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THERAPEUTIC GOODS AND COSMETICS ACT 1972—REGULATION

(Relating to labelling and standards)

NEW SOUTH WALES

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HIS Excellency the Governor, with the advice of the Executive Council, and in pursuance of the Therapeutic Goods and Cosmetics Act 1972, has been pleased to make the Regulation set forth hereunder.

J. P. HANNAFORD
Minister for Health and Community Services.

The Therapeutic Goods and Cosmetics Regulations are amended:

(a) by inserting in Regulation 23 (1) in alphabetical order the following definitions:

"herbal substance" means all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin):

(a) that is obtained solely by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and

(b) that is not subjected to any other treatment or process (except a treatment or process that is necessary for its presentation in a pharmaceutical form);

"homoeoparation preparation" means a preparation:

(a) formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate; and

(b) prepared according to the practices of homoeopathic pharmacy using the methods of:

(i) serial dilution and succussion of a mother tincture in water, ethanol, glycerol or aqueous ethanol; or

(ii) serial trituration in lactose;

"practitioner of alternative medicine" means a herbalist, homoeopath, naturopathor practitioner of traditional Chinese medicine;

(b) by omitting Regulation 23 (4) (k) and by inserting instead the following paragraph:

(k) the purpose or purposes for which it is intended thatthe substance be used, except:

(i) where the substance contains a substance to which:

(a) Schedule Four, Seven or Eight of the Poisons List applies; or

(b) Regulation 33B of the Poisons Regulations applies; or

(ii) where the substance is a homoeopathc preparation or a herbal substance intended for supply to a practitioner of alternative medicine and is labelled with the statement "practitioner only product" (or some equivalent statement) and is for the purpose of supply to a patient under the practitioner's care.

(c) by inserting at the end of Regulation 23 (4) (k) the following word and paragraph:

; and

(1) from 1 June 1992, the registration number or the listing number of the substance where required under the Therapeutic Goods Act 1989 of the Commonwealth.

(d) by omitting from Regulation 23 (9) (b) the words "profession; or" and by inserting instead the word "profession;";

(e) by omitting from Regulation 23 (9) (c) the word "profession," and by inserting instead the words "profession; or";

(f) by inserting after Regulation 23 (9) (c) the following paragraph:

(c1) supplied extemporaneously as a medicine for a specific and individual case, in the presence of the person to whom it is supplied, by a practitioner of alternative medicine,

(g) by omitting from Regulation 23 (9) the words "or veterinary surgeon" wherever occurring (except in Regulation 23 (9) (a) and (c)) and by inserting instead the words ", veterinary surgeon or practitioner of alternative medicine";

(h) by omitting from Regulation 23 (9) (i) the words "book; and" and by inserting instead the word "book;";

(i) by omitting from Regulation 23 (9) (j) the word "acts." and by inserting instead the words "acts; and";

(j) by inserting after Regulation 23 (9) (i) the following paragraph:

(k) the date on which the prescription was dispensed except where that date is clearly identifiable from the details specified in paragraph (i).

(k) by omitting Regulation 23DA (2), (3) and (4);

(1) by omitting from Regulation 24 (1) all of the matter relating to "Prescribed publication No. 1" and by inserting instead the following matter:

Prescribed publication No. 1: the British Pharmacopoeia 1988, the British Pharmacopoeia 1988 Addendum 1989, the British Pharmacopoeia 1988 Addendum 1990 and the British Pharmacopoeia 1988 Amendment No. 4.

(m) by omitting from Regulation 31A (1) the words "fungus infections including tinea (athlete's foot), other than relief or treatment by dermal application;'' and by inserting instead the following matter:

fungus infections, other than:

(i) the treatment of tinea (athlete's foot); or

(ii) where the representation is required by the Poisons Act 1966 or the Poisons Regulations;

(n) by omitting from Regulation 31A (1) the words "genito-urinary system diseases, ailments, defects or injuries;" and by inserting instead the words "genito-urinary system diseases, ailments, defects or injuries, other than where the representation is required by the Poisons Act 1966 or the Poisons Regulations;".

EXPLANATORY NOTE

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

(a) to exempt homoeopathic/herbal preparations from certain labelling requirements where those preparations are supplied by a practitioner of alternative medicine to a patient;

(b) to require, in the case of supply on a prescription, the date the prescription was dispensed on the label of a therapeutic substance unless that date has been included in the relevant prescription book;

(c) to require (from 1 June 1992) a registration or listing number to appear on the label of a therapeutic substance where that is required under the Commonwealth Therapeutic Goods Act 1989;

(d) to remove certain labelling requirements in relation to sunscreen preparations as those requirements are now contained in the current Australian Standard for those products;

(e) to update references to various publications concerning therapeutic substances;

(f) to exempt certain preparations from provisions dealing with prohibited representations in advertisements so that labelling requirements under the NSW Poisons List in respect of those preparations can be satisfied.