1994/299

THE MEDICINES REGULATIONS 1984, AMENDMENT NO. 6

CATHERINE A. TIZARD, Governor-General

ORDER IN COUNCIL

At Wellington this 19th day of December 1994

Present:

THE HON. DOUG KIDD PRESIDING IN COUNCIL

PURSUANT to section 105 of the Medicines Act 1981, Her 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.

ANALYSIS

REGULATIONS

1. Title and commencement—(1) These regulations may be cited as the Medicines Regulations 1984, Amendment No. 6, 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 1st day of January 1995.

2. Interpretation—Regulation 2 (1) of the principal regulations is hereby amended by omitting from paragraph (b) of the definition of the term "safety container" the word "opaque" in both places where it appears.

3. Labelling of medicines—(1) Regulation 13 (1) of the principal regulations is hereby amended by revoking paragraphs (f) to (h), and substituting the following paragraphs:

"(f) In the case of a medicine specified in Part I of the First Schedule to these regulations,—

"(i) The words 'PRESCRIPTION MEDICINE' or words of a similar meaning; or

"(ii) The words 'PRESCRIPTION ONLY MEDICINE' or words of a similar meaning; or

"(iii) The acronym 'POM':

"(g) In the case of a medicine specified in Part II of the First Schedule to these regulations,—

"(i) The words 'RESTRICTED MEDICINE'; or

"(ii) The words 'PHARMACIST ONLY MEDICINE':

"(h) In the case of a medicine specified in Part III of the First Schedule to these regulations,—

"(i) The words 'PHARMACY-ONLY MEDICINE' or words of a similar meaning; or

"(ii) The words 'PHARMACY MEDICINE' or words of a similar meaning:".

(2) Regulation 13 (3) of the principal regulations is hereby amended by inserting, after the words "Subject to", the words "subclause (5A) of this regulation and to".

(3) Regulation 13 (4) of the principal regulations is hereby amended by inserting, after the expression "subclauses (5)", the expression ", (5A),".

(4) Regulation 13 of the principal regulations is hereby further amended by inserting, after subclause (5), the following subclause:

"(5A) In the case of a prescription medicine, compliance with the requirements of subclauses (3) and (4) of this regulation is required only at the time at which that medicine—

"(a) Is sold by retail; or

"(b) Is supplied in circumstances corresponding to retail sale; or

"(c) Is supplied by way of gift or sample for the purpose of promoting a sale."

4. Principal display panel—Regulation 15 (1) of the principal regulations is hereby amended by omitting the words ", and the matters required by subclauses (3) and (4),".

*S.R. 1984/143
Amendment No. 1: S.R. 1985/228
Amendment No. 2: S.R. 1988/61
Amendment No. 3: S.R. 1990/221
Amendment No. 4: S.R. 1991/134
Amendment No. 5: S.R. 1992/43

5. Labelling of prescription medicines, restricted medicines, and pharmacy-only medicines—The principal regulations are hereby amended by revoking regulation 19, and substituting the following regulation:

"19. Subject to regulation 37 (3) of these regulations, where a label on a container is required by these regulations to bear—

"(a) The words 'PRESCRIPTION MEDICINE' or words of a similar meaning; or

"(b) The words 'PRESCRIPTION ONLY MEDICINE' or words of a similar meaning; or

"(c) The acronym 'POM'; or

"(d) The words 'RESTRICTED MEDICINE'; or

"(e) The words 'PHARMACIST ONLY MEDICINE'; or

"(f) The words 'PHARMACY-ONLY MEDICINE' or words of a similar meaning; or

"(g) The words 'PHARMACY MEDICINE' or words of a similar meaning,—

the words or the acronym, as the case may require, shall be placed prominently and legibly on the label."

6. Consumer information panel—(1) Regulation 20 (1) of the principal regulations is hereby amended by omitting the words "(other than the principal display panel)".

(2) Regulation 20 of the principal regulations is hereby further amended by repealing subclause (3).

MARIE SHROFF,
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, which come into force on 1 January 1995, amend the Medicines Regulations 1984.

Regulation 2 amends the definition of the term "safety container" so that a container made of transparent material may, for the purposes of regulation 37 of the principal regulations, be approved by the Director-General of Health as a safety container.

Regulation 3: Subclause (1) amends regulation 13 of the principal regulations (which relates to the labelling of medicines). The amendments allow containers of medicines to bear on their labels words with similar meanings to the words "prescription medicine" and "pharmacy-only medicine".

Subclauses (2) and (3) effect amendments that are consequential on the insertion into regulation 13 of the principal regulations, by *subclause (4)* of these regulations, of a new subclause (5A).

Subclause (4) inserts a new subclause (5A) into regulation 13 of the principal regulations. The new subclause provides that, in the case of a prescription medicine, compliance with the labelling requirements with regard to the use of that medicine is to be required only at the time at which that medicine—

(a) Is sold by retail; or

(b) Is supplied in circumstances corresponding to retail sale; or

(c) Is supplied by way of gift or sample for the purpose of promoting a sale.

Regulation 4 amends regulation 15 of the principal regulations (which relates to the principal display panel of the label of a medicine). The effect of the amendment is that the principal display panel is no longer required to contain the labelling requirements with regard to the use of the medicine.

Regulation 5 revokes regulation 19 of the principal regulations (which relates to the labelling of prescription medicines, restricted medicines, and pharmacy-only medicines), and substitutes a new regulation. The new regulation provides that where a label on a container is required by the principal regulations to bear words such as the words "prescription medicine", those words are to be shown prominently and legibly on the label. The requirements of the existing regulation (as made in 1984), while intended to achieve the same effect as the new requirement, are very detailed.

Regulation 6 removes two restrictions on the way in which the consumer display panel required by regulation 20 of the principal regulations may be set out.

Issued under the authority of the Acts and Regulations Publication Act 1989.
Date of notification in *Gazette:* 21 December 1994.
These regulations are administered in the Ministry of Health.