駐菲律賓臺北經濟文化辦事處與馬尼拉經濟文化辦事處間
健康產品管理合作瞭解備忘錄

本瞭解備忘錄之制定及簽署者為：
駐菲律賓臺北經濟文化辦事處由駐菲代表王樂生先生代表(以下簡稱TECO)；
馬尼拉經濟文化辦事處由駐臺代表安東尼・白熙禮先生代表(以下簡稱MECO)；

鑑於，期望促進臺灣食品藥物管理署(TFDA)及菲律賓食品藥物管理署(FDAP)相互瞭解對方之管理要求及流程；
鑑於，便於交換健康產品管理相關資訊及文件；及
鑑於，能發展臺灣食品藥物管理署與菲律賓食品藥物管理署間之合作活動；
鑑於，「健康產品」一詞係指人類使用之健康產品，包括臺灣食品藥物管理署及菲律賓食品藥物管理署管理之食品、藥品、醫療器材及化粧品；
鑑於，TECO及MECO，以下簡稱「參與雙方」，希能簽署本瞭解備忘錄；
是以，為考慮上述前提，經參與雙方達成以下協議：

第一條　參與雙方之責任

參與雙方將各自指定代表機關來執行本瞭解備忘錄。TECO之執行機關為臺灣食品藥物管理署(TFDA)，MECO之執行機關為菲律賓食品藥物管理署(FDAP)。

第二條　合作領域

在其權限、利益及責任之架構下行事，執行機關將：

一、建立健康產品管理相關資訊及文件交換之溝通管道，包括政策、規範、標準、製造、品質、實驗室檢驗、上市前評估、上市後監視、藥物警戒、市場符合性及健康產品之管理要求；

