

**MEDICINES ACT
(CHAPTER 176, SECTIONS 44, 45, 46 AND 52)**

**MEDICINES
(LABELLING OF CHINESE PROPRIETARY MEDICINES)
REGULATIONS**

ARRANGEMENT OF REGULATIONS

Regulation

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The Schedule

[1st September 1999]

Citation

1. These Regulations may be cited as the Medicines (Labelling of Chinese Proprietary Medicines) Regulations.

Definitions

- 2.** In these Regulations, unless the context otherwise requires —
- “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” has 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;
- (m) the possible side effects that the Chinese proprietary medicine may have on persons to whom it is administered; and

- (n) directions as to how the Chinese proprietary medicine is to be used (including the time and method of administration).
- (3) The particulars referred to in paragraph (2) (h) and (i) need not be stated as required by paragraph (1) if —
 - (a) it is proved to the satisfaction of the Minister that the formula for the Chinese proprietary medicine has been certified by the relevant health authority of the country of manufacture of the Chinese proprietary medicine as being a secret or protected formula; or
 - (b) where the Chinese proprietary medicine is manufactured in a country which does not certify secret or protected formulae, the Minister is satisfied that the formula for the Chinese proprietary medicine is a secret or protected formula.
- (4) Where the container of a Chinese proprietary medicine is too small for it to be reasonably practicable to state thereon the particulars as specified in paragraph (2) (h) and (i), such of those particulars as there is space for shall be stated on that container in accordance with the following criteria:
 - (a) precedence shall be given to the particulars in accordance with the order in which they appear in paragraph (2); and
 - (b) the other particulars not stated on the container shall be stated on the package in which the container is immediately enclosed.
- (5) Where any Chinese proprietary medicine is sold or supplied without any package, the particulars specified in paragraph (2) (e), (f) and (g) shall be stated on the container of the Chinese proprietary medicine.
- (6) Where any Chinese proprietary medicine is sold or supplied without any leaflet, the particulars specified in paragraph (2) (j), (k), (l), (m) and (n) shall be stated on the container or the package of the Chinese proprietary medicine in any order.

Exception for clinical trial

4. Regulation 3 shall not apply to any Chinese proprietary medicine for administration in a clinical trial which is labelled with

the particulars specified in regulation 18 (1) of the Medicines (Clinical Trials) Regulations (Rg 3).

Certain substances to be labelled

5. No person shall sell or supply any Chinese proprietary medicine which contains any substance specified in the first column of the Schedule unless the container of the Chinese proprietary medicine and, where the container is immediately enclosed in a package, every such package, is labelled with a statement in English declaring the presence of that substance which may describe that substance by a corresponding term specified in the second column of the Schedule or any other equivalent term.

Prohibition of certain labels and leaflets

6.—(1) No person shall sell or supply any Chinese proprietary medicine if the container or package of the Chinese proprietary medicine contains any statement or other representation which, directly or indirectly, claims, indicates or suggests that the Chinese proprietary medicine will prevent, alleviate or cure any disease or condition specified in the First Schedule to the Act.

(2) No person shall supply, with any Chinese proprietary medicine, or have in his possession for the purpose of so supplying, any leaflet which contains any statement or other representation which, directly or indirectly, claims, indicates or suggests that the Chinese proprietary medicine will prevent, alleviate or cure any disease or condition specified in the First Schedule to the Act.

Manner in which particulars are to be stated

7.—(1) The particulars required by regulation 3 to be stated on the container or package of, or on any leaflet supplied with, any Chinese proprietary medicine shall —

- (a) be printed in letters not less than 1.5 millimetres in height;
- (b) be clearly legible;
- (c) be printed in an indelible manner; and

- (d) appear conspicuously in a prominent position on such container, package or leaflet so as to be easily read by an intending purchaser or user of the Chinese proprietary medicine under normal conditions of purchase or use.

