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International Cooperation and Cross-strait Exchanges

Section 1. International Cooperation and Communication

Section 2. Cross-strait Communication

Involvement of international organizations

● Official Member

APEC

The “Good Registration Management” roadmap and “Good Submission Practice Guideline” jointly submitted by Taiwan and Japan have been endorsed by RHSC.

AHWP

As one of the founding members, Taiwan has been the Chair of AHWP WG2-Pre-market: IVD Work Group for a long while, and developed four IVD-related international guidance documents endorsed by AHWP 2016.

● Observer

ICCR

For the first time attended ICCR as an observer and obtained first-hand information on the current status and trends of international cosmetics regulations.

EDQM

Attended 2016, The 1st European Pharmacopoeia Advisory Committee as an observer of EDQM, observed the process, focuses and operation of establishing European Pharmacopoeia.

ICH

TFDA attend ICH as observer to discuss and develop the international guidelines for pharmaceuticals review, which could promote regulatory harmonization

Bilateral consultation

Poland

Signed “Memorandum of Understanding on Cooperation Concerning Pharmaceutical Products and Medical Devices between Taiwan and Poland” to facilitate medical and pharmaceutical industry development.

Japan

Completed joint reviews of dental implant cases, established the foundation of mutual trust on pre-market review through the 4th Joint Conference of Taiwan and Japan on Medical Products Regulation.

European Union

For the first time attended “The 1st Europe cosmetics testing technology symposium” and “The 13th meeting of the Laboratory Network of Official Cosmetics Control Laboratories”, to establish communication channels for exchanging international cosmetics management regulations, standards and testing methods.

Indonesia

Recommended 3 national food certification laboratories to Indonesia Government, where had also been recognized by Indonesia Government. Assist domestic food businesses in exporting products to Indonesia.

Participation and hosting of large-scale international symposiums

AOAC

TFDA gave a lecture in “Taiwan Section Business Meeting” at 130th AOAC Annual Meeting to present the competence of Taiwan on analyses.

APMP

TFDA was invited to present articles at “Grain Products Safety Measurement and Standards Symposium” hosted by APMP to present TFDA previous research outcomes in fungi toxin area

Food Conference

Hosted the 8th AOAC Internal, Taiwan Section Annual Meeting, expressing the capability of testing in analytical area and establishing communication channels with international experts.

Medicinal Product Conference

Hosted “2016 Asia-Pacific Good Registration Management Practice Scientific Excellence Center Preliminary Symposium” and trained seed trainers of Good Registration Management Practices from 15 APEC economic members.

Medical Device Conference

Hosted “2016 International Medical Devices PIC/S and Implementation Symposium”, and exchanged opinions about management regulations, pre-market review process, post-market surveillance and UDI printing practice.

Cosmetics Symposium

Hosted “2016 International Symposium on Cosmetic Regulation” to help domestic cosmetic industry understand relevant product regulatory status and future trends.

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International Cooperation and Cross-strait Exchanges

International politics, economic and trade and medical health would mutually influence each other. One of the key strategies of the government's administration would be to align with international standards. Through international and cross-strait collaborations and exchanges, TFDA exchanges significant information, align with international standards and promote collaboration and development in the pharmaceutical and health industries and related provisions.

» Section 1. International Cooperation and Communication

Current Status

To improve the international visibility of Taiwan's food, medicinal products, medical devices, and cosmetic product quality and industries, TFDA actively participates in international harmonization organizations, hosts conferences on international regulations, and establishes platforms for bilateral partnerships to align with international standards.

Policies and Outcomes

1. Participate in international organizations and events

(1) Food

TFDA attended the Asia-Pacific Economic Cooperation (APEC) Sub-Committee on Standards and Conformance (SCSC) meeting from August 17 to 23, 2016. TFDA also attended the 67th routine meetings of WTO/SPS and the Expert Workshop on Harmonization of Pesticide Maximum Residue Limits (MRLs) to actively exchange food safety standards and activities with other members from October 22 to 30, 2016.

