1985/228

THE MEDICINES REGULATIONS 1984, AMENDMENT NO. 1

DAVID BEATTIE, Governor-General

ORDER IN COUNCIL

At the Government House at Wellington this 9th day of September 1985

Present:

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to section 105 (1) (j) of the Medicines Act 1981, His Excellency the Governor-General, acting on the advice of the Minister of Health tendered after consultation with the organisations and bodies that appeared to the Minister to be representatives of persons likely to be substantially affected, and by and with the advice and consent of the Executive Council, hereby makes the following regulations.

REGULATIONS

1. Title and commencement—(1) These regulations may be cited as the Medicines Regulations 1984, Amendment No. 1, and shall be read together with and deemed part of the Medicines Regulations 1984* (hereinafter referred to as the principal regulations).

(2) These regulations shall come into force on the 14th day after the date of their notification in the *Gazette*.

2. New prescription medicines—(1) The substances named or described in the First Schedule to these regulations are hereby declared to be prescription medicines.

(2) Part I of the First Schedule to the principal regulations is hereby amended by inserting, in their appropriate alphabetical order, the names and descriptions of substances declared by subclause (1) of this regulation to be prescription medicines.

*S.R. 1984/143

3. Further amendments to Part I of the First Schedule to the principal regulations—Part I of the First Schedule to the principal regulations (as amended by regulation 2 (2) of these regulations) is hereby further amended—

(a) By omitting the item "ENALAPRIL MALEATE", and substituting the following item:

"ENALAPRIL; and its salts and esters":

(b) By omitting the item "IBUPROFEN; and its salts", and substituting the following item:

"IBUPROFEN; and its salts, except in solid dose forms containing not more than 200 milligrams of ibuprofen in each dose form":

(c) By omitting the item "KETOCONAZOLE; and its salts", and substituting the following item:

"KETOCONAZOLE; and its salts; except in dermatological medicines":

(d) By omitting the item that begins with the word "LIGNOCAINE", and substituting the following item:

"LIGNOCAINE; and its salts; in medicines for internal use by ingestion, except in throat lozenges":

(e) By omitting the item "METRIZAMIDE":

(f) By omitting the item that begins with the word "THEOPHYLLINE", and substituting the following item:

"THEOPHYLLINE; and its salts; in solid dose forms or for parenteral use".

4. New restricted medicine—(1) The substance metrizamide is hereby declared to be a restricted medicine.

(2) Part II of the First Schedule to the principal regulations is hereby amended by inserting, after the item "METHANTHELINE; and its salts", the item "METRIZAMIDE".

5. Further amendment to Part II of the First Schedule to the principal regulations—Part II of the First Schedule to the principal regulations (as amended by regulation 4 (2) of these regulations) is hereby further amended by omitting the item "LOPERAMIDE; and its salts".

6. New pharmacy-only medicines—(1) The substances named or described in the Second Schedule to these regulations are hereby declared to be pharmacy-only medicines.

(2) Part III of the First Schedule to the principal regulations is hereby amended by inserting, in their appropriate alphabetical order, the names and descriptions of substances declared by subclause (1) of this regulation to be pharmacy-only medicines.

7. Further amendments to Part III of the First Schedule to the principal regulations—Part III of the First Schedule to the principal regulations (as amended by regulation 6 (2) of these regulations) is hereby further amended—

(a) By omitting the item that begins with the words "CARDAMOM COMPOUND", and substituting the following item:

"CARDAMOM; compound tincture, aromatic tincture":

(b) By omitting the item that begins with the word "HYDROCORTISONE", and substituting the following item:

"HYDROCORTISONE; and hydrocortisone acetate; in dermatological medicines containing 0.5 percent or less by weight of hydrocortisone base with no other active ingredient and in a quantity of not more than 15 grams or 15 millilitres per container":

(c) By omitting the item that begins with the word "LIGNOCAINE", and substituting the following item:

"LIGNOCAINE; and its salts, not specified elsewhere in this Schedule; except in medicines for external use containing 2 percent or less of lignocaine or its salts":

(d) By omitting the item "PANCREATIN", and substituting the following item:

"PANCREATIN, in medicines for internal use":

(e) By omitting the item that begins with the words "QUATERNARY AMMONIUM COMPOUNDS", and substituting the following item:

"QUATERNARY AMMONIUM ANTISEPTIC COMPOUNDS; except in medicines for external use":

(f) By omitting the item that begins with the word "SELENIUM", and substituting the following item:

"SELENIUM; and compounds of selenium, in medicines for internal use, when the recommended daily dose does not exceed 150 micrograms of selenium; except in medicines containing 3 parts per million or less of selenium; and except in medicines for external use containing 2.5 percent or less of selenium":

(g) By omitting the item that begins with the word "THEOPHYLLINE", and substituting the following item:

"THEOPHYLLINE; and its salts, except in solid dose forms; and except in medicines for parenteral use":

(h) By omitting the item "TRICLOSAN", and substituting the following item:

"TRICLOSAN, in medicines containing more than 1 percent of triclosan".

SCHEDULES

Reg 2 (1)

FIRST SCHEDULE

NEW PRESCRIPTION MEDICINES

ALBENDAZOLE.
AMSACRINE.
AZTREONAM.
BACAMPICILLIN.
BUSERELIN.
BUTOCONAZOLE; and its salts, except in dermatological medicines.
CEFONICID; and its salts.
CEFOTETAN; and its salts.
CEFTAZIDIME; and its salts.
CICLOPIROX; and its salts, except in dermatological medicines.
CILASTATIN; and its salts.
EPIDOXORUBICIN; and its salts.
FAMOTIDINE.
IMIPENEM.
INDAPAMIDE.
ISOPRINOSINE.
LEUPROLIDE; and its salts.
LEVOBUNOLOL; and its salts.
MEFLOQUINE; and its salts.
MEPTAZINOL; and its salts.
MISOPROSTOL.
MITOXANTRONE; and its salts.
MUPIROCIN.
NABUMETONE.
PIPEMIDIC ACID.
URAPIDIL.
VINCAMINE; and its salts.
ZOPICLONE.

Reg 6 (1)

SECOND SCHEDULE

NEW PHARMACY-ONLY MEDICINES

ANTIHAEMOPHILIC FACTOR (HUMAN).
BISMUTH SUBCITRATE.
BUTOCONAZOLE; and its salts, in dermatological medicines.
CICLOPIROX; and its salts, in dermatological medicines.
IBUPROFEN; and its salts, in solid dose forms containing not more than 200 mg of ibuprofen in each dose form.
KETOCONAZOLE; and its salts, in dermatological medicines.
LOPERAMIDE; and its salts.
PHENOTHRIN.
PIROCTONE; and its salts, in medicines containing more than 1 percent of piroctone.
TOLCICLATE.

P. G. MILLEN,
Clerk of the Executive Council.

EXPLANATORY NOTE

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations make various changes to the First Schedule to the Medicines Regulations 1984, relating to the classification of medicines. The changes follow the recommendations of the Medicines Classification Committee.

Issued under the authority of the Regulations Act 1936.
Date of notification in *Gazette:* 12 September 1985.
These regulations are administered in the Department of Health.