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THERAPEUTIC GOODS AND COSMETICS ACT 1972— REGULATION

(Relating to labelling, advertising and miscellaneous matters)

NEW SOUTH WALES

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HIS Excellency the Governor, with the advice of the Executive Council, and on the recommendation of the Therapeutic Goods and Cosmetics Advisory Committee, and in pursuance of the Therapeutic Goods and Cosmetics Act 1972, has been pleased to make the Regulation set forth hereunder. (C.7964/10)

PETER COLLINS
Minister for Health.

The Therapeutic Goods and Cosmetics Regulations are amended:

(a) by inserting in regulation 8 in alphabetical order the matter "sun-screening preparations;";

(b) by inserting in regulation 23 (1) in alphabetical order the following definitions:

"adjuvant" means a substance which, when administered with an antigen, modifies the immune response to that antigen;

"antimicrobial agent" means a substance added to goods to inhibit the growth of micro-organisms in the goods;

"batch" means a limited quantity of product which is made in one designated cycle of manufacture and, if applicable, in one cycle of sterilisation or freeze drying, being uniform with respect to composition, method of manufacture and probability of exposure to chemical or microbial contamination;

"concentrated solution for injection" means a liquid which must be diluted with another liquid in order to prepare an injection;

"date of manufacture", in relation to goods, means the date (month and year) on which the processing of the bulk product, from which the goods are to be filled, is completed;

"large volume injection" means an injection having a volume of 100 millilitres or more;

(c) by omitting regulation 23 (2) and by inserting instead the following clause:

(2) The requirements of this regulation are prescribed as standards in respect of substances, other than the following substances:

disinfectants (except disinfectants that are represented to be suitable for the treatment of water only or for antifungal use only);

antiseptics (except antiseptics that are represented to be suitable for antifungal use only);

sun-screening preparations.

(d) by omitting regulation 23 (4) (c) and by inserting instead the following paragraph:

(c) the quantity or proportion of the substance or each substance which is to be expressed:

(i) for a discrete dosage unit—as the quantity of the active substance in the dosage unit;

(ii) for a liquid for ingestion—as the quantity of the active substance contained in the stated volume of a suitable dose of the liquid;

(iii) for goods which are required to be prepared before use and which after preparation are a liquid for ingestion—as the quantity of the active substance contained in the stated volume of a suitable dose of the liquid, after preparation in accordance with the instructions set out on the label of the goods;

(iv) for a preparation for injection:

(a) where the preparation is a medicament for injection—as the quantity of the active substance in the container;

(b) where the contents of the container are usually intended for administration as a single dose, other than a large volume injection—as the quantity of active substance in the nominal volume of the contents of the

container;

(c) where the preparation is a large volume injection or is intended as an additive to a large volume injection:

(i) as the number of millimoles in the nominal volume of the contents of the container for each substance or ion of precisely known molecular weight; or

(ii) as the weight contained in the nominal volume of the contents of the container for each substance for which the molecular weight is not precisely known;

(d) in any other case—as the quantity of the active substance in one millilitre or in a suitable dose volume of the preparation;

(v) for antibiotic preparations where potency units are used as a measure of activity—as the number of such units expressed as International Units (I.U.) established by the World Wealth Organisation;

(vi) for any other goods which are required to be prepared before use—as the weight or volume of active substance in a stated weight or volume of the goods after preparation in accordance with the instructions set out on the label of the goods;

(vii) in respect of any other goods:

(a) where the goods are a liquid and include an active substance which is a liquid—as the appropriate amount of the active substance (either weight or volume) in a stated volume of the goods;

(b) where the goods are a liquid and include an active substance which is a solid—as the weight of the active substance in a stated volume of the goods;

(c) where the goods are a liquid and include an active substance which is a gas—as the weight of the active substance in a stated volume of the goods;

(d) where the goods are a solid and include an active substance which is a liquid—as the

appropriate amount of the active substance (either weight or volume) in a stated weight of the goods;

(e) where the goods are a solid and include an active substance which is a solid—as the weight of the active substance in a stated weight of the goods;

(9 where the goods are a solid and include an active substance which is a gas—as the weight of the active substance in a stated weight of the goods; or

(g) where the goods are a gas and include an active substance which is a gas—as the weight of the active substance in a stated weight of the goods;

(e) by omitting regulation 23 (4) (h) and by inserting instead the following paragraph:

