

Cross-strait Cooperation Agreement on Medicine and Public Health Affairs

[The translation is for reference only. The interpretation of the agreement shall be based solely on the authentic copy in the Chinese language.]

In order to uphold the value of health for human beings, protect the rights and interests in health for the people on both sides of the Strait, and promote cross-strait cooperation and development in medicine and public health, the Straits Exchange Foundation and the Association for Relations Across the Taiwan Straits, after having conducted consultation based on equality, have agreed to the following conditions for cooperation in medicine and public health affairs:

Chapter 1: General Principles

1. Fields of Cooperation

Both Parties agree to engage in exchanges and cooperation based on the principles of equality and reciprocity in the following fields:

- (1) Prevention and control of communicable diseases;
- (2) Safety administration and research and development of medicinal products;
- (3) Research and exchange in traditional Chinese medicine and safety administration in traditional Chinese medicinal materials;
- (4) Assistance for medical emergency;
- (5) Other fields mutually agreed upon by both Parties.

2. Forms of Cooperation

Both Parties agree to engage in exchanges and cooperation through the following forms:

- (1) To promote periodical working meetings, professional visits, technical exchanges, and seminars or conferences, among others, by officials in charge of relevant subject matters;
- (2) To exchange, notify, provide inquiry assistance, and publish information, regulations, and actual practices and measures concerning relevant subject matters;
- (3) To engage in other forms of cooperation agreed upon by both Parties.

3. Contact Points

Contact persons designated by relevant agencies of the Parties in charge of the subject matters are responsible for the mutual communication for the matters set forth in this Agreement. If necessary, the Parties may also designate, through mutual agreement, other agencies to conduct communication.

The Straits Exchange Foundation and the Association for Relations Across the Taiwan Straits shall be responsible for communication concerning other relevant matters under this Agreement.

4. Work Planning

Both Parties agree to set up the following working groups responsible for specific work planning and proposals:

- (1) The Working Group on Prevention and Control of Communicable Diseases;
- (2) The Working Group on Safety Administration and Research and Development of Medicinal Products;
- (3) The Working Group on Research and Exchange in Traditional Chinese Medicine and Safety Administration in Traditional Chinese Medicinal Materials;
- (4) The Working Group on Assistance for Medical Emergency;
- (5) The Working Group on Inspections and Quarantines;
- (6) Other working groups mutually agreed upon by both Parties.

Each working group shall convene its respective first meeting within three months after the entry into force of this Agreement to discuss relevant matters concerning items, contents, formats, frequencies and the designated contact points, among others, for the exchange of information and notifications.

When necessary, each working group may decide, based upon mutual agreement, to change their respective working agenda and may establish sub-working group(s).

Chapter 2: Prevention and Control of Communicable Diseases

5. Scope of Cooperation

Both Parties agree to engage in exchanges and cooperation concerning communicable diseases that may affect the health of people on both sides of the Taiwan Strait, which include quarantine and control of diseases, exchange of information and notifications, handling of serious epidemics, research and development of vaccines, and other relevant matters.

The scope and the categories of communicable diseases shall be decided in accordance with the respective regulation of each Party and the mutual agreement of both Parties.

6. Quarantine and Control Measures of Communicable Diseases

Both Parties agree to abide by the core capacities governed by the universally recognized rules for quarantine and control of communicable diseases, to enhance cooperation, and to take necessary quarantine and control measures in order to avoid or reduce the spread of communicable diseases to the other Party.

Both Parties agree that when there is a suspected or confirmed patient with communicable disease who comes from the other Party, they are to take appropriate measures or to assist in the patient's return to the original place of residence for medical treatment.

7. Exchanges and Notification of Epidemic Information

Both Parties agree to regular exchange of epidemic and quarantine information, among others, in written form in ordinary times.

Both Parties agree to notify each other of epidemic information of communicable diseases that may constitute or have constituted serious emergent public health events at the earliest possible time, and to continue communications and notifications of relevant information. A Party shall respond and provide assistance at the earliest possible time when receiving inquiries from the other Party.

