Medicines (Labelling of Chinese Proprietary Medicines) Regulations

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

MEDICINES (LABELLING OF CHINESE PROPRIETARY MEDICINES) REGULATIONS

Rg 13

G.N. No. S 494/1998

REVISED EDITION 2005

(31st March 2005)

[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.

Scope of Regulations

2A. These Regulations do not apply to any Chinese proprietary medicine that is clinical research material as defined in regulation 2 of the Medicines (Medicinal Products as Clinical Research Materials) Regulations 2016 (G.N. No. S 336/2016).

[S 546/2016 wef 01/11/2016]

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