(h) the storage conditions applicable to the substance, indicated by one of the following statements:

(i) Store below -18°C (Deep freeze);

(ii) Store below -5°C (Freeze);

(iii) Store below 8°C (Refrigerate);

(iv) Store at 2°C to 8°C (Refrigerate. Do not freeze);

(v) Store below 25°C;

(vi) Store below 30°C;

(f) by inserting after regulation 23 (4) the following clause:

(4A) If there is insufficient space on the label of the container or on the primary pack to include directions for use as required by clause (4) (j), it is sufficient compliance with that paragraph if there is included in a label on that container or primary pack, as the case may be, a statement to the effect that those directions for use are set out in a leaflet inserted in the primary pack of the goods and the required directions are set out in the leaflet.

(g) by omitting regulation 23 (6) and by inserting instead the following clause:

(6) Where:

(a) a substance is enclosed in a container having a capacity of 10 millilitres or less; and

(b) the container is enclosed in a primary pack,

the container is exempt from the requirements of clause (4) other than the particulars referred to in paragraphs (a), (b), (c), (f) and (g) of that clause.

(h) by inserting after Regulation 23 (6) the following clauses:

(6A) Where the goods are a preparation for ophthalmic use, the label on the container or, where clause (6) applies, on the primary pack must include, in addition to the requirements of clauses (4) and (5):

(a) the name and proportion of any antimicrobial agent in the goods; or

(b) where the goods, other than an ophthalmic ointment, are contained in a resealable container and an antimicrobial agent is not included in the goods, the words, "Contains no antimicrobial agent. Use once only and discard any residue." or words to that effect;

(c) where the goods consist of eye drops—a statement to the effect that the eye drops should not be used later than four weeks after the container of the goods is first opened; or

(d) where the goods consist of a solid ophthalmic medicament for preparing eye drops—a statement to the effect that the goods when prepared should not be used later than four weeks after the container of the goods is first opened or, if the shelf life of the prepared goods is less than four weeks, that lesser period after the container is first opened.

(6B) In addition to the requirements referred to in clauses (4) and (5), where the goods are an injection or a medicament for injection other than a large volume injection or a live vaccine:

(a) the main label on the container and on the primary pack of the goods must include a statement of the recommended route or routes of administration such as "intravenous", "intramuscular" or "subcutaneous" or other phrase, word or abbreviation denoting the recommended route or routes of administration;

(b) the label on the container or, where clause (6) applies, on the primary pack of the goods must include:

(i) the name and quantity of all excipients in the goods; and

(ii) where the goods are contained in a resealable container and an antimicrobial agent is not included

in the goods, the words "Contains no antimicrobial agent. Use once only and discard any residue." or words to that effect; and

(c) the label on the container, where the goods consist of a concentrated solution for injection, must include:

(i) a direction not to administer the solution undiluted; and

(ii) a direction to dilute the solution with the specified diluent by the appropriate factor or to the appropriate volume before use.

(6C) Where the goods are a large volume injection and:

(a) are not described in a standard prescribed by regulation 24, the name of the goods is to be in accordance with a name approved by the Director-General; or

(b) are intended for electrolyte replacement or nutritional therapy or are intended for use as radio-opaque agents or plasma expanders, the label on the container and on the primary pack must include, in the name of the goods, statements of the proportions of dissolved, emulsified or suspended substances in the goods in terms of percentages; or

(c) contain an active substance which is not intended for electrolyte replacement or nutritional therapy and is not intended for use as a radio-opaque agent or plasma expander, the label on the container and on the primary pack must include, in the name of the goods, a statement of the proportion of that active substance expressed in terms of weight (or potency, if appropriate) in one litre of the injection,

and in addition to the requirements referred to in clauses (4) and (5), the label on the container and on the primary pack of the goods must include:

(d) the names and quantities of all active substances and excipients in the nominal volume of fluid in the container, listed in descending order of magnitude within each group of chemically similar substances;

(e) where one or more substances are amino acids or protein, a statement in grams of the total amount of nitrogen in the nominal volume of fluid in the container;

(f) where the goods are intended for use as an energy source, a statement in kilojoules of the energy equivalent of the

nominal volume of fluid in the container;

(g) the nominal osmolality;

(h) a statement which specifies if the fluid is nominally "hypotonic" or "hypertonic";

(i) the nominal pH range of the fluid; and

(j) the words "single use" or "single dose";

(6D) In addition to the requirements referred to in clauses (4) and (5), there must be set out on the label on the container and on the primary pack of goods which are intended for use as additives to large volume injections:

(a) the names and quantities of all excipients and active substances in the nominal volume of fluid in the container, listed in descending order of magnitude within each group of chemically similar substances; and

(b) the words "single use" or "single dose".

