

L.N. 173 of 1993

**MEDICAL AND KINDRED PROFESSIONS ORDINANCE
(CAP. 31)**

Drugs (Control) (Amendment) Regulations, 1993

IN exercise of the powers conferred by section 40A of the Medical and Kindred Professions Ordinance, the Minister for Home Affairs and Social Development, on the advice of the Council of Health, has made the following regulations:—

1. These regulations may be cited as the Drugs (Control) (Amendment) Regulations, 1993 and shall be read and construed as one with the Drugs Control Regulations, 1985, hereinafter referred to as "the principal regulations."

Citation.

L.N. 22 of
1985.

2. Immediately after regulation 13 of the principal regulations there shall be added the following new regulation:—

Adds new
regulation 13A
to the principal
regulations.

“Information by
manu-
facturer
and by
importer.

13A. (1) Any person who manufactures or imports any drug or any pharmaceutical preparation shall, within eight days of any manufacture or importation, give notice thereof to the Superintendent giving details as to the contents and dosage form of such drug or pharmaceutical preparation:

Provided that when a person has complied once with the provisions of this paragraph in respect of a particular drug or pharmaceutical preparation, he shall not be bound to comply herewith in respect of any other manufacture or importation of the same drug or pharmaceutical preparation having the same trade name and made up of the same contents and dosage form.

(2) The Superintendent may at any time request the manufacturer or importer of any drug or pharmaceutical preparation, as the case may be, to give such information as the Superintendent may require in respect of such drug or pharmaceutical preparation and the said manufacturer or importer, as the case may be, shall comply with such request within fifteen days.

(3) The Superintendent may:—

(a) prohibit the importation of any drug unless such drug is accompanied by:—

(i) a certificate, acceptable to the Superintendent, from the competent Government authority in the country of origin, stating that the drug has been manufactured by a firm duly authorised to produce such drug for sale in the same country, and that the quality control facilities at the firm are satisfactory, and

(ii) a certificate, acceptable to the Superintendent, stating that the drug complies with the standard referred to in the British Pharmacopoea or in the British Pharmaceutical Codex or with other standards acceptable to the Superintendent, or, where no such standard exists in respect of such drug, a certificate, similarly acceptable, of analysis of such drug;

(b) suspend or prohibit the distribution, supply, sale or keeping or offering for sale, of any drug already imported, until the certificates referred to in items (i) and (ii) of sub-paragraph (a) of this paragraph are produced:

Provided that no such suspension or prohibition shall take effect before the expiry of one month from the date of the demand of such certificates by the said Superintendent.

(4) Notwithstanding the provisions of paragraph (3) of this regulation, the Superintendent may withdraw or cause to be withdrawn from the market any drug or pharmaceutical preparation if, because of adverse reactions or of other information relating to ill effects, manufacturing practices or other technical or scientific information, such withdrawal is in his opinion indicated in the interest of the health of patients.

(5) For the purposes of this regulation, "drug" includes any medicinal preparation for internal or external use, whether or not listed or specified in the First or Second Schedule to these regulations."

Repeal of
regulation 13
of L.N. 31
of 1976.

3. (1) Regulation 13 of the Drugs (Control) Regulations, 1976 is hereby repealed without prejudice to any liability incurred and to any proceedings taken or that may be taken thereunder.

(2) Any dispensed prescription, register, record, invoice or other document which, immediately before the coming into force of these regulations, are preserved under the said regulation 13 hereby revoked, shall continue to be preserved and to be open for inspection and shall for these purposes be deemed to have always been preserved under the principal regulations.