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

REVISED EDITION 2000

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[30th June 1987]

Citation

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

Definitions

2. In these Regulations —

"Authority's website" means the Authority's Internet website at http://www.hsa.gov.sg;

"Chinese proprietary medicine" has the same meaning as in the Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order (O 6);

"competent drug regulatory agency" means a national regulatory authority participating in the World Health Organization's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, and listed as such on the World Health Organization's website;

"licensing authority" means the Chief Executive of the Authority;

"major variation", in relation to a medicinal product, means any change to the product specifications of the medicinal product that relate to any of the following:

(*a*) the indications of the medicinal product;

(*b*) the dosage recommendations of the medicinal product;

(*c*) the patient groups for the medicinal product;

(*d*) clinical trial information on the medicinal product;

"psychotropic substance" has the same meaning as in the Medicines (Export Licence for Psychotropic Substances) Regulations (Rg 9);

"reference drug regulatory agency" means a national regulatory authority, specified by the Authority on the Authority's website, from whose regulatory decisions the Authority takes reference.

[S 547/2016 wef 01/11/2016]

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 and until 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 all the substances specified in the First Schedule to the Medicines (Prohibition of Sale and Supply) Order (O 4) in the medicinal product;

[S 413/2019 wef 01/09/2019]

(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);

[S 621/2003 wef 01/01/2004]

(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) ; and

[S 621/2003 wef 01/01/2004]

(v) such other documents and test results as may be required by the licensing authority.

[S 621/2003 wef 01/01/2004]

(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 for paragraph 4(*b*)

thereof and except that —

(i) paragraph 4(*a*) 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;

[S 309/2001 wef 01/09/2001]

(*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.

Grant of licences

4.—(1) Every product licence, wholesale dealer's licence and manufacturer's licence granted shall be for a period of one year or such shorter period as specified in that licence.

(2) Every import licence granted to any person authorised by the holder of a product licence shall be for a period of one year or such shorter period as specified in the licence.