations, which sets out what therapeutic goods or substances may be manufactured without a manufacturing licence. The amendment inserts a new substance - bulk hamamelis water - as another substance that need not be manufactured under licence if it is manufactured by a person only for use by other licensed manufacturers as a starting material to make other therapeutic goods.

Item 34

This Item removes the requirement for non-sterile bandages, dressings, adhesive tapes and similar products (other than casting materials) from the requirement to be manufactured under licence, in compliance with local manufacturing standards. The effect of this amendment will be to align locally manufactured non-sterile bandages, dressings, adhesive tapes and similar products (other than casting materials) with those that are imported.

Item 35

This Item increases the fees that are currently charged for performing the function of preclearing advertisements for therapeutic goods that are published in mainstream print media. This function has been delegated to 2 peak industry bodies, the Complementary Healthcare Council of Australia, and the Proprietary Medicines Association of Australia, under subregulations 5Q(3) and (4) of the Regulations.

Items 36 and 38

These Items insert new headings for the 2 Parts to Schedule 11. The new headings more clearly describe the function of Schedule 11. Part 1 of Schedule 11 provides for a list of "Therapeutic goods for which quality or safety criteria are prescribed" under paragraph 26(1)(k) of the Act. Part 2 of Schedule 11 sets out the "Quality and safety criteria" that are to apply to the therapeutic goods listed under Part 1 of Schedule 11.

Item 37

This Item inserts "non-sterile preserved multi-use gel wound dressings (hydrogels)" as one of the goods that will be subject to quality or safety requirements set out in Part 2 of Schedule 11.

Item 39

This Item makes the meaning of Item 1 clearer. The amendment makes it clear that except as provided by another item in Part 2 of Schedule 11, goods listed in Part 1 of this Schedule must be sterile.

Item 40

This Item inserts the prescribed quality or safety criteria that is to apply to nonsterile preserved multi-use eel wound dressings (hydrogels). The criteria include the acceptable level of aerobic microbial count, labelling requirements for the goods, and representations that must not be made in relation to the goods.