(6E) In addition to the requirements referred to in clauses (4) and (9, the label on the container and on the primary pack of goods which are a concentrated solution for use in dialysis must include:

(a) the names and quantities of all active substances and excipients in each litre of the concentrate;

(b) a direction not to use the solution undiluted;

(c) a direction to dilute the solution with the specified diluent by the appropriate factor or to the appropriate volume before use; and

(d) the names and quantities of all active substances and excipients in each litre of solution following dilution in accordance with directions.

(6F) In addition to the requirements referred to in clauses (4) and (5), the main label of goods which are topical preparations must include the name and proportion of any antimicrobial agent present in the goods.

(6G) In addition to the requirements referred to in clauses (4), (5) and (6B), the main label of goods which are biological products must include:

(a) the name and proportion of any antimicrobial agent in the goods;

(b) the name of any adjuvants in the goods;

(c) for viral vaccines produced in animal cells or cell cultures:

(i) the name of the cell culture substrate or the name of the species of animal and tissue used in the manufacture of the goods; and

(ii) the name of any residual antibiotic present in the goods unless exempted by the Director-General;

(d) for antisera, the name of the species of animal in which the goods have been prepared;

(e) for monoclonal antisera, the name of the species source or the name of the species of origin of the hybridoma cell line used in the preparation of the goods;

(f) for other biological products, the name of the species of animal or organism from which the goods have been prepared; and

(g) for live vaccines:

(i) a statement of the recommended route or routes of administration such as "intravenous", "intramuscular" or "subcutaneous" or other phrase, word or abbreviation denoting the recommended route or routes of administration; and

(ii) where the contents of the container are intended to be used on one occasion only, the words "single use" or "single dose".

(i) by omitting regulation 23 (7A) and by inserting instead the following clause:

(7A) Where:

(a) a substance is prepared in the form of individual items, being tablets, capsules, pastilles, cachets, lozenges, pessaries, suppositories or single doses of powder or granules;

(b) 2 or more of the items are individually enclosed in a container consisting of 2 layers of material bonded together so that the items are separated and protected and can only be extracted singly; and

(c) the container is enclosed in a primary pack,

the container is exempt from the requirements of clause (4) other than the particulars referred to in paragraphs (a), (b), (c), (f) and (g) of that clause.

(j) by omitting regulation 23 (9) (g) and by inserting instead the following paragraph:

(g) the conditions of storage applicable to the substance;

(k) by omitting regulation 23A (2) and by inserting instead the following clause:

(2) Subject to clause (3) and except as provided in regulation 23 (6), (7), (7A), (8) and (9), the container and any primary pack containing a preparation for internal use of a substance containing aspirin must be labelled with the statement in paragraph (a) and with the statements in paragraph (b) or (c):

(a) Consult a doctor before giving this medicine to children or teenagers with chicken pox, influenza or fever.

(b) DOSE FOR CHILDREN

Under 2 years, administer only on doctor's advice.

2 years: 75 mg (stated as equivalent number of tablets)

3–5 years: 150 mg (stated as equivalent number of tablets)

6–12 years: 300 mg (stated as equivalent number of tablets)

Over 12 years: 600 mg (stated as equivalent number of tablets)

Repeat dose after 6 hours if necessary.

Do not administer for more than 24 hours except on doctor's advice.

(c) DO NOT ADMINISTER TO CHILDREN EXCEPT ON DOCTOR'S ADVICE.

(l) by inserting in regulation 23DA (3) after the matter " '15' " the matter ", '15+' or '15 plus' ";

(m) by omitting the list of publications from regulation 24 (1) and by inserting instead the following list of publications:

Prescribed publication No. 1: the British Pharmacopoeia 1988, the British Pharmacopoeia 1988 Addendum 1989, and the British Pharmacopoeia 1988 Amendment No. 3.