(2) Notwithstanding paragraph (1), the particulars required by regulation 3 to be stated on the container or package of, or on any leaflet supplied with, any Chinese proprietary medicine may be printed in reduced size where such container, package or leaflet is so small as to prevent the use of wording of the size specified in paragraph (1), provided the particulars are clearly legible.

(3) Where a container which is in the form of a bubble, blister or other sealed unit is part of a continuous series comprising a sheet or strip of like containers, regulation 3 shall be deemed to have been complied with if the particulars required by that regulation to be stated are displayed at regular intervals on the sheet or strip of such containers.

(4) Where the package immediately enclosing a container referred to in paragraph (3) is itself in the form of a bubble, blister or other sealed unit and is part of a continuous series comprising a sheet or strip of like packages, regulation 3 shall be deemed to have been complied with if the particulars required by that regulation to be stated are displayed at frequent intervals on the sheet or strip of such packages.

Language in which particulars are to be stated

8. The particulars referred to in regulation 3 shall be stated in the English language.

Additional information to be shown on container, etc., of Chinese proprietary medicine

9.—(1) No person shall sell or supply any Chinese proprietary medicine unless it is labelled in accordance with this regulation —

- (a) with the following statement in English:

“Allowed for sale as a Chinese Proprietary Medicine”;
and

(b) with the following statement in Chinese:

“允许作为中成药销售”.

(2) The statements specified in paragraph (1) shall be appended in the following manner:

- (a) where the Chinese proprietary medicine is or is intended to be sold or supplied by way of retail in a container without being enclosed in any other package, on that container;
- (b) where the Chinese proprietary medicine is or is intended to be sold or supplied by way of retail in a container which is immediately enclosed in a package, on that package; or
- (c) where the Chinese proprietary medicine is or is intended to be sold or supplied by way of retail packaged together with any other Chinese proprietary medicine (whether or not of the same type) so as to form a single unit, on the outermost package of that unit.

(3) Subject to paragraph (4), the statements specified in paragraph (1) —

- (a) shall be printed —
 - (i) in the case of the statement in English, in a font size not less than 1.5 millimetres in height; and
 - (ii) in the case of the statement in Chinese, in a font size not less than 2 millimetres in height;
- (b) shall be clearly legible;
- (c) shall be printed in an indelible manner;
- (d) shall appear conspicuously in a prominent position on the relevant container or package so as to be easily read by an intending purchaser or user of the Chinese proprietary medicine under normal conditions of purchase or use;
- (e) may appear together or separately; and
- (f) shall, wherever appearing, be in a boxed area which does not contain any other information or particulars.

(4) Notwithstanding paragraph (3) (a), the statements specified in paragraph (1) may be printed in a reduced font size where the relevant container or package is so small as to prevent the use of the relevant font size specified in paragraph (3) (a).

(5) For the purposes of paragraph (2) —

- (a) where a container is in the form of a bubble, blister or other sealed unit and is part of a continuous series comprising a sheet or strip of like containers, each sheet or strip of such containers by which the Chinese proprietary medicine is sold or supplied shall be treated as the container specified in paragraph (2) (a); and
- (b) where the package immediately enclosing a container referred to in sub-paragraph (a) is itself in the form of a bubble, blister or other sealed unit and is part of a continuous series comprising a sheet or strip of like packages, each sheet or strip of such packages by which the Chinese proprietary medicine is sold or supplied shall be treated as the package specified in paragraph (2) (b).

THE SCHEDULE

Regulation 5

SUBSTANCES TO BE LABELLED

<i>Substance</i>	<i>Term to be used</i>
1. Tartrazine	tartrazine (Code E102) tartrazine (Code 102) tartrazine (Code FD and C Yellow No.5)
2. Benzoic acid	benzoic acid benzoic acid (Code E210)
3. Sodium benzoate	sodium benzoate sodium benzoate (Code E211)

[G.N. Nos. S 494/98; S 557/2002]
