

HE303

HEALTH ACT 1911

**HEALTH (DRUGS AND ALLIED SUBSTANCES) AMENDMENT
REGULATIONS 1993**

Made by His Excellency the Governor in Executive Council on the advice of the Drug Advisory Committee.

Citation

1. These regulations may be cited as the *Health (Drugs and Allied Substances) Amendment Regulations 1993*.

Principal regulations

2. In these regulations the *Health (Drugs and Allied Substances) Regulations 1961** are referred to as the principal regulations.

Regulation A.01.001A inserted

3. After regulation A.01.001 the following regulation is inserted —

“ **Application of Therapeutic Goods Act
of the Commonwealth**

A.01.001A For the purposes of section 245 of the Act the substances contained in those therapeutic goods included in the Register of Therapeutic Goods maintained under section 17 of the *Therapeutic Goods Act 1989* of the Commonwealth are therapeutic substances for the purposes of these regulations.

”.

Regulation R.01.001 amended

4. Regulation R.01.001 of the principal regulations is amended by deleting paragraph (a) and substituting the following paragraph —

- “ (a) indicates or suggests any matter or thing with respect to the use of those therapeutic substances, drugs or medicines for the purpose of or in connection with —
- (i) abortifacient action;
 - (ii) AIDS — see immune system diseases;
 - (iii) alcoholism;
 - (iv) anaemia;
 - (v) arthritis (all forms including rheumatoid arthritis) — other than the temporary relief of pain;
 - (vi) asthma;
 - (vii) baldness, including hair growth, hair loss or hair thinning;
 - (viii) blindness;
 - (ix) boils — other than treatment by topical application;
 - (x) breast development;
 - (xi) bronchitis — other than relief of cough;
 - (xii) carbuncles — other than treatment by topical application;
 - (xiii) cardiovascular system diseases ailments or defects (including high or low blood pressure) other than —
 - (A) the advertising of blood pressure appliances where the advertisement includes a statement to the effect that a medical practitioner is the only person qualified to evaluate the meanings of recorded blood pressure; or
 - (B) the advertising of cholesterol measurement appliances where the advertisement includes a statement to the effect that a medical practitioner is the only person qualified to evaluate the meanings of recorded cholesterol levels; or
 - (C) the advertising of purpose specific bandages for the relief or treatment of circulation related ailments; or
 - (D) a statement to the effect of “aids or assists in the maintenance of peripheral circulation”, other than a statement to the effect of “aids or assists in the treatment of fluid retention” provided the advertisement carries a warning to the effect of —
 - “ If fluid retention persists, seek medical advice. ”;
 - (xiv) cataract;
 - (xv) catarrh, other than temporary relief;
 - (xvi) chilblains, other than temporary relief of symptoms;

- (xvii) colds, other than temporary relief;
- (xviii) coughs, other than temporary relief;
- (xix) croup;
- (xx) deafness, other than relief by an appliance;
- (xxi) diabetes, other than the advertising of urine testing or blood glucose monitoring products or insulin syringes;
- (xxii) diphtheria;
- (xxiii) eczema, other than temporary relief of symptoms;
- (xxiv) endocrine system diseases, ailments or defects;
- (xxv) erysipelas;
- (xxvi) fertility;
- (xxvii) fungus infections, including tinea (athlete's foot), other than for relief or treatment by topical application;
- (xxviii) gall bladder diseases, ailments or defects;
- (xxix) gastric, peptic or duodenal ulcer;
- (xxx) genito-urinary system diseases, ailments or defects — other than for products offering temporary relief of the pain and burning sensation associated with cystitis provided the advertisement carries a warning to the effect —
 - “ If pain or irritation persists for more than 48 hours, consult your doctor. ”;

and

 - “ The presence of blood in the urine warrants immediate medical attention. ”;
- (xxxi) glandular diseases, ailments or defects (including glandular enlargement);
- (xxxii) glaucoma;
- (xxxiii) goitre;
- (xxxiv) gout;
- (xxxv) haemorrhoids, other than —
 - (A) temporary relief of discomfort by local application and where the directions for use include the statement that sufferers should consult a medical practitioner if the symptoms persist; or
 - (B) reference to bulk producing laxatives being of indirect benefit to people suffering from haemorrhoids;

