Medicines (Licensing, Standard Provisions and Fees) Regulations

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MEDICINES ACT
(CHAPTER 176, SECTION 74)

MEDICINES (LICENSING, STANDARD PROVISIONS AND FEES) REGULATIONS

Rg 6

G.N. No. S 174/1987

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Citation

1. These Regulations may be cited as the Medicines (Licensing, Standard Provisions and Fees) Regulations.

Definition

2. 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).

Standard provisions for licences

3.—(1) Subject to paragraph (2), the standard provisions for licences (including provisional licences) to be granted under Part II of the Act shall be the following:

(*a*) for product licences, those provisions set out in the First Schedule;

(*b*) for import licences, those provisions set out in the Second Schedule;

(*c*) for wholesale dealer's licences, those provisions set out in the Third Schedule; and

(*d*) for manufacturer's licences, those provisions set out in the Fourth Schedule.

(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 processes).

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(3) The standard provisions for wholesale dealer's licences to be granted under Part II of the Act in respect of Chinese proprietary medicines shall be those provisions set out in the Third Schedule except that paragraph 6 thereof shall read as if the words "or by the holder of the product licence" in the second line have been deleted.

(4) The standard provisions for manufacturer's licences to be granted under Part II of the Act in respect of Chinese proprietary medicines shall be —

(*a*) those provisions set out in the Fourth Schedule, except that —

(i) paragraph 4 thereof shall read as if the words "under the relevant product licences" at the end thereof have been deleted; and

(ii) paragraph 12 thereof shall read as if the words ", except so far as the conditions of the relevant medicinal product licence may otherwise provide," in the third and fourth lines have been deleted;

(*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 manufacture, assemble, 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 manufacture, assembly, sale or supply, as the case may be, of the medicinal product; and

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

(*d*) the provision that the holder of the licence shall inform the licensing authority of any decision to cease the manufacture or assembly of the medicinal product to which the licence relates and shall state the reason for that decision.

Ordinary and provisional product licences and import licences

4.—(1) An ordinary product licence shall be granted for a period of 5 years.

(2) A provisional product licence, a wholesale dealer's licence and a manufacturer's licence shall be granted for a period of 3 years or such shorter period as the licensing authority may determine.

(3) An import licence shall be granted to any person authorised by the holder of a

product licence for a period of 3 years and to any other person on a per consignment basis.

(4) Notwithstanding paragraphs (2) and (3), a wholesaler dealer's licence, a manufacturer's licence and an import licence issued in respect of Chinese proprietary medicines may be granted for a period of one year or 3 years.

Fees

5.—(1) The fees in respect of applications for, and the grant of, licences and certificates and for any variation or amendment thereof shall be as specified in the Fifth Schedule.

(2) No refund shall be made in respect of any fee paid under these Regulations.

Offences

6. A holder of a licence who contravenes or fails to comply with any standard provision applicable to his licence shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $5,000 or to imprisonment for a term not exceeding 2 years or to both.

FIRST SCHEDULE

Regulation 3(1)(*a*)

STANDARD PROVISIONS FOR PRODUCT LICENCE

1. The holder of the licence shall forthwith report to the licensing authority any change in his name and address and in any address at which there is carried on a business to which the licence relates.

2.—(1) The holder of the licence shall forthwith inform the licensing authority of any material change that has been made or that he proposes to make in the particulars contained in his application, in relation to any medicinal product to which the licence relates, that is to say —

(*a*) in the specification of the medicinal product;

(*b*) in the specification of any of the constituents of the medicinal product;

(*c*) in the composition of the medicinal product, or of any of the constituents of the medicinal product;

(*d*) in the methods of manufacture or assembly of the medicinal product, or of any of the constituents of the medicinal product;

(*e*) in the methods and procedures described in the application for ensuring compliance with the specifications relating to the medicinal product;

(*f*) in the arrangements described in the application for storage of the medicinal product;