Medicines Act
(Chapter 176)

Revised Edition 1985
Act 52 of 1975
S156/93
7 of 1998

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Protection of Confidential Supporting Information About Innovative Medicinal Product

19A.—(1) Where the licensing authority receives, or has received not more than 5 years before the commencement of the Medicines (Amendment) Act 1998, an innovative medicinal product application and confidential supporting information, the licensing authority, during the protected period in relation to that confidential supporting information—

(a) shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the licensing authority; and

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

(2) For the purposes of this section and section 19B, unless the context otherwise requires—

"application" means an application for a product licence;

"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 medicinal product application; and

(b) about the medicinal product that is or was, as the case may be, the subject of that application;

"innovative medicinal product application" means—

(a) in relation to an application made after the commencement of the Medicines (Amendment) Act 1998, an application that refers to a substance—

(i) that is an ingredient in the manufacture or preparation of the medicinal product to which the application relates; and

(ii) that has not, before that application is received by the licensing authority, been referred to in any other application as an ingredient in the manufacture or preparation of the medicinal product; and

(b) in relation to an application made before the commencement of the Medicines (Amendment) Act 1998, an application that referred to a substance—

(i) that is or was, as the case may be, an ingredient in the manufacture or preparation of the medicinal product to which the application related; and

(ii) that had not, before that application was received by the licensing authority, been referred to in any other application as an ingredient in the manufacture or preparation of the medicinal product;

"licensing authority" includes any officer designated by the licensing authority under section 4(2) to determine an application for a product licence;

"protected period", in relation to confidential supporting information relating to an innovative medicinal product application received by the licensing authority, means a period of 5 years from the date the innovative medicinal product application is or was, as the case may be, received by the licensing authority.

Circumstances Where Protection Under Section 19A Does Not Apply

19B.—(1) Notwithstanding section 19A, the licensing authority 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 licensing authority, necessary to protect the health or safety of members of the public;

(b) disclose that confidential supporting information to—

(i) a Government department or statutory body for the purposes of the Government department or statutory body; or

(ii) any adviser engaged by the licensing authority to advise on any aspect of the medicinal product to which the confidential supporting information relates or is related,

if, in the opinion of the licensing authority, the Government department, statutory body or adviser, as the case may be, will take reasonable steps to ensure the confidential supporting information is kept confidential; 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 advisory committee established under section 73;

(v) any person or organisation, or a person or organisation within a class or classes of persons or organisations, approved by regulations made under this Act, if the disclosure is in accordance with such conditions as may be specified in the regulations.

(2) The power to grant consent under subsection (1)(*a*)(i) may be exercised by a person other than the applicant referred to in that subsection if—

(a) that applicant—

(i) has notified the licensing authority in writing that that other person may grant that consent; and

(ii) has not notified the licensing authority 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 licensing authority in writing of the transfer.

(3) For the purposes of this section, "WTO Country" means a country that is a party to the Agreement establishing the World Trade Organisation adopted at Marrakesh on 15th April 1994.