The notification contents in serious epidemics shall include case definition, laboratory data, the sources of the epidemic, the number of cases, the number of deaths, and the control measures being taken. When necessary, both Parties may mutually decide to change the notification contents.

A Party on whose side a serious epidemic occurs shall notify the other Party of the information about the latter Party's people who are infected in the epidemic, if available.

8. Handling of Serious Epidemics

A Party on whose side a serious epidemic occurs shall instantly take effective surveillance and control measures. When necessary, it may request the other Party to provide positive assistance.

A Party on whose side a serious epidemic occurs shall, upon request of the other Party, provide the outcomes of the epidemic investigation and positively consider assisting the other Party in understanding the epidemic situation on site.

9. Exchange and Cooperation for the Prevention and Control of Communicable Diseases of Mutual Concern

Both Parties agree to engage in exchanges and cooperation concerning communicable diseases of mutual concern, which include prevention and control strategies, quarantine standards, handling measures and exercises, laboratory techniques, laboratory specimens, and research and development of vaccines, among others.

Chapter 3: Safety Administration and Research and Development of Medicinal Products

10. Scope of Cooperation

The term “medicinal product(s)” in this Agreement refers to pharmaceutical products, medical devices, health food, and cosmetics, but not including traditional Chinese medicinal materials.

Both Parties agree to engage in cross-strait exchanges and cooperation in regulations, technical standards, testing techniques and other relevant matters for non-clinical safety evaluation, clinical trials, pre-marketing approval, manufacturing administration, and post-marketing administration, among others.

11. Quality and Safety Administration

Both Parties agree to establish a cooperation mechanism for the following cross-strait medicinal product affairs:

- (1) Inspections under the guidelines for Good Laboratory Practice (GLP), the guidelines for Good Clinical Practice (GCP), and the guidelines for Good Manufacturing Practice (GMP);
- (2) Notification, handling and tracking for adverse reactions and adverse events reporting;
- (3) Investigation of counterfeit, inferior, prohibited, and other illicit medicinal products; exchange of information; and tracking of their sources.

12. Coordination and Handling Mechanism

Both Parties agree to establish mechanisms for the coordination and handling of major cross-strait medicinal products safety events, and shall adopt the following measures for satisfactory handling thereof:

- (1) Holding emergency discussions, and exchanging relevant information;
- (2) Adopting control measures to prevent the worsening or extension of the situation;
- (3) Facilitating on-site visiting and understanding of the situation;
- (4) Verifying and announcing information, and performing mutual notification;
- (5) Providing analysis of the cause of events, and notifying the investigation and results in a timely manner;
- (6) Monitoring and urging relevant responsible enterprises and their responsible persons to handle the disputes appropriately; and providing active assistance so as to ensure the protection of the rights and interests of the aggrieved enterprises and consumers.

13. Coordination on Standards and Regulations

Both Parties agree to strengthen the cooperation and to actively promote the harmonization or coordination of mutual technical standards and regulations under the universally recognized standards for the safety administration of medicinal products (such as ICH and GHTF, among others), so as to enhance the safety and efficacy of medicinal products.

There will be cooperation in testing, registration, inspection, and regulated manufacturing administration, so as to explore the progressive adoption of implementation results of the other Party on the basis of the above provision.

14. Cooperation in Clinical Trials

Concerning clinical trials, both Parties agree to engage in exchange and cooperation in the relevant regulations, the management of institute(s) for implementation and executing teams, the protection of human subjects' rights, and the review and approval of the protocols and trial results, among others in matters.

For the purpose of reducing repetition of clinical trials, specifically approved institutes and trial projects conforming to the guidelines for Good Clinical Practice (GCP) will be put into operation first so as to positively promote cross-strait cooperation in clinical trials and research and development for medicinal products.

Based on this, there will be review of the progressive recognition and acceptance of the trial results of both Parties.

Chapter 4: Research and Exchange in Traditional Chinese Medicine and Safety Administration in Traditional Chinese Medicinal Materials

15. Scope of Cooperation

Both Parties agree to engage in exchange and cooperation in quality and safety assurance measures for traditional Chinese medicinal materials, research in diagnostic and therapeutic methods, and academic research in traditional Chinese medicine, and other relevant matters.