Prescribed publication No. 2: the British Pharmaceutical Codex 1973, as amended or supplemented by the British Pharmaceutical Codex Supplement 1976 and amendments to the British Pharmaceutical Codex Supplement 1976 and including 1979 amendments to the British Pharmaceutical Codex 1973.

Prescribed publication No. 3: the 14th Edition of the book named the "Australian Pharmaceutical Formulary and Handbook", published by the Pharmaceutical Society of Australia.

(n) by omitting from regulation 31A (1) (a) the matter "acidity of the stomach, other than temporary relief;";

(o) by omitting from regulation 31A (1) (a) the matter "asthma, other than relief of mild spasms;" and by inserting instead the matter "asthma;";

(p) by omitting from regulation 31A (1) (a) the matter "baldness;" and by inserting instead the matter "baldness, including hair growth or hair loss;";

(q) by omitting from regulation 318 (1) (a) the matter "boils, other than treatment by local application;" and by inserting instead the matter "boils, other than treatment by dermal application;";

(r) by omitting from regulation 31A (1) (a) the matter "carbuncles;" and by inserting instead the matter "carbuncles, other than treatment by dermal application;";

(s) by omitting from regulation 31A (1) (a) the matter "cardio-vascular system diseases, ailments or defects (including high or low blood pressure), other than temporary relief of varicose veins by use of elastic hosiery;" and by inserting instead the following matter:

cardio-vascular system diseases, ailments or defects (including high or low blood pressure) other than:

(i) the advertising of blood pressure monitoring appliances provided such advertising includes a statement to the effect that a medical practitioner is the only person qualified to evaluate the meanings of recorded blood pressure; or

(ii) the temporary relief of the symptoms of varicose veins or varicose ulcers by the use of elastic hosiery;

(t) by omitting from regulation 31A (1) (a) the matter "endocrine system diseases, ailments, defects or injuries (including diabetes and goitre);" and by inserting instead the matter "endocrine system diseases, ailments, defects or injuries (including diabetes and goitre), other than the advertising of blood glucose monitoring products;";

(u) by omitting from regulation 31A (1) (a) the matter "fungus infections, other than treatment of tinea (athlete's foot);" and by inserting instead the matter "fungus infections including tinea (athlete's foot), other than relief or treatment by dermal application;";

(v) by omitting from regulation 31A (1) (a) the matter "gastric or duodenal ulcer;" and by inserting instead the matter "gastric, peptic or duodenal ulcer;";

(w) by omitting from regulation 31A (1) (a) the matter "haemorrhoids, other than temporary relief of discomfort by local application;" and by inserting instead the following matter:

haemorrhoids, other than:

(i) the temporary relief of discomfort by local application provided that the directions for use include a statement to the effect that sufferers should consult a doctor if the symptoms persist; or

(ii) reference to bulk producing laxatives being of indirect benefit to people suffering from haemorrhoids;

(x) by omitting from regulation 31A (1) (a) the matter "herpes, other than relief of the symptoms of cold sores and reduction of the risk of the transmission of genital herpes by the use of condoms;" and by inserting instead the matter "herpes virus infections, other than the relief of the symptoms of cold sores and reduction of risk of the transmission of genital herpes by the use of condoms;";

(y) by omitting from regulation 31A (1) (a) the matter "impetigo;" and by inserting instead the matter "impetigo, other than treatment by dermal application;";

(z) by omitting from regulation 31A (1) (a) the matter "menopausal diseases, ailments or defects;" and by inserting instead the matter "menopausal diseases, ailments, defects or conditions;";

(aa) by omitting from regulation 31A (1) (a) the matter "menstrual diseases, ailments, defects or injuries, other than temporary relief of pain;" and by inserting instead the matter "menstrual cycle diseases, ailments, defects or injuries, other than temporary relief of menstrual pain or pre-menstrual symptoms provided that the advertisement also carries the statement 'Use only as directed and consult your doctor if pain or symptoms persist';";

(ab) by omitting from regulation 31A (1) (a) the matter "mouth ulcers, other than temporary relief of recurrent ulcers;" and by inserting instead the matter "mouth ulcers, other than temporary relief;";

(ac) by omitting paragraph (ii) of the matter relating to "neoplastic diseases" in regulation 31A (1) (a) and by inserting instead the following paragraph:

(ii) sun-screening preparations (having a protection factor of 4 or greater) as an aid in the prevention of skin cancer, but without implying that long hours of exposure in the sun are desirable;

