

法規名稱：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

簽訂日期：民國 102 年 07 月 09 日

生效日期：民國 102 年 07 月 09 日

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 Fruhauf CEO,
AGES

Date:
2013.06.19
Place: Taipei

For the Austrian Federal
Office for Safety in Health
Care Dr. Marcus Mullner
Head AGES Division
Medizinmarktaufsicht
Operational officer BASG
Date: 2013.07.09
Place: Vienna