16. Quality and Safety Assurance

Both Parties agree to engage in following cooperation:

- (1) Exchange and cooperation in the standards for the quality and safety of and inspection/testing methods for traditional Chinese medicinal materials.
- (2) Mutual assistance for the verification and identification of inspection/testing certificates for traditional Chinese medicinal materials.

17. Export Inspection/Testing Measures

Both Parties agree to adopt measures to ensure that traditional Chinese medicinal materials exported to the other Party comply with quality and safety requirements:

- (1) The importing Party shall inform the exporting Party of the most up-dated regulations, inspection/testing standards, inspection/testing methods and content/contamination limits on a timely basis. The exporting Party shall then inform its relevant agencies and enterprises, and require its enterprises to obtain inspection/testing certificates in accordance with the requirements of the importing Party to ensure the quality and safety of traditional Chinese medicinal materials exported to the importing Party.
- (2) The exporting Party shall conduct inspections/tests on traditional Chinese medicinal materials to be applied for export and shall conduct intensive export inspections/tests based on actual need for the items, if reported by the importing Party two or more times to have failed complying with quality and safety requirements.

18. Mechanisms for Notification and for Coordination and Handling

Both Parties agree to establish cross-strait mechanisms for notification and for coordination and handling of matters concerning serious safety events, adverse reactions, and quality and safety problems of traditional Chinese medicinal materials, and to properly handle the matters in accordance with the measures provided in Article 12.

19. Researches and Exchanges in Traditional Chinese Medicine Matters

Both Parties agree to mutually decide upon the priority items for cooperation in researches and exchanges in matters concerning traditional Chinese medicine, to establish a cooperation platform and to actively conduct exchange activities for promoting the development of traditional Chinese medicine.

Chapter 5: Assistance for Medical Emergency

20. Scope of Cooperation

Both Parties agree to engage in cooperation for assistance in emergency measures, exchange of information, and transferring of injured persons, among others, arising from major accidents.

21. Emergency Measures

Both Parties agree to provide emergency assistance for persons from the other Party injured at major accidents that have occurred on its side, including emergency rescue, arrangement of treating hospitals, and other appropriate medical measures.

22. Exchange of Information in Medical Emergencies

Both Parties agree that if a major accident occurs on their respective sides, they shall provide to the other Party the list of injured persons, the situations of their injuries, the treating hospitals and their respective means of communication, as well as other relevant information.

23. Assistance in Transferring Injured Persons

Both Parties agree that the Party on whose side a major accident occurs shall actively assist in the transferring of injured persons upon the request of the other Party.

Chapter 6: Other Provisions

24. Confidentiality Obligations

Both Parties agree that personal information, business secrets, and other relevant information obtained in the implementation and conducting of relevant activities under this Agreement shall be kept confidential. However, this provision does not apply if the use of such information is in accordance with the purpose of the request for such information.

25. Restriction of Use

Both Parties agree that they will use the information provided by the other Party only in accordance with the purpose of the request. However, this provision does not apply if both Parties mutually decide differently.

26. Documentation Formats

Both Parties agree to use the documentation formats agreed upon by them for exchanges of information, notifications, inquiries, and business communications, among others.

27. Implementation and Amendment of this Agreement

Both Parties shall abide by this Agreement.

Amendments to this Agreement shall be subject to mutual consent through consultations between both Parties and shall be confirmed in writing.

28. Settlement of Disputes

Both Parties shall consult and settle the disputes arising from the application of this Agreement within the earliest time-frame. Unless otherwise agreed upon by both Parties, the consultation shall be held within 15 working days from the date of the request.

29. Matters not Mentioned

Both Parties may consult and mutually decide through appropriate means concerning matters not specifically mentioned in this Agreement.

30. Entry into force

After the signing of this Agreement, the Parties shall complete their respective relevant procedures for approval and notify each other in writing. This Agreement

shall enter into force as of the day following the date that both Parties have received such notification from each other.

This Agreement is signed on December 21. There are four authentic copies. Each Party holds two of them.

Chairman Chiang Pin-kung
Straits Exchange Foundation

President Chen Yunlin
Association for Relations Across the
Taiwan Strait