



**MEMORANDUM OF UNDERSTANDING
BETWEEN
THE TAIWAN FOOD AND DRUG ADMINISTRATION
AND
THE FEDERAL OFFICE FOR SAFETY IN HEALTH CARE/
AUSTRIAN AGENCY FOR HEALTH AND FOOD SAFETY
ON COOPERATION CONCERNING SAFETY INFORMATION
OF MEDICAL PRODUCTS**

This Memorandum of Understanding is entered into by the Taiwan Food and Drug Administration (hereinafter referred to as "TFDA") and the Federal Office for Safety in Health Care / Austrian Agency for Health and Food Safety (hereinafter referred to as "BASG/AGES")(hereinafter referred to as "the Parties"), for the purposes of furthering cooperation and collaboration between the Parties and fostering information exchange concerning safety of medical. In this Memorandum of Understanding, the term "medical products" includes medicinal products and medical devices.

The Parties agree to cooperate on equal and reciprocal terms and ensure that there is adequate exchange of information concerning pharmaceuticals and medical devices to the benefit of the Parties.

This Memorandum of Understanding will be implemented directly between TFDA and BASG/AGES. Each Party will designate competent agents as contact point to enhance information-sharing between the Parties in dealing with safety of medical products that may constitute a public health emergency of international concern on request. The sharing information may include the each Party's policies, practices, standards, manufacturing quality, laboratory testing, pre-market assessment, post-market vigilance/surveillance, inspection reports, market compliance and requirements for the regulation of medical products. Each Party is responsible for its own expenses for the above collaboration.

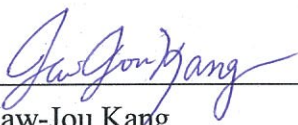
This Memorandum of Understanding shall enter into force upon the date of the later signature and remain effective until terminated by either Party upon 365 days prior notice in writing to the other Party. This Memorandum of Understanding may be modified by written agreement between the Parties.




This Memorandum of Understanding is done in duplicate in the English language.

For the Taiwan Food and Drug
Administration

For the Austrian Agency for Health and Food
Safety



Dr. Jaw-Jou Kang
Director-General, TFDA

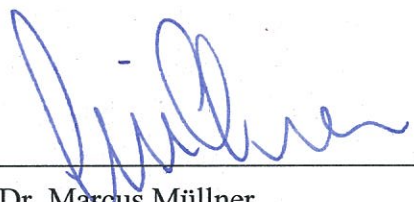


Dr. Heinz Frühauf
CEO, AGES

Date: 6-19-2013

For the Austrian Federal Office for Safety in
Health Care

Place: Taipei



Dr. Marcus Müllner
Head AGES Division Medizinmarktaufsicht
Operational officer BASG

Date: 3.7.2013

Place: Vienna

臺灣食品藥物管理局
(於 102 年 7 月 23 日改制為食品藥物管理署)

與

奧地利醫療保健安全聯邦辦公室/健康暨食品安全署

醫藥品安全資訊合作瞭解備忘錄(中譯文)

臺灣食品藥物管理局(以下簡稱 TFDA)與奧地利醫療保健安全聯邦辦公室/健康暨食品安全署(以下簡稱 BASG/AGES)(以下簡稱「雙方」)，為增進雙方醫藥品安全及其相關事務之資訊交流及合作，爰簽訂本瞭解備忘錄。本瞭解備忘錄中所稱之「醫藥品」包含藥品及醫療器材。

雙方同意在平等互惠原則下進行合作，並確保藥品及醫療器材之資訊交換

使雙方均蒙其利。

本瞭解備忘錄將直接由 TFDA 與 BASG/AGES 負責執行，各方將指派主管人員擔任聯絡窗口，於一方要求之情況下，促進雙方可能構成國際關切之醫藥品安全之資訊交換，其包含政策、規範、準則、生產品質、實驗室檢驗、上市前審查、上市後監視、查廠報告、市場管理及藥物管理法規等相關訊息。雙方自行負擔前項合作所需之費用。

本瞭解備忘錄自雙方最後簽署之日起生效，並持續有效，除非任一方

於 365 日前以書面通知對方終止之。本瞭解備忘錄得經雙方書面同意修正之。

本瞭解備忘錄以英文繕製及簽署一式二份。

臺灣食品藥物管理局

奧地利健康暨食品安全署

康照洲 博士

Dr. Heinz Frühauf

局長

執行長

日期：2013 年 6 月 19 日

奧地利醫療保健安全聯邦辦公室

地點：台北

Dr. Marcus Müllner

奧地利健康暨食品安全署

藥品市場監督處處長

BASG 營運官

日期：2013 年 7 月 9 日

地點：維也納