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(2) Medicinal products

TFDA has long-term participated in Regulatory Harmonization Steering Committee (RHSC) of Life Science Innovation Forum (LSIF) under Asia-Pacific Economic Cooperation (APEC). In February 2016, the APEC Regulatory Harmonization Steering Committee (RHSC) endorsed the Roadmap to promote Good Registration Management jointly proposed by Taiwanese and Japanese Governments and “Good Registration Management Center of Excellence Pilot workshop” in Taiwan. The “Good Submission Practice (GSubP) Guideline for Applications” developed by Asia Partnership Conference of Pharmaceutical Associations (APAC) in cooperation with TFDA was endorsed by the RHSC as one of the APEC guidelines in April 2016.

(3) Medical devices

- A. Taiwan is one of the founding members of the Asian Harmonization Working Party (AHWP). TFDA official has long-term served as the Chair of In Vitro Diagnostic Devices Work Group (WG2 - Premarket: IVDD) for the AHWP technical committee and led the development of in vitro diagnostic medical devices (IVDs) international guidance documents endorsed as AHWP official documents. During 2016, TFDA completed 4 AHWP endorsed guidances. Moreover, the International Standard Organization / Technical Committee 212 (ISO/TC 212) also agreed on having a TFDA staff person to become member of the expert committee of work group 3 for TFDA to continue participating in the establishment of relevant standards.
- B. Attend the 9th “International Medical Device Regulators Forum (IMDRF)” annual meeting in Brasilia, Brazil from March 5 to 12, 2016 and a workshop on medical software by “Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)” to remain updated on the latest regulatory trends.
- C. Attend “The 21st Asian Harmonization Working Party (AHWP) Annual Meeting” in the Philippines from November 20 to 26, 2016 to participate in important decision making, give an update on the latest progress and future plans in IVDD Work Group (led by Taiwan) and discuss matters with regulatory representatives from New Southbound countries.

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(4) Cosmetics

TFDA attended “International Cooperation on Cosmetics Regulation (ICCR)” (Figure 7-1) on behalf of Taiwan between July 12-14, 2016 for the first time and served as the 10th Meeting Observer to further understand current status and trends of international cosmetics regulations and to enhance the international visibility of its cosmetics management .



Figure 7-1 International Cooperation on Cosmetics Regulation (ICCR)

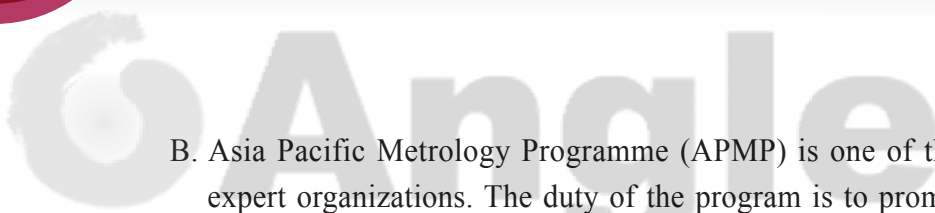
(5) Controlled drugs

- A. Attend “National Prescription Drug Abuse and Heroin Summit” from March 21 to April 2, 2016 to observe US experience in drug abuse prevention.
- B. Attend “The 47th American Addictive Drug Association Annual Meeting” between April 12-19, 2016 and discuss addiction medicine, overdose prevention and marijuana-related issues with experts from the US and Canada as the reference for establish our policies.
- C. Attend “The 8th Global Pain Management Association” between May 19-25, 2016 to discuss pain management, clinical/technical training and international collaboration issues with global experts and scholars.

2. Multi-channel communications about international tests

(1) Food area

- A. The 130th AOAC Annual Meeting was held in Dallas, USA during September 18-21, 2016. A total of more than one thousand experts and scholars attended the meeting. TFDA presented articles as well as 3 posters relating to fight against food adulterations, and addressed a keynote speech during organizer-arranged section “Taiwan Section Business Meeting” to exhibit the competitiveness of testing technology in Taiwan and establish communication channel with international experts.



B. Asia Pacific Metrology Programme (APMP) is one of the five APEC district expert organizations. The duty of the program is to promote the development, collaboration and freedom of trade between individual Asian-Pacific Economic Bodies. The organization hosts a “Seminar for grain products safety measurements and standards” to discuss and exchange opinions and comments relating fungi toxins and heavy metals. TFDA was invited to orally present the research outcomes in fungi toxin studies (Figure 7-2).



