An Act to amend the Medicines Act 1981

1994, No. 128

ANALYSIS

Title

[9 December 1994

BE IT ENACTED by the Parliament of New Zealand as follows:

1. Short Title and commencement–

(1) This Act may be cited as the Medicines Amendment Act 1994, and shall be read together with and deemed part of the Medicines Act 1981 (hereinafter referred to as the principal Act).

(2) This Act shall come into force on a date to be appointed by the Governor–General by Order in Council; and one or more orders may be made bringing different provisions into force on different dates.

2. New sections inserted–

The principal Act is hereby amended by inserting, after section 23, the following sections:

"23A. **Interpretation–**

In this section, and in sections 23B and 23C of this Act, unless the context otherwise requires,–

" 'Applicant' means–

"(a) A person who makes or has made, as the case may be, an application; and

"(b) A person on whose behalf an application is, or has been, made, as the case may be:

" 'Application' means an application for the consent of the Minister under section 20 of this Act, or for the provisional consent of the Minister under section 23 of this Act, in relation to a medicine:

" 'Commencement date' means the date this section, and sections 23B, and 23C of this Act come into force:

" 'Confidential information' includes–

"(a) Trade secrets; and

"(b) Information that has commercial value that would be, or would be likely to be, diminished by disclosure:

" 'Confidential supporting information' means confidential information given–

"(a) In, or in relation to, an innovative medicine application; and

"(b) About the medicine that is or was, as the case may be, the subject of that application:

" 'Ingredient' includes a chemical or biological entity:

" 'Innovative medicine application' means,–

"(a) In relation to an application made after the commencement date, an application that refers to an active ingredient–

"(i) That is an active ingredient of the medicine to which the application relates; and

"(ii) That has not, before that application is received by the Minister, been referred to in any other application (except in an application by the applicant for provisional consent for that medicine) as an active ingredient of a medicine; and

"(b) In relation to an application made before the commencement date, an application that referred to an active ingredient–

"(i) That is or was, as the case may be, an active ingredient of the medicine to which the application related; and

"(ii) That had not, before that application was received by the Minister, been referred to in any other application (except in an application by the applicant for provisional consent for that medicine) as an active ingredient of a medicine:

" 'Protected period' means–

"(a) In relation to confidential supporting information, relating to an innovative medicine application, received by the Minister after the commencement date, a period commencing on the date that information is received by the Minister and ending,–

"(i) Where–

"(A) The Minister has either notified consent, not being provisional consent, not being provisional consent, in the Gazette under section 20 of this Act, or refused to grant such consent, in relation to the medicine that is the subject of the innovative medicine application; and

"(B) The date of that notification or refusal is not more than 5 years after the Minister received an application in relation to that medicine,–

on the date 5 years after the date of that notification or refusal; or

"(ii) In any other case, on the date 5 years after the innovative medicine application to which that information relates is or was, as the case may be, received by the Minister:

"(b) In relation to confidential supporting information, relating to an innovative medicine application, received by the Minister not more than 5 years before the commencement date, a period commencing on the commencement date and ending,–

"(i) Where–

"(A) The Minister has notified or notifies consent, not being provisional consent, in the Gazette under section 20 of this Act, or refused or refuses to grant such consent, in relation to the medicine that was the subject of the innovative medicine application; and

"(B) The date of that notification or refusal is or was, as the case may be, not more than 5 years after the Minister received an application in relation to that medicine,–

on the date 5 years after the date of that notification or refusal; or

"(ii) In any other case, on the date 5 years after the innovative medicine application to which that information related was received by the Minister:

" 'WTO Country' means a country that is a party to the Agreement establishing the World Trade Organization adopted at Marrakesh on the 15th day of April 1994.

"23B. **Protection of confidential supporting information about innovative medicines–**

Where the Minister receives, or received not more than 5 years before the commencement date, an innovative medicine application and confidential supporting information, the Minister, during the protected period in relation to that confidential information,–

"(a) Shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the Minister; and

"(b) Shall not use that confidential supporting information for the purposes of determining whether to grant any other application.

"23C. **Circumstances where protection under section 23B does not apply–**

(1) Notwithstanding section 23B of this Act, the Minister may, during the protected period in relation to confidential supporting information,–

"(a) Disclose that confidential supporting information, or use that confidential supporting information for the purposes of determining whether to grant any application other than the application to which it relates or related, as the case may be,–

"(i) With the consent of the applicant who made the application to which the confidential supporting information relates or related; or

"(ii) If that disclosure or use is, in the opinion of the Minister, necessary to protect the health or safety of members of the public; or

"(b) If, in the opinion of the Minister, the relevant committee, adviser, Government department, statutory body, or person will take reasonable steps to ensure the confidential supporting information is kept confidential, disclose that confidential supporting information to–

"(i) An advisory or technical committee appointed under section 8 of this Act; or

"(ii) The Medicines Classifications Committee appointed under section 9 of this Act; or

"(iii) The Medicines Review Committee established under section 10 of this Act; or

"(iv) Any adviser for the purpose of obtaining advice about the medicine to which the confidential supporting information relates; or

"(v) A Government department or statutory body for the purposes of the Government department or statutory body; or

"(c) Disclose that confidential supporting information to any one or more of the following–

"(i) The World Health Organisation:

"(ii) The Food and Agriculture Organisation:

"(iii) Any regulatory agency of a WTO Country:

"(iv) Any person or organisation, or a person or organization within a class or classes of persons or organizations, approved by regulations made under this Act.

"(2) The power to grant consent under subsection (1) (a) (i) of this section may be exercised by a person other than the applicant referred to in that subsection if–

"(a) That applicant–

"(i) Has notified the Minister in writing that that other person may grant that consent; and

"(ii) Has not notified the Minister in writing that that person's authority to grant that consent has been withdrawn; or

"(b) That applicant's rights in respect of the relevant confidential supporting information have been transferred to that person and the applicant or that other person has notified the Minister in writing of the transfer."

3. Regulations–

Section 105 of the principal Act is hereby amended by inserting, after paragraph (a), the following paragraph:

"(aa) Approving persons or organizations, or classes of persons or organizations, for the purposes of section 23c (1) (c) (iv) of this Act:".

This Act is administered in the Ministry of Health.

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