

Medicines (Amendment) Bill

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Bill No: 25/2004

Read the first time: 19th May 2004

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Expenditure of Public Money

Medicines (Amendment) Bill

Bill No. 25/2004

Read the first time on 19th May 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 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), to the reasonable satisfaction of the licensing authority.

(5) If the licensing authority is satisfied that a notice referred to in subsection (3)(a) has been served on the proprietor of the patent, the licensing authority may grant the licence to the applicant if the proprietor has not, before the expiration of the period prescribed for the purposes of this subsection —

- (a) applied for the order or declaration by a court or the Registrar of Patents or a Deputy Registrar of Patents holding office under the Patents Act (Cap. 221), as specified in that notice; and
- (b) given written notice to the licensing authority stating that such application has been made.

(6) The licensing authority may grant the licence to the applicant if —

- (a) application for the order or declaration referred to in subsection (5)(a) has been made; and