(ad) by omitting from regulation 31A (1) (a) the matter "nervous system diseases, ailments, defects or injuries (including convulsions, epilepsy, fits, mental illness or paralysis);" and by

inserting instead the matter "nervous system diseases, ailments, defects or injuries (including convulsions, epilepsy, fits or paralysis); ";

(ae) by omitting from regulation 31A (1) (a) the matter "overweight, other than suppression of appetite in conjunction with a medically sound diet;" and by inserting instead the matter "overweight, other than suppression of appetite in conjunction with a balanced low joule (calorie) diet;";

(af) by omitting from regulation 31A (1) (a) the matter "psoriasis;" and by inserting instead the following matter:

psoriasis, except for the relief or treatment of psoriasis on the skin;

(i) where the advertisement (other than an advertisement appearing on the goods or any part of the goods or on any label, container or package of the goods) carries the warning—"Do not use for prolonged periods without consulting a medical practitioner"; and

(ii) if the advertisement is an advertisement for products that contain coal tar—where the advertisement (other than an advertisement appearing on the goods or any part of the goods or on any label, container or package of the goods) carries the additional warning "Do not use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed to do so by a medical practitioner";

(ag) by omitting from regulation 31A (1) (a) the matter "rupture or hernia;" and by inserting instead the matter "hernia or rupture other than the advertising of hernia appliances; ";

(ah) by omitting from regulation 3 1A (1) (a) the matter "scabies;" and by inserting instead the matter "scabies, other than relief by dermal application; ";

(ai) by omitting from regulation 31A (1) (a) the matter "sexual potency or virility;" and by inserting instead the matter "sexual function, potency or virility; ";

(aj) by inserting in regulation 31A (1) (a), in alphabetical order, the following matters:

fertility;

hormonal diseases, ailments, defects or injuries;

mental diseases, disorders or illness;

obesity, including the reduction of subcutaneous fat also referred to as "cellulite";

psychiatric diseases, disorders or illness;

short stature;

(ak) by omitting from regulation 31A (1) (b) (v) the word "and" and by inserting instead the word "or";

(al) by inserting after regulation 31A (1) (b) (v) the following subparagraph:

(vi) makes a reference to a dose of a substance in excess of a therapeutic dose; and

(am) by omitting regulation 318 (1) (c) (iii) and by inserting instead the following subparagraph:

(iii) possess unique or absolute properties;

(an) by omitting regulation 31A (1) (c) (xii) and by inserting instead the following paragraph:

(xii) will effect rejuvenation or regeneration of the human body or part of it or arrest or reverse the ageing process, except for broad-spectrum sunscreen preparations, in which it is averred or implied that they will arrest the ageing process;

(ao) by omitting from Column 2 in the Schedule to Regulation 3 1A (2) the third paragraph relating to "Analgesics" and by inserting instead the following paragraph:

an unsubstantiated representation that an analagesic is appreciably less irritating to the stomach, more rapidly absorbed, faster in action, more effective or less harmful than any other analgesic or some other analgesic.

(ap) by inserting after regulation 3 1 A (3) the following clause:

(4) The Director-General may by instrument in writing exempt from all or specified provisions of this regulation specified goods or goods of a specified class.

EXPLANATORY NOTE

The object of this Regulation is to amend the Therapeutic Goods and Cosmetics Regulations as follows:

(a) to remove the requirement that manufacturers of sun-screen preparations be licensed under the Act;

(b) to disapply the packaging and labelling requirements of the regulations in relation to sun-screen preparations;

(c) to alter the manner in which the quantity or proportion of a therapeutic substance in goods is to be expressed on a label;

(d) to require an expiry date to appear on containers smaller than 10 millilitres and "blister packs" of tablets (along with the other matter currently required to appear on them);

(e) to require certain additional information to appear on the labels of preparations for ophthalmic use, preparations for injection, large volume injections, additives for large volume injections, dialysis concentrates, topical preparations and biological products;

(f) to make minor changes to the requirements for the labelling of analgesics;

(g) to update references to various reference publications concerning therapeutic substances;

(h) to make various amendments to the provisions that deal with prohibited representations and advertisements and to empower the Director-General of the Department of Health to grant exemptions from those provisions;

(i) to make other miscellaneous minor amendments.