附件

駐澳大利亞臺北經濟文化辦事處
與
澳大利亞商工辦事處間
藥物管理合作

瞭解備忘錄

一、 背景

「駐澳大利亞臺北經濟文化辦事處」及「澳大利亞商工辦事處」(以下簡稱「雙方」)爲建立藥物管理之資訊交換合作關係，簽訂本瞭解備忘錄。

執行單位

本瞭解備忘錄執行單位爲:

1. 臺灣食品藥物管理局(以下簡稱 TFDA)，代表駐澳大利亞臺北經濟文化辦事處。
2. 澳洲藥物管理局(以下簡稱 TGA)，代表澳大利亞商工辦事處。

二、 合作宗旨

本瞭解備忘錄之宗旨爲:

1. 促進 TFDA 及 TGA 藥物管理法規及流程之瞭解；
2. 提供藥物管理資訊之訊息交換管道；
3. 鼓勵 TFDA 及 TGA 發展合作活動。

三、定義

3.1 本瞭解備忘錄所稱之「藥物」，係指：

1.澳洲 1989 年藥物法第三節所定義之藥物，可依需要或實際情形隨時修改之；以及

2.臺灣法規所定義之藥品及醫療器材，即 2006 年藥事法所稱之「藥物」，可依需要或實際情形隨時修改之。

3.2 本瞭解備忘錄所規範之「機密資訊(信息)」爲:

1. 本身爲機密形式之資訊(信息)；

2. 由一方認定爲機密之資訊(信息)；
3. 法律定義下之機密資訊(信息)，

以上不包含已公開之資訊(信息)。

四、合作範圍

4.1 執行單位在其權限、利益及任務之架構下將:

1. 成立藥物管理相關訊息及文件交換之溝通管道，相關訊息及文件包含政策、規範、準則、生產品質、實驗室檢驗、上市前審查、上市後監視、市場管理及藥物管理法規等相關訊息。
2. 探究合作活動之可能性，包含人員交流、觀摩查廠、舉辦訓練、研討會及相關會議。

五、資訊(信息)保密

5.1 TFDA

5.1.1 本瞭解備忘錄不需 TFDA 對 TGA 釋出機密資訊(信息)。

5.1.2 除非經法律核可，TFDA 未取得 TGA 書面同意前，不得公開 TGA 在本瞭解備忘錄下所提供之資訊(信息)。

5.1.3 除非經法律核可，TFDA 不得爲履行藥物管理外之其他目的，使用自本瞭解備忘錄下所取得之資訊(信息)。

5.2 TGA

5.2.1 本瞭解備忘錄不需 TGA 對 TFDA 釋出機密資訊(信息)。

5.2.2 除非經法律核可，TGA 未取得 TFDA 書面同意前，不得公開 TFDA 在本瞭解備忘錄下所提供之資訊(信息)。

5.2.3 除非經法律核可，TGA 不得爲履行藥物管理外之其他目的，使用自本瞭解備忘錄下所取得之資訊(信息)。

六、財務規劃

6.1 執行單位必須自籌行政或在本瞭解備忘錄下活動之經費。

6.2 如一執行單位要求另一執行單位舉辦特定活動，前者須提供後者活動所需之所有經費 (包含各類稅項)，但執行單位另有書面約定者，不在此限。

七、內容異動

本瞭解備忘錄得經雙方書面同意修正之。

八、爭端解決

雙方因本瞭解備忘錄之闡釋或履行而引起之任何爭端將透過雙

方磋商友好地解決。

九、簽署生效

本瞭解備忘錄自雙方簽署之日起生效，並持續有效至雙方依照第十一條終止。

十、聯繫主體

本瞭解備忘錄雙方之聯繫主體爲:

1. TFDA：企劃及科技管理組主管。
2. TGA： 行政單位主管。

十一、終止

11.1 任一方得隨時以書面通知另一方終止本瞭解備忘錄。本瞭解備忘錄(除第五條外)於另一方收到終止通知後六個月起終止。

11.2 除非另經雙方共同書面約定外，於終止前依本瞭解備忘錄提供的資訊（信息）或執行的行動，仍然有效。

本瞭解備忘錄以中文及英文各繕製 2 份，2 種文本同一作準，於 坎培拉 在 2010年4月13日 簽署，雙方解釋上如有歧見，以英文本爲主。

林松德 ..... 駐澳大利亞臺北經濟文化辦事處代表	..... 澳大利亞商工辦事處代表

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

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 13 April 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 and Industry Office in Taipei