Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2004

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No. S 384

MEDICINES ACT
(CHAPTER 176)

MEDICINES (LICENSING, STANDARD PROVISIONS AND FEES) (AMENDMENT) REGULATIONS 2004

In exercise of the powers conferred by section 74 of the Medicines Act, Mr Khaw Boon Wan, Senior Minister of State, Ministry of Finance, charged with the responsibility of 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 2004 and shall come into operation on 1st July 2004.

New regulation 5B

2. The Medicines (Licensing, Standard Provisions and Fees) Regulations (Rg 6) are amended by inserting, immediately after regulation 5A, the following regulation:

"**Declaration, notice and prescribed periods under section 12A of Act**

5B.—(1) The declaration under section 12A(2) of the Act shall be in the form set out in Part I of the Sixth Schedule.

(2) The notice under section 12A(3)(*a*) of the Act shall be in the form set out in Part II of the Sixth Schedule.

(3) The period under section 12A(5) of the Act shall be 45 days from the date that notice is served on the proprietor of the patent concerned.

(4) The period under section 12A(6)(*b*) of the Act shall be 30 months from the date the application for the order or declaration referred to in section 12A(5)(*a*) of the Act is made.".

New Sixth Schedule

3. The Medicines (Licensing, Standard Provisions and Fees) Regulations are amended by inserting, immediately after the Fifth Schedule, the following Schedule:

"SIXTH SCHEDULE

Regulation 5B(1)

PART I

REPUBLIC OF SINGAPORE

HEALTH SCIENCES AUTHORITY

MEDICINES ACT
(CHAPTER 176)

DECLARATION ON PATENT RELATED INFORMATION FOR APPLICATION FOR PRODUCT LICENCE

Application No (for HSA use only):

SECTION 1: APPLICANT PARTICULARS

Name

Address

SECTION 2: PRODUCT PARTICULARS

Proprietary Name

Active Substance(s) and Strength

Dosage Form

SECTION 3: APPLICATION CATEGORY

Application Category *(check one box)**

☐ Category A1 (Proceed to Section 4)
Refers to an application where no patent is in force in respect of the medicinal product to which the application relates.

☐ Category A2 (Proceed to Section 5)
Refers to an application where a patent is in force in respect of the medicinal product to which the application relates; and the applicant is either the proprietor of the patent or, if the applicant is not the proprietor of the patent, the proprietor has consented to or acquiesced in the grant of the product licence.

☐ Category A3 (Proceed to Section 6)
Refers to an application where a patent is in force in respect of the medicinal product to which the application relates, the applicant is not the proprietor of the patent, the proprietor has not consented to nor acquiesced in the grant of the product licence; and the applicant is requesting for grant of product licence after the expiry of the patent. Such an application may not be made earlier than 18 months before the expiry of the patent.

☐ Category B (Proceed to Section 7)
Refers to an application where a patent is in force in respect of the medicinal product to which the application relates, the applicant is not the proprietor of the patent, the proprietor has not consented to nor acquiesced in the grant of the product licence; and in the opinion and to the best belief of the applicant, the patent is invalid or will not be infringed by the doing of the act for which the licence is sought.

SECTION 4: INFORMATION FOR CATEGORY A1 APPLICATIONS

I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that —

there is no patent under the Patents Act (Cap. 221) in force in respect of the product stated in Section 2 on the date of this declaration.

SECTION 5: INFORMATION FOR CATEGORY A2 APPLICATIONS

I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that — *(check one box)*

☐ a patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration. I am the proprietor of the patent. The Singapore Patent No. for the patent is _____.

☐ a patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration. I am not the proprietor of the patent but the proprietor has consented to or acquiesced in the grant of the product licence for the product stated in Section 2 to me. The name and address of the proprietor of the patent or his authorised agent are _____. The Singapore Patent No. for the patent is _____.

*For categories A2, A3 and B, please submit a separate declaration for each patent that is in force in respect of the medicinal product.