Figure 7-2 Seminar for grain products safety measurements and standards

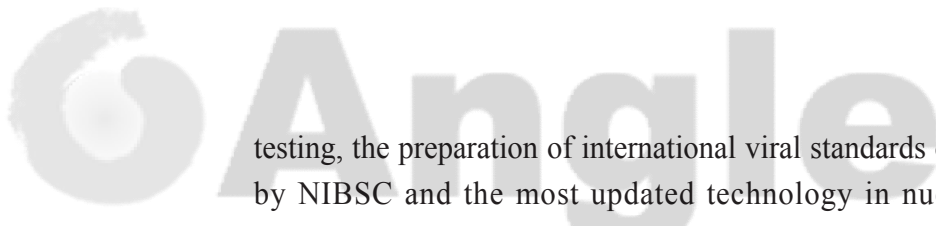
(2) Medicinal product areas

A. TFDA attended the 1st EP Committee Meeting from March 15 to 16, 2016 (Figure 7-3) as Observer of European Directorate for the Quality of Medicines & Healthcare, Council of European (hereinafter referred to as EDQM) to learn about the preparation process, highlights and operation model of EP and exchange opinions on medicinal product quality requirements and testing technology with representatives from different countries.

B. TFDA attended “2016 23rd blood-borne pathogen screening and monitoring seminar” jointly hosted by International Plasma Fractionation Association (IPFA) and Paul Ehrlich-Institut (PEI) between May 23-28, 2016, and “2016 Standard blood-borne pathogen genetic amplification seminar” hosted by NUBSC between June 5-10, 2016 to improve the knowledge about blood-borne pathogen



Figure 7-3 2016 The 1st European Pharmacopoeia (EP) Committee Meeting



testing, the preparation of international viral standards of blood-borne pathogens by NIBSC and the most updated technology in nucleic acid amplification techniques and genetic sequencing analysis.

(3) Cosmetics area

Attending Global Summit on Regulatory Science (GSRs) hosted by US FDA between September 5-11, 2016. The theme was the standards and applications of nanotechnology. TFDA oral presented 2 articles on the meeting and communicated with international experts.

3. Bilateral activities (including signing related agreements and Memorandum of Understanding (MOU))

- (1) Taiwan and Poland signed “TAIWAN-POLAND Medicinal Products and Medical Devices Memorandum of Understanding (MOU)” on January 14, 2016 and successfully expanded our international collaborations. The MOU allows both parties exchanging information regarding medicinal products and medical device pre-marketing management and clinical trials, so industry may have provision harmonization, improved efficiency and predictable benefits; in the meanwhile, the public may access to safe and good quality medicinal products.
- (2) Attend Taiwan-EU Economic and Trade Consultation Pharma Working Group Meeting on April 27 and October 12, 2016, so both sides exchanged opinions about strengthening medical devices and cosmetics laws, administrative legal entities and bilateral collaborations.
- (3) TFDA firstly designates a staff to attend “The 1st Europe cosmetics testing technology symposium” and “The 13th meeting of the Laboratory Network of Official Cosmetics Control Laboratories” hosted by the European Network of Official Cosmetics Control Laboratories (OCCLs) between June 14-19, 2016. Attend “The 5th European Union post-marketing surveillance platform meeting of cosmetic product analysis” and “The 14th European Network of Official Cosmetics Control Laboratories” hosted by the OCCLs between December 4-9 to establish communication channels for exchanging international cosmetics management regulations, standards and testing methods.
- (4) TFDA attended Nation Institution of Infection Disease (NIID) in Japan from June 26 to July 9, 2016 to demonstrate critical technology of novel virus-inactivation tests and the Plaque reduction neutralization test (PRNT) of JapENnc.

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第四屆台日醫藥交流會議

Figure 7-5 The 4th Joint Conference of Taiwan and Japan on Medical Products Regulation in 2016

- (5) TFDA attended the 10th TIFA meeting held in Washington D.C. on October 4, 2016 to give explanations of its future cosmetics management, labeling and plans to the U.S. delegation. Both sides also discussed marketing procedures of medical devices.
- (6) Attend the 4th Joint Conference of Taiwan and Japan on Medical Products Regulation (Figure 7-5) between December 7-8, 2016 to discuss topics related to pharmaceuticals and medical devices regulations, health insurance, and the outcomes of working groups. As for medical devices, both sides agreed to establish a medical device information sharing group. As for pharmaceuticals, representatives from the government and industry of Taiwan requested Japanese Government to revise bioequivalence guidelines in the meeting.
- (7) TFDA has recommended 3 accredited domestic food testing laboratories to Indonesian Government, which has been recognized by Department of Agriculture, Indonesia on November 8, 2016. Such laboratories are permitted to issue test reports of 103 fresh plant origin products. During exporting products, if domestic food businesses attach reports issued by one of the above laboratories, the products may directly pass custom inspection in Indonesia in order to reduce trade obstacles and ensure product quality.