- (xxxvi) hair and scalp — see baldness;
- (xxxvii) headaches, other than temporary relief;
- (xxxviii) height increase;
- (xxxix) hernia or rupture, other than advertising hernia appliances;
- (xl) herpes virus infections, other than —
(A) the relief of symptoms of cold sores; or
(B) reduction of risk of the transmission of genital herpes by the use of condoms;
- (xli) hormonal disease, ailments or defects;
- (xlii) immune system diseases, ailments or defects, including HIV induced diseases or ailments, such as Acquired Immune Deficiency Syndrome (AIDS), other than the reduction in the risk of the transmission of disease by the use of condoms;
- (xliii) impetigo, other than treatment by topical application;
- (xliv) impotence;
- (xlv) indigestion, other than temporary relief or treatment of digestive disorders, provided the advertisement carries a warning to the effect of —
“ If symptoms persist, seek medical advice. ”;
- (xlvi) infertility;
- (xlvii) influenza, other than temporary relief of symptoms;
- (xlviii) liver diseases, ailments, defects or injuries;
- (xlix) lupus;
- (l) menopause or menopausal ailments or defects;
- (li) menstrual cycle diseases, ailments or defects other than the temporary relief of menstrual pain;
- (lii) pre-menstrual symptoms where the advertisement includes a statement to the effect of —
“ Use only as directed and consult your doctor if pain or symptoms persist. ”;
- (liii) mental diseases, ailments or defects;
- (liv) mouth ulcers, other than temporary relief;
- (lv) muscular aches and pains, other than temporary relief;

- (lvi) neoplastic diseases (including cancer and leukaemia), other than use of suncreening preparations as an aid in the prevention of skin cancer (being S.P.F. 4 or greater) and premature skin ageing (being a broad spectrum sun screen as defined in the current Australian Standard) but without implying that long hours of exposure in the sun are desirable;
- (lvii) nervous system diseases, ailments, defects or injuries (including convulsions, epilepsy, fits or paralysis);
- (lviii) obesity including the reduction of subcutaneous fat also referred to as "cellulite";
- (lix) overweight, other than suppression of appetite in conjunction with a balanced low joule (calorie) diet;
- (lx) phlebitis;
- (lxi) pregnancy testing kits — see sexual intercourse;
- (lxii) prostate gland disease, ailments or defects;
- (lxiii) psoriasis, other than for the relief or treatment of the effects of psoriasis on the skin provided the advertisement carries a warning to the effect of —
 " Do not use for prolonged periods without consulting a medical practitioner. ",
 and provided an advertisement for products which contain coal tar carries an additional warning to the effect of —
 " 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. ";
- (lxiv) psychiatric disease, ailments or defects;
- (lxv) purpura;
- (lxvi) pyorrhoea;
- (lxvii) rheumatism, other than temporary relief of pain;
- (lxviii) scabies, other than relief by topical application;
- (lxix) sexual intercourse, other than —
 (A) reduction in the possibility of conception;
 or
 (B) pregnancy test kits where the advertisement includes a statement to the effect that a medical practitioner is the only person qualified to evaluate the test results;
- (lxx) sexually transmissible diseases, other than the reduction of the risk of transmission of sexually transmissible disease by the use of condoms;

- (lxxi) sexual function potency or virility;
- (lxxii) short stature;
- (lxxiii) sinus infection, other than temporary relief of sinusitis;
- (lxxiv) sleeplessness, other than temporary relief;
- (lxxv) sun screening — see neoplastic diseases;
- (lxxvi) thrombosis, other than for the relief or treatment of circulation related ailments by means of purpose specific bandages;
- (lxxvii) tuberculosis;
- (lxxviii) varicose ulcers or varicose veins, other than the temporary relief by the use of elastic hosiery;
- (lxxix) whooping cough. ”.

**References to “goods”
amended in Part R**

5. Part R of the principal regulations is amended by deleting “goods” wherever it occurs in the provisions referred to in the Table to this regulation and substituting in each case the following —

“ substances ”.

TABLE

Part R heading
Regulation R.01.001
Regulation R.01.001 (b)
Regulation R.01.001 (b) (iii)
Regulation R.01.001 (b) (v)
Regulation R.01.001 (c)
Regulation R.01.002
Regulation R.01.004

Regulation T.01 amended

6. Regulation T.01.001 of the principal regulations is amended by deleting the definition of “the Standard” and substituting the following definition —

“ “the Standard” means Australian Standard AS 2604-1986 entitled “Sunscreen Products — Evaluation and Classification” published by the Standards Association of Australia. ”.

Schedule repealed

7. The Schedule to Part T of the principal regulations is repealed.

By His Excellency's Command,

D. G. BLIGHT, Clerk of the Council.