Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 1998

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No. S 496

MEDICINES ACT
(CHAPTER 176)

MEDICINES (LICENSING, STANDARD PROVISIONS AND FEES) (AMENDMENT) REGULATIONS 1998

In exercise of the powers conferred by sections 15 and 74 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 (Licensing, Standard Provisions and Fees) (Amendment) Regulations 1998 and shall come into operation on 1st September 1999.

New regulation 1A

2. The Medicines (Licensing, Standard Provisions and Fees) Regulations (Rg 6) (referred to in these Regulations as the principal Regulations) are amended by inserting, immediately after regulation 1, the following regulation:

"**Definition**

1A. In these Regulations, "Chinese proprietary medicine" shall have the same meaning as in the Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order (O 6).".

Amendment of regulation 2

3. Regulation 2 of the principal Regulations is amended —

(*a*) by deleting the word "The" in the first line and substituting the words "Subject to paragraph (2), the"; and

(*b*) by renumbering the regulation as paragraph (1) of that regulation and by inserting immediately thereafter the following paragraphs:

"(2) The standard provisions for import licences to be granted under Part II of the Act in respect of Chinese proprietary medicines shall be as follows:

(*a*) those provisions set out in the Second Schedule except paragraphs 8, 9(2) and 11;

(*b*) the provision that the holder of the licence shall seek the prior approval of the licensing authority to deal with any medicinal product under his licence, and he shall, within such time as the licensing authority may specify, provide such information and documents as may be required by the licensing authority;

(*c*) the provision that the holder of the licence shall not import, sell or supply any medicinal product to which the licence relates unless —

(i) the approval of the licensing authority to deal with that medicinal product under his licence continues to be valid at the time of the import, sale or supply, as the case may be, of the medicinal product; and

(ii) he complies with any written law applicable to the import, sale or supply, as the case may be, of the medicinal product;

and

(*d*) the provision that the holder of the licence shall not sell or supply any medicinal product to which the licence relates unless he has submitted to the licensing authority the following documents within 2 months of the import of the consignment of the medicinal product —

(i) a declaration of the absence of any poison as defined in the Poisons Act (Cap.234) and any synthetic active substance in the medicinal product;

(ii) test results on the content of Arsenic, Copper, Lead and Mercury in the medicinal product;

(iii) where the medicinal product is for oral consumption, test results on the content of Escherichia coli, Salmonella, Staphylococcus aureus, *the total yeast and mould count, and *the total aerobic microbial count per gram or millilitre of the medicinal product (*not necessary if the medicinal product contains any active substance which is derived from plants, animals or a combination thereof and which has been produced by fermentation processes); and

(iv) where the medicinal product is for external application, test results on the content of Pseudomonas aeruginosa, Staphylococcus aureus, *the total yeast and mould count, and *the total aerobic microbial count per gram or millilitre of the medicinal product (*not necessary if the medicinal product contains any active substance which is derived from plants, animals or a combination thereof and which has been produced by fermentation