4. Organize large-scale international seminars

- (1) TFDA and European Chamber of Commerce Taiwan jointly organized “2016 EU-Taiwan International food trade seminar” and “2016 Taiwan and European food safety management seminar” on March 9, 2016. TFDA addressed two speeches on

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the seminar, which were: “The Regulations and Implementation of the Systematic Inspection for Import Food According to *Act Governing Food Safety and Sanitation* in Taiwan” and “Introduction of Taiwan food traceability system”.

- (2) Host “International seminar for food adulteration and Chinese herb misuse” on March 29, 2016 and invite experts from the US and UK to Taiwan sharing their opinions regarding such hot topic among international society. Such seminar greatly improves national identification technology, non-specific target analysis and Chinese herbal medicinal products.
- (3) Host “International seminar for processing aids” on July 29, 2016 and invite experts and industry representatives from New Zealand, EU, USA, China, Japan and Taiwan sharing their opinions regarding laws, management and industrial application of processing aids, and the most updated management regulations as well as experience.
- (4) Host “International seminar for import food safety management” between September 29-30, 2016 and invite food safety officials from Austria, Hungary and Japan sharing their food management system and boarder inspection measures.
- (5) Host “2016 International Symposium on Cosmetic Regulation” on August 2, 2016 and invite government officials and experts from EU, Association of Southeast Asian Nations (ASEAN), USA, Japan and China to assist representatives of Taiwan’s government, industry and academic sectors in understanding the current regulatory status and future trends of related products.
- (6) Organize “International Conference on Medical Device Regulations for Implementation” in Taiwan on August 25, 2016. TFDA invited experts from EU, Canada and USA to address relevant regulation and future perspectives as well as Unique Device Identification (UDI). Additionally, experiences on pre-marketing



review process, post-marketing surveillance and UDI printing and labeling practices were exchanged (Figure 7-6).

Figure 7-6 International Conference on Medical Device Regulations for Implementation



Figure 7-7 2016 APEC Good Registration Management Regulatory Science Center of Excellence Pilot Workshop

- (7) Host “2016 International seminar for plastic food utensils, containers and packaging management policies” on October 13, 2016 to invite scholars and experts from Germany, UK and Japan sharing their opinions about risk assessment on food contact materials, the management of suppliers, the promotion of self-certification system. Representatives from relevant governmental departments, associations also attended such seminar to facilitate multi-channel communications.
- (8) TFDA scheduled a “2016 Global Health Forum in Taiwan-Session 9” with MOHW between October 23-24, 2016: Drug Accessibility and Quality Management, and invited the former Officials from Department of Health, the Philippines, Dr. Kenneth Y. Hartigan-Go, M.D. as well as Mr. Naoyuki Yasuda, Minister of International Department, PMDA, Japan, as speakers. Additionally, Chung-Hua Institution for Economic Research and Div. of International Collaboration, MOHW jointly organized “APEC International seminar for medical products trade and regulatory laws” and invited APEC officials from Indonesia, Vietnam, Malaysia, Thailand, the Philippines sharing their experience in management.
- (9) Host “APEC Good Registration Management Regulatory Science Center of Excellence Pilot Workshop” in Taiwan between November 15-17, 2016 and invite experts from USA, Japan, Taiwan, Singapore and UK to share their experience in practice. Seed trainers for Good Registration Management 15 APEC economic bodies are also trained at the seminar (Figure 7-7).

» Section 2. Cross-strait Communication

Current Status

Since the “Cross-Strait Food Safety Agreement” signed in 2008, TFDA plans to establish “Cross-strait collaboration plans for expanding food safety management” based

on the professions of academic/research fields or civil groups to promote cross-strait business cooperation in food safety. Through cross-strait department leaders/experts routine meetings, the organization of conferences or seminars, visiting food-related institutes and businesses, TFDA facilitates cross-strait collaboration in food safety surveillance and reaches consensus for management.