二、探究合作活動之可能性，可包括人員交流、觀摩查廠與規劃聯合研討會、討論會及會議。

三、制定適當之監管合作活動，包括訓練計畫及科學討論或合作。適當之監管活動可包括但不限於下列：

（一）發展及協調法規稽查員之培訓方案；

（二）與優良臨床試驗規範(GCP)運用相關之技術交流及培訓，以確保受試者之安全與有效臨床試驗數據之收集；及

（三）培訓及交流評估方法之制定、查廠技巧、電腦資料庫之建立、評估報告之標準格式，及技術指導文件之制定；

四、制定一個聯合疫苗開發研究技術措施、重點研究及應用研究，以進一步完善及促進疫苗之安全性。

五、促進參與有關法規調和之國際活動

第三條　本瞭解備忘錄之執行

一、除非另有約定，參與雙方將自負執行本瞭解備忘錄之成本。

二、對本瞭解備忘錄之合作活動費用所進行之財務規劃，將由雙方共同依個案之可用資金和其他資源而決定。

三、本瞭解備忘錄所定計畫、方案及具體活動之執行，將取決於雙方共同以書面決定之明確規劃。

第四條　資訊保密

一、TFDA

（一）本瞭解備忘錄不要求 TFDA 釋出機密資訊給 FDAP。

（二）除非法律另有規定，TFDA 於未取得 FDAP 書面同意前，將不會公開 FDAP 在本瞭解備忘錄下所提供之資訊。

（三）除非法律另有規定，TFDA 將不會為履行健康產品管理外之其他目的，使用自本瞭解備忘錄下所取得之資訊。

二、FDAP

（一）本瞭解備忘錄不要求 FDAP 釋出機密資訊給 TFDA。

（二）除非法律另有規定，FDAP 於未取得 TFDA 書面同意前，將不會公開 TFDA 在本瞭解備忘錄下所提供之資訊。

（三）除非法律另有規定，FDAP 將不會為履行健康產品管理外之其他目的，使用自本瞭解備忘錄下所取得之資訊。

第五條　爭端解決

參與雙方因本瞭解備忘錄之闡釋或履行而引起之任何爭端，將透過參與雙方磋商友好地解決。

第六條　修正

本瞭解備忘錄得經參與雙方書面同意隨時修正之。

第七條　有效性及持續期間

一、本瞭解備忘錄自參與雙方最後簽署之日起生效。

二、本瞭解備忘錄將持續有效，除非任一參與方予以暫停或終止：

（一）任一參與方於書面預先通知另一參與方有關暫停本瞭解備忘錄之決定後，得暫停本瞭解備忘錄之適用。

（二）任一參與方於三個月前以書面預先通知另一參與方其終止本瞭解備忘錄之決定後，得終止本瞭解備忘錄。

三、除非另經參與雙方共同決定外，給予終止通知前所進行之任何活動或計畫將不受本瞭解備忘錄終止之影響。

第八條　聯繫主體

本瞭解備忘錄行政事務之聯繫主體為：

一、TFDA：企劃及科技管理組主管。

二、FDAP：政策規劃室主管 人員。

為此，雙方簽署人各經合法授權，爰簽署本瞭解備忘錄，以昭信守。本瞭解備忘錄以中文及英文各繕兩份，兩種文本同一作準。解釋上如有歧見，以英文本為準。

駐菲律賓臺北經濟文化辦事處	馬尼拉經濟文化辦事處
王樂生	
王樂生	安東尼・白熙禮
代表	常駐代表
（日期）SEPT 12, 2014	（日期）SEPT 12, 2014
（地點）MAKATI CITY, MANILA	（地點）MAKATI CITY, MANILA

見證人：

葉明功	
葉明功博士	KENNETH Y. HARTIGAN-GO, M.D.
臺灣食品藥物管理署署長	菲律賓食品藥物管理署署長

MEMORANDUM OF UNDERSTANDING BETWEEN THE TAIPEI ECONOMIC AND CULTURAL OFFICE IN THE PHILIPPINES AND THE MANILA ECONOMIC AND CULTURAL OFFICE IN TAIWAN ON COOPERATION IN THE REGULATION OF HEALTH PRODUCTS

This Memorandum of Understanding (MoU) made and entered into between:

The TAIPEI ECONOMIC AND CULTURAL OFFICE in the Philippines represented by MR. RAYMOND L.S. WANG, Representative, hereinafter referred to as "TECO";

and

The MANILA ECONOMIC AND CULTURAL OFFICE in Taiwan represented by MR. ANTONIO I. BASILIO, Resident Representative, hereinafter referred to as "MECO";

WHEREAS, desiring to promote an understanding between the Taiwan Food and Drug Administration (TFDA) and the Food and Drug Administration Philippines (FDAP) of each other's regulatory requirements and processes;

WHEREAS, to facilitate the exchange of information and documentation relating to the regulation of health products; and

WHEREAS, to enable the development of collaborative activities between the TFDA and the FDAP;

WHEREAS, the term "Health Product" refers to human use health products including food, drugs, medical devices and cosmetics, which are regulated by TFDA and FDAP;

WHEREAS, the TECO and MECO, hereinafter referred to as "Participants" wish to enter into this Memorandum of Understanding (MoU);

NOW THEREFORE, for and in consideration of the foregoing premises, the Participants have come to the following understanding:

PARAGRAPH I
Responsibilities of Participants

The Participants will designate respectively, a representative agency to implement this MoU. For TECO, the implementing agency is the Taiwan Food and Drug Administration (TFDA), and for the MECO, the implementing agency is the Food and Drug Administration Philippines (FDAP).

PARAGRAPH II
Areas of Cooperation

Acting within the framework of their power, interests and responsibilities, the Implementing Agencies will:

1. Establish avenues of communication to facilitate the exchange of information and documents about the regulation of health products by each implementing agency, including policies, practices, standards, manufacturing, quality, laboratory testing, pre-market assessment, post-market surveillance, pharmacovigilance, market compliance and requirements for the regulation of health products;

2. Explore the potential for collaborative activities, which may include the exchange of personnel, observing inspections and the planning of joint workshops, seminars and meetings.

