

Medicines (Amendment) Act 2004
(No. 26 of 2004)

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REPUBLIC OF SINGAPORE
GOVERNMENT GAZETTE
ACTS SUPPLEMENT

Published by Authority

NO. 22]

FRIDAY, JULY 2

[2004

The following Act was passed by Parliament on 15th June 2004 and assented to by the President on 24th June 2004:—

MEDICINES (AMENDMENT) ACT 2004

(No. 26 of 2004)

I assent.

S R NATHAN,
President.
24th June 2004.

Date of Commencement: 1st July 2004

An Act to amend the Medicines Act (Chapter 176 of the 1985 Revised Edition).

Be it enacted by the President with the advice and consent of the Parliament of Singapore, as follows:

Short title and commencement

1. This Act may be cited as the Medicines (Amendment) Act 2004 and shall come into operation on such date as the Minister may, by notification in the *Gazette*, appoint.

New section 12A

2. The Medicines Act is amended by inserting, immediately after section 12, the following section:

“Whether medicinal product subject to patent

12A.—(1) Subject to the provisions of this Part, in dealing with an application for a product licence, the licensing authority shall consider whether a patent under the Patents Act (Cap. 221) is in force in respect of any medicinal product to which the application relates and, if so —

- (a) whether the applicant is the proprietor of the patent; or
- (b) if he is not the proprietor of the patent, whether —
 - (i) the proprietor has given his consent to or has acquiesced in the grant of the licence to the applicant; or
 - (ii) the patent is invalid or will not be infringed by the doing of

the act for which the licence is sought.

(2) Unless the licensing authority otherwise determines, an applicant for a product licence shall, at the time of his application and at such other time as the licensing authority may require, make and furnish to the licensing authority a declaration in the prescribed form —

- (a) stating whether a patent under the Patents Act is in force in respect of any medicinal product to which the application relates;
- (b) if he states that there is such a patent, stating whether he is the proprietor of the patent; and
- (c) if he states that he is not the proprietor of the patent, stating —
 - (i) the name and other particulars of the proprietor of the patent;
 - (ii) whether —
 - (A) the proprietor has consented to or has acquiesced in the grant of the licence to the applicant; or
 - (B) in his opinion and to the best of his belief, the patent is invalid or will not be infringed by the doing of the act for which the licence is sought; and
 - (iii) such other information as may be prescribed.

(3) The licensing authority may, if the applicant has declared that in his opinion and to the best of his belief the patent is invalid or will not be infringed by the doing of the act for which the licence is sought, or if the licensing authority considers it appropriate in any particular case, require the applicant to do the following within such time as the licensing authority may determine:

- (a) serve on the proprietor of the patent under the Patents Act that is in force in respect of a medicinal product to which the application relates, a notice in the prescribed form of his application; and
- (b) furnish to the licensing authority such evidence of the service as the licensing authority may require.

(4) The licensing authority need not determine the application until the applicant has complied with subsection (2) and, where applicable, subsection (3),