As of medicinal products, “Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs” was signed by Taiwan and China in 2010. TFDA thereby established “The Working Group on Safety Administration and Research and Development of Medicinal Products” and set four taskforces (i.e. medicinal products and cosmetics, medical devices, health food and testing methods) to discuss bilateral cooperation mechanisms, construct systemic work frame platform, assure product quality and safety management, handle significant safety incidents relating to medicinal products and coordinate standards and regulations. TFDA also implemented clinical trial collaboration projects to learn implementation outcomes from each other, and fully use bilateral medicinal products management and research capacity to develop safe and effective medicinal products for the public.

Policies and Outcomes

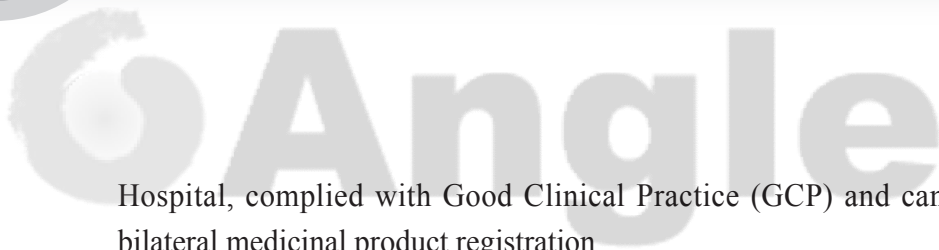
1. Systemic meetings

(1) Food

In 2016, TFDA hosted several cross-strait food safety seminars in Taiwan and invited representatives from food associations and businesses to participate, including “Seminars for Food safety risk evaluation: The meaning of scientific, operational regulations and food safety protection in Taiwan”, “Seminar for cross-strait online trading – food safety management regulations and practice”, “2016 International seminar for microorganisms and food safety management”, “Round table seminar for cross-strait microorganism standards and testing” and “Seminar for the application of big data in food safety management”.

(2) Medicinal products

TFDA and China Food and Drug Administration promulgated “Cross-strait clinical trial center collaboration – reduce test duplication on April 25, 2016 based on ” “Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs”: a total of 8 clinical trial centers, including National Taiwan University Hospital, Taipei Veterans General Hospital, Chang Gung Medical Foundation - Linkou branch, Tri-Service General Hospital, Peking Union Medical College Hospital, Peking University First Hospital, Shanghai Fudan University Zhongshan Hospital, Shanghai Jiao Tong University Ruijin



Hospital, complied with Good Clinical Practice (GCP) and can be the reference for bilateral medicinal product registration.

2. Border control information notification

- (1) TFDA and its Mainland China counterpart have established contact windows to notify nonconforming food products information in order to facilitate effective response and handling of these cases. 890 cases were reported by both parties in 2016. In 2016, 72 nonconforming food exported from Taiwan to China were reported majorly due to different standards of microorganism in food hygiene between the two parties. The rest factors included different boarder sampling rate between the two parties and China included nonconformity products but not involving food safety issues. In 2016, 118 incidents of food exported from China to Taiwan that failed to conform to Taiwan's regulations were reported, and most of them have beyond scope pesticide residues.
- (2) With regard to previous nonconformity products, those exported from China to Taiwan all have been returned or destroyed. For those exported from Taiwan to China that failed to conform to Taiwan's regulations of the responsible local health bureaus, the local health bureaus would take actions against the violating cases. Consultations were provided to businesses that food exports must comply with the regulations of the trading counterparty as well.

3. Harmonization of regulations and standards

Cross-Strait notification for addenda and revisions to regulations such as the “*food additive standards*” and “*food safety and sanitation standards*” was conducted through the contact window in order to promote exchange of relevant opinions and achieve mutual understanding. From the time of its establishment to the end of 2016, in total, both sides made 28 notifications on food additive standards and 12 notification on food safety and sanitation standards.

4. Others – cross-strait drug prevention

TFDA attended “the 2nd cross-strait drug abuse and drug prevention seminar” in August 2016. During this seminar, TFDA exchanged business and information with experts in relevant fields, achieve consensus, fully use bilateral management sources to enhance anti-drug efficacy.