

Medicines (Amendment) Bill

Bill No. /2004.

Read the first time on

2004.

A BILL

intituled

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.

5 New section 12A

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

“Whether medicinal product subject to patent

10 **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, whether —

(a) the applicant is the proprietor of the patent; or

15 (b) if he is not the proprietor, whether —

(i) the proprietor has given his consent to or has acquiesced in the grant of the licence to the applicant; or

20 (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 time as the licensing authority may determine, make and furnish to the licensing authority a declaration in the prescribed form

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(a) stating whether a patent under the Patents Act is in force in respect of any medicinal product to which the application relates;

30 (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, of 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 notice to the licensing authority stating that such application had 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

(b) at the expiration of the period prescribed for the purposes of this subsection, the order or declaration has not been obtained.

(7) For the purpose of subsection (1), the licensing authority may rely upon, and shall not be concerned to inquire into the truth of any statement made in a declaration furnished under subsection (2).

(8) This section applies only to an application for a product licence made on or after the date of commencement of the Medicines (Amendment) Act 2004.”.

Amendment of section 16

3. Section 16 of the Medicines Act is amended —

(a) by inserting, immediately after subsection (1), the following subsections:

“(1A) Without prejudice to the generality of subsection (1), the licensing authority may, upon the request of the holder of a licence, revoke the licence.

(1B) Without prejudice to the generality of subsection (1), the licensing authority may, upon an application by any interested person, revoke a product licence if he is satisfied that —

(a) the Registrar of Patents or a Deputy Registrar of Patents holding office under the Patents Act (Cap. 221), or a court, has determined that the doing of an act authorised by the licence infringes a patent under the Patents Act;

(b) the person who made the declaration referred to in section 12A(2) in support of the application for the licence has been convicted for an offence under section 20 in respect of the declaration; or

(c) a court has determined that the declaration —

(i) contains a statement that is false or misleading in a material particular; or

(ii) omits to disclose any matter that is material to the application,

5 and the determination or conviction (as the case may be) is final.”; and

(b) by inserting, immediately after subsection (3), the following subsection:

10 “(4) For the purposes of subsection (1B), a determination or conviction is final if —

(a) it is upheld on appeal, review or revision;

(b) it is not subject to further appeal;

(c) it is not appealed against within the permitted time; or

15 (d) any appeal against it is or is deemed to be withdrawn.”.

New sections 19C and 19D

4. The Medicines Act is amended by inserting, immediately after section 19B, the following sections:

“Licensing authority may publish information on applications

20 **19C.**—(1) Notwithstanding any restriction on the disclosure of information imposed by any written law or rule of law, the licensing authority may from time to time publish, for the information of the public and in the manner determined by it, such particulars of applications for licences which it received as it may determine.

25 (2) The particulars referred to in subsection (1) excludes —

(a) any trade secret; and

(b) any information that has commercial value that would be, or would be likely to be, diminished by disclosure.

No product licence to be granted on basis of previous grant

30 **19D.**—(1) Where —

(a) information has been provided by an applicant for a product licence to the licensing authority relating to the safety or efficacy of a medicinal product in support of such application; and

5 (b) a product licence has been granted in respect of that medicinal product (referred to in this section as the earlier licence),

10 the licensing authority may not, for a period of 5 years from the date of such grant, grant a product licence to another person in respect of that or a similar medicinal product on the basis of the grant of the earlier licence unless the holder of the earlier licence has given his consent to the grant on that basis.

(2) This section applies where the earlier licence is granted —

15 (a) on or after the date of commencement of the Medicines (Amendment) Act 2004; or

(b) at any time between the date that is 5 years before that date, and that date.

Amendment of section 20

20 **5.** Section 20 of the Medicines Act is amended by deleting subsection (3) and substituting the following subsections:

25 “(3) Any person who, when making an application under section 11 or a declaration under section 12A(2) or giving any information he is required to give under section 19, makes a statement which he knows or has reason to believe is false in a material particular, shall be guilty of an offence.

(3A) Any person who, when required to furnish to the licensing authority any evidence or document under section 12A(3), furnish to the licensing authority any thing which he knows or has reason to believe is forged or altered, shall be guilty of an offence.”.

Amendment of section 54

30 **6.** Section 54 of the Medicines Act is amended by inserting, immediately after subsection (1), the following subsection:

“(1A) An order under subsection (1) may —

- (a) apply to any class or description of chewing gum that is intended for use in promoting dental health or oral hygiene; and
- (b) require the chewing gum to be sold or supplied by prescription or by or under the supervision of a pharmacist.”.
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EXPLANATORY STATEMENT

This Bill seeks to amend the Medicines Act (Cap. 176) to implement certain obligations undertaken by Singapore under the United States-Singapore Free Trade Agreement concluded in 2003.

Clause 1 relates to the short title and commencement.

Clause 2 inserts a new section 12A which requires the licensing authority to consider, when dealing with an application for a product licence, whether the medicinal product is subject to a patent that is in force, whether the applicant is the proprietor of the patent and (if not) whether the proprietor has consented to or acquiesced in the grant of the licence to the applicant or the act for which the licence is sought will or will not infringe the patent.

The new section also requires an applicant for such licence to make one or more declarations stating whether the medicinal product is subject to a patent and other particulars relating to that patent. The applicant may also be required to notify the proprietor of the patent of his application, whereupon the licensing authority may proceed to grant the licence if the proprietor has not within a prescribed time applied for a specified order or declaration from a court or the Registrar or a Deputy Registrar of Patents, or if after such application has been made the order or declaration is not obtained after a prescribed time.

Clause 3 amends section 16 to clarify that the licensing authority may revoke a product licence, inter alia, if —

- (a) the act authorised by the licence is determined to have infringed a patent; or
- (b) if the maker of the declaration referred to in new section 12A has been convicted under section 20 in respect of the declaration.

Clause 4 inserts new sections 19C and 19D.

The new section 19C permits the licensing authority to publish certain information relating to applications for licences.

The new section 19D provides that, where a product licence has been granted for a medicinal product and certain information has been given in support of the application for that licence, another product licence for the same or a similar product may not be granted on the basis of the earlier grant for a period of 5 years from the earlier grant, except with consent.

Clause 5 amends section 20 to prohibit the making of a false statement in an application for a licence or a declaration under new section 12A(2), and to prohibit the giving of any forged or altered evidence or document pursuant to a requirement under new section 12A(3).

Clause 6 amends section 54 to clarify that the Minister may make orders to subject chewing gum intended for use in promoting dental health or oral hygiene to the provisions of the Act, including provisions relating to the sale and supply of such chewing gum by prescription or by or under the supervision of a pharmacist.

EXPENDITURE OF PUBLIC MONEY

This Bill will not involve the Government in any extra financial expenditure.
