

法規名稱：MEMORANDUM OF UNDERSTANDING BETWEEN THE TAIPEI ECONOMIC AND CULTURAL OFFICE IN AUSTRALIA AND THE AUSTRALIAN COMMERCE AND INDUSTRY OFFICE IN TAIPEI CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC GOODS

簽訂日期：民國 99 年 04 月 13 日

生效日期：民國 99 年 04 月 13 日

1. BACKGROUND

The Taipei Economic and Cultural Office in Australia and the Australian Commerce and Industry Office in Taipei (hereinafter referred to as the “ Parties ”) wish to develop a cooperative relationship by exchanging information in the area of therapeutic goods regulation.

Implementing Authorities:

This Memorandum of Understanding (MOU) will be implemented on behalf of

- a) the Taipei Economic and Cultural Office in Australia by the Taiwan Food and Drug Administration (TFDA), Taiwan.
- b) the Australian Commerce and Industry Office in Taipei by the Therapeutic Goods Administration (TGA), Australia.

2. OBJECTIVES

The objectives of this MOU are:

- a. to promote an understanding between the TFDA and the TGA of each other ’ s regulatory requirements and processes;
- b. to facilitate the exchange of information and documentation relating to the regulation of therapeutic goods; and
- c. to enable the development of collaborative activities between the TFDA and the TGA.

3. DEFINITIONS

3.1 In this MOU, the term “therapeutic goods” means:

- a. therapeutic goods as defined in Section 3 of the Australian Therapeutic Goods Act 1989, as amended from time to time; and
- b. pharmaceuticals and medical devices as defined in Taiwan’ s regulations. The term "medicament" as used in the Pharmaceutical Affairs Act 2006; as amended from time to time.

3.2 In this MOU, the term “confidential information” means information that:

- a. is by its nature confidential;
- b. is designated by an implementing authority to be confidential; or

- c. is designated by law to be confidential, but does not include information which is or becomes public knowledge.

4. AREA OF COOPERATION

- 4.1 Acting within the framework of their power, interests and responsibilities, the Implementing Authorities will:
 - a. establish avenues of communication to facilitate the exchange of information and documents about the regulation of therapeutic goods by each implementing authority, including policies, practices, standards, manufacturing quality, laboratory testing, pre-market assessment, post-market vigilance/surveillance, market compliance and requirements for the regulation of therapeutic goods; and
 - b. explore the potential for collaborative activities, which may include the exchange of personnel, observing inspections and the planning of joint workshops, seminars and meetings.

5. CONFIDENTIALITY

5.1 TFDA

- 5.1.1 Nothing in this MOU requires TFDA to release confidential information to TGA.
- 5.1.2 Unless otherwise required by law, TFDA will not disclose any information received from the TGA under this MOU, except with the written consent of the TGA.
- 5.1.3 Unless otherwise required by law, the TFDA will not use the information disclosed to it under this MOU for any other purpose than the performance of its therapeutic goods regulatory activities.

5.2 TGA

- 5.2.1 Nothing in this MOU requires the TGA to release confidential information to TFDA.
- 5.2.2 Unless otherwise required by law, the TGA will not disclose any information received from the TFDA under this MOU, except with the written consent of the TFDA.
- 5.2.3 Unless otherwise required by law, the TGA will not use the information disclosed to it under this MOU for any other purpose than the performance of its therapeutic goods regulatory activities.

6. FINANCIAL ARRANGEMENTS

- 6.1 The Implementing Authorities will be responsible for the administration and expenditure of their respective resources in relation to activities performed under this MOU.
- 6.2 The Implementing Authorities mutually determine that activities conducted by an Implementing Authority at the request of the other Implementing Authority, will be

provided on the basis of full cost recovery (including taxes, duties and charges), unless otherwise mutually determined in writing between the Implementing Authorities.

7. VARIATION

This MOU may be amended at any time by the mutual consent in writing of the Parties.

8. SETTLEMENT OF DISPUTES

Any disputes between the Parties arising from the interpretation or implementation of this Memorandum of Understanding will be settled amicably through consultations between the Parties.

9. EFFECTIVE DATE

This MOU will come into effect upon the date of the signatures for the Parties and will continue in effect until terminated in accordance with clause 11.

10. AGENCY CONTACT

The liaison officers responsible for the administration of this MOU are:

- a. for the TFDA, the person holding the position of Head, Planning and Research Development Division of the TFDA; and
- b. for the TGA, the person holding the position of Head, Executive Support Unit of the TGA.

11. TERMINATION

11.1 Either Party may, at any time, give written notice of termination of this MOU to the other Party. This MOU (excepting clause 5) will terminate six months after the date of receipt of the notice of termination by the other Party.

11.2 The termination of this MOU will not affect the implementation of arrangements made under it before notice of termination was given, unless otherwise mutually determined in writing by the Parties.

Signed at Canberra on April 13, 2010, in duplicate in the Chinese and English languages, the two texts being equally valid. In case of any divergence in interpretation, the English text governs.

by the Representative of
the Taipei Economic and
Cultural Office in
Australia

by the Representative of
the Australian Commerce
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