3. Develop appropriate regulatory cooperative activities, including training programs and scientific discussions or cooperation. Appropriate regulatory cooperative activities may include but not limited to the following:

    a. Development and coordination of the training programs for regulatory inspectors;
    b. Technical exchanges and training relating to the use of Good Clinical Practice (GCP) to ensure the safety of human subjects and the collection of valid clinical data; and
    c. Training and exchange on the development of evaluation methods, inspection techniques, establishment of computer databases, evaluation report standard formats, and the development of technical guidance documents;

4. Develop a joint research on vaccine development with focus on technological initiatives and applied research to further improve and promote vaccine safety.
5. Promote the participation of each agencies in international activities concerning regulatory convergence.

PARAGRAPH III
Implementation of this MoU

1. Unless otherwise agreed upon, each Participant will be responsible for the costs in the implementation of this MoU.

2. Financial arrangements to cover expenses for cooperative activities under this MoU will be mutually decided upon, on a case-to-case basis and subject to the availability of funds and other resources.

3. The implementation of plans, programs and activities as specified under this MoU will be subject to specific arrangements to be mutually decided in writing.

PARAGRAPH IV
Confidentiality

1. TFDA
   a. Nothing in this MoU requires TFDA to release confidential information to FDAP.
   b. Unless otherwise required by law, TFDA will not disclose any information received from the FDAP under this MoU, except with the written consent of the FDAP.
   c. 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 health product regulatory activities.

2. FDAP

   a. Nothing in this MoU requires the FDAP to release confidential information to TFDA.
   b. Unless otherwise required by law, the FDAP will not disclose any information received from the TFDA under this MoU, except with the written consent of the TFDA.
   c. Unless otherwise required by law, the FDAP will not use the information disclosed to it under this MoU for any other purpose than the performance of its health product regulatory activities.

PARAGRAPH V
Settlement of Disputes

Any disputes between the Participants arising from the interpretation or implementation of this MoU will be settled amicably through consultations between the Participants.

PARAGRAPH VI
Amendment

This MoU may be amended at any time by the mutual consent in writing of the Participants.

PARAGRAPH VII
Effectivity and Duration

1. This MoU will come into effect upon the date of the last signatures of the Participants.

2. This MoU will remain effective unless suspended or terminated by either Participant,
   a. Either Participant may suspend the application of this MoU upon prior written notice to the other Participant of its decision to suspend this MoU.
   b. Either Participant may terminate this MoU upon three (3) months prior written notice to the other Participant of its decision to terminate this MoU.

3. The termination of this MoU will not affect the implementation of any on-going activity or project before the notice of termination was given, unless both Participants mutually decide otherwise.

PARAGRAPH VIII
Agency Contact

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

1. for the TFDA, the person holding the position of Head, Planning and Research Development Division of the TFDA; and
2. for the FDAP, the person holding the position of the Head of Policy Planning Office.

IN WITNESS WHEREOF the undersigned, being duly authorized thereto, have signed this MoU in duplicate in the Chinese and English languages, the two texts being equally valid. In case of any divergence in interpretation, the English text shall prevail.

For:

THE TAIPEI ECONOMIC AND CULTURAL OFFICE IN THE PHILIPPINES

RAYMOND L.S. WANG
Representative
(Date) Sep 12, 2014
(Place) MAKATI CITY, MANILA

THE MANILA ECONOMIC AND CULTURAL OFFICE IN TAIWAN

ANTONIO I. BASILIO
Resident Representative
(Date) SEPT 12, 2014
(Place) MAKATI CITY, MANILA

Witnessed by:

MING-KUNG YEH, Ph.D.
Director-General
Food and Drug Administration
Ministry of Health and Welfare
Taiwan

KENNETH Y. HARTIGAN-GO, M.D.
Director
Food and Drug Administration
Republic of the Philippines