

Medicines (Labelling of Chinese Proprietary Medicines) Regulations 1998

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No. S 494

MEDICINES ACT (CHAPTER 176)

MEDICINES (LABELLING OF CHINESE PROPRIETARY MEDICINES) REGULATIONS 1998

In exercise of the powers conferred by sections 44, 45, 46 and 52 of the Medicines Act, the Minister for Health hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medicines (Labelling of Chinese Proprietary Medicines) Regulations 1998 and shall come into operation on 1st September 1999.

Definitions

2. In these Regulations —

“appropriate non-proprietary name”, in relation to any Chinese proprietary medicine or any ingredient thereof, means —

- (a) the name of the Chinese proprietary medicine or ingredient as stipulated in the current edition of “A Dictionary of Chinese Pharmacy” <<中药大辞典>>, “The Chinese Herbal Medicine Materia Medica” <<本草纲目>> or such other publication as may be approved by the Minister; or
- (b) the accepted scientific name or other name descriptive of the true nature of the Chinese proprietary medicine or ingredient;

“appropriate quantitative particulars”, in relation to any Chinese proprietary medicine, means —

- (a) the quantity of each ingredient, identified by its appropriate non-proprietary name, in each dosage unit of the Chinese proprietary medicine expressed in terms of weight, volume, capacity or units of activity; or
- (b) where there is no dosage unit, the quantity of each active ingredient identified by its appropriate non-proprietary name expressed in terms of weight, volume, capacity or units of activity or percentage by weight or volume of the total quantity;

“Chinese proprietary medicine” shall have the same meaning as in the Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order (O 6);

“current edition”, in relation to any publication, means an edition which is current at the time the Chinese proprietary medicine in question is sold or supplied, and includes any amendment, addition or deletion made to it up to that time.

Particulars to be shown on container, package and leaflet

3.—(1) Subject to this regulation, no person shall sell or supply any Chinese proprietary medicine unless —

- (a) the container of the Chinese proprietary medicine is labelled with the particulars as specified in paragraph (2)(a), (b), (c), (d), (h) and (i) in accordance with these Regulations;
- (b) where the container of the Chinese proprietary medicine is immediately enclosed in a package, such package is labelled with the particulars as specified in paragraph (2)(a), (b), (c), (d), (e), (f) and (g) in accordance with these Regulations; and
- (c) the particulars as specified in paragraph (2)(a), (b), (f), (h), (i), (j), (k), (l), (m) and (n) are stated in accordance with these Regulations on any leaflet supplied with the Chinese proprietary medicine.

(2) The particulars specified for the purposes of paragraph (1) are —

- (a) the trade or brand name under which the Chinese proprietary medicine is sold;
- (b) the appropriate non-proprietary name of the Chinese proprietary medicine;
- (c) the batch reference given by the person who manufactured the Chinese proprietary medicine to the batch of which it forms a part;
- (d) the date after which the Chinese proprietary medicine should not be used;
- (e) the name and address of the wholesaler of the Chinese proprietary medicine or, if the Chinese proprietary medicine is imported, the importer thereof;
- (f) the name and address (including the name of the country of manufacture) of the manufacturer of the Chinese proprietary medicine;
- (g) the name and address of the person who assembled the Chinese proprietary medicine, if any;
- (h) the appropriate non-proprietary name of the ingredients of the Chinese proprietary medicine;
- (i) the appropriate quantitative particulars of the ingredients of the Chinese proprietary medicine;
- (j) the recommended dosage of the Chinese proprietary medicine;
- (k) the purpose or purposes for which the Chinese proprietary medicine is to be used;
- (l) the purpose or purposes for which the Chinese proprietary medicine should not be used;