海峽兩岸醫藥衛生合作協議

Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs

行政院衛生署
Department of Health, The Executive Yuan
Taiwan, R.O.C.

海峽兩岸醫藥衛生合作協議

（本協議尚待完成相關程序後生效）

本於維護人的健康價值，保障海峽兩岸人民健康權益，促進兩岸醫藥衛生合作與發展，財團法人海峽交流基金會與海峽兩岸關係協會就兩岸醫藥衛生合作事宜，經平等協商，達成協議如下：

第一章 總則

一、合作領域

雙方同意本著平等互惠原則，在下列領域進行交流合作：

（一）傳染病防治；

（二）醫藥品安全管理及研發；

（三）中醫藥研究與交流及中藥材安全管理；

（四）緊急救治；

（五）雙方同意的其他領域。

二、合作方式

雙方同意以下列方式進行醫藥衛生業務交流與合作：

（一）推動業務主管部門人員定期工作會晤、考察參訪、技術交流及舉辦研討會等；

（二）交換、通報、查詢及公布相關業務資訊、制度規範及實際運作措施；

（三）雙方同意的其他合作方式。

三、聯繫主體

本協議議定事項，由雙方相關業務主管部門指定的聯絡人相互聯繫實施。必要時，經雙方同意得指定其他單位進行聯繫。

本協議其他相關事宜，由財團法人海峽交流基金會與海峽兩岸關係協會聯繫。

四、工作規劃

雙方同意分別設置下列工作組，負責商定具體工作規劃、方案：

（一）傳染病防治工作組；

（二）醫藥品安全管理及研發工作組；

（三）中醫藥研究與交流及中藥材安全管理工作組；

（四）緊急救治工作組；

（五）檢驗檢疫工作組；

（六）雙方商定設置的其他工作組。

各工作組應於本協議生效後三個月內召開會議，商討資訊交換和通報項目、內容、格式、頻率及聯繫窗口等相關事宜。

必要時，各工作組得商定變更相關事宜，並得另設工作分組。

第二章 傳染病防治

五、合作範圍

雙方同意就可能影響兩岸人民健康之傳染病的檢疫與防疫、資訊交換與通報、重大傳染病疫情處置、疫苗研發及其他事項，進行交流與合作。

傳染病範圍、類別依雙方各自規定及商定辦理。

六、檢疫與防疫措施

雙方同意依循公認檢疫防疫準則所規範的核心能力，加強合作，採取必要檢疫及防疫措施，避免或減少傳染病傳播至對方。

雙方同意對在己方發現對方的疑似或確診傳染病病人，進行適當處置或協助返回原居住地治療。

七、傳染病疫情資訊交換與通報

雙方同意平時應以書面方式定期互相交換傳染病疫情及衛生檢疫等資訊。

雙方同意儘速通報可能或已構成重大突發公共衛生事件的傳染病疫情，並持續溝通及通報相關資訊。如接獲對方查詢時，應儘速給予回應與協助。

重大疫情通報的內容，包括病例定義、實驗室檢驗數據、疫情來源、病例數、死亡數及採取的防治措施等。必要時，雙方得商定變更通報內容。

如有對方人民在發生重大疫情方受感染的資訊，該方應通報對方。

八、重大疫情處置

發生重大疫情方，應即時採取有效監測及處置措施；必要時，得請求對方積極提供協助。

發生重大疫情方，於對方請求時，應提供疫情調查情況，並積極考量協助對方實地瞭解疫情。

九、共同關切的傳染病防治交流與合作

雙方同意就共同關切的傳染病防治策略、檢疫標準、處置措施及其實務演練、檢驗技術與實驗室標本以及疫苗研發等，進行交流與合作。

第三章 醫藥品安全管理及研發

十、合作範圍

本協議所稱醫藥品，指藥品、醫療器材、健康食品（保健食品）及化粧品，不包括中藥材。

雙方同意就兩岸醫藥品的非臨床檢測、臨床試驗、上市前審查、生產管理、上市後管理等制度規範，及技術標準、檢驗技術與其他相關事項，進行交流與合作。

十一、品質與安全管理

雙方同意就下列兩岸醫藥品事項，建立合作機制：

（一）非臨床試驗管理規範（GLP）、臨床試驗管理規範（GCP）及生產管理規範（GMP）的檢查；

（二）不良反應及不良事件通報、處置與追蹤；

（三）偽、劣、禁及違規醫藥品的稽查，並交換資訊及追溯其來源。

十二、協處機制

雙方同意建立兩岸重大醫藥品安全事件協處機制，採取下列措施妥善處理：

（一）緊急磋商，交換相關資訊；

（二）採取控制措施，防止事態蔓延；

（三）提供實地瞭解便利；

（四）核實發布資訊，並相互通報；

（五）提供事件原因分析，及時通報調查及處理結果；

（六）督促應負責的廠商及其負責人妥善處理糾紛，並就受損害廠商及消費者權益的保障，給予積極協助。

十三、標準規範協調

雙方同意在醫藥品安全管理公認標準（ICH、GHTF等）的原則下，加強合作，積極推動雙方技術標準及規範的協調性，以提升醫藥品的安全、有效性。

在上述基礎上，進行醫藥品檢驗、查驗登記（審批）及生產管理規範檢查合作，探討逐步採用對方執行的結果。

十四、臨床試驗合作

雙方同意就彼此臨床試驗的相關制度規範、執行機構及執行團隊的管理、受試者權益保障和臨床試驗計畫及試驗結果審核機制等，進行交流與合作。

在符合臨床試驗管理規範（GCP）標準下，以減少重複試驗為目標，優先以試點及專案方式，積極推動兩岸臨床試驗及醫藥品研發合作，並在此基礎上，探討逐步接受雙方執行的結果。

第四章　中醫藥研究與交流及中藥材安全管理

十五、合作範圍

雙方同意就中藥材品質安全保障措施、中醫藥診療方法研究、中醫藥學術研究及其他相關事項，進行交流與合作。

十六、品質安全

雙方同意進行下列合作：

（一）中藥材品質安全標準及檢驗方法的交流合作；
（二）相互協助中藥材檢驗證明文件查核及確認。

十七、輸出檢驗措施

雙方同意採取措施，保障輸往對方的中藥材符合品質安全要求：

（一）輸入方應及時通知輸出方最新制度規範、檢驗標準、檢測方法及限量要求，並由輸出方轉知相關機構及企業，要求企業對輸往對方的中藥材，依輸入方要求取得檢驗證明文件，保證品質和安全；

（二）輸出方應對申報輸出的中藥材實施檢驗，並對輸入方多次通報的品質安全不合格項目，根據需要實施密集輸出檢驗。

十八、通報及協處機制

雙方同意建立兩岸中藥材重大的安全事件、不良反應及品質安全問題通報及協處機制，並依第十二條所定措施妥善處理。

十九、中醫藥研究與交流

雙方同意共同商定中醫藥研究與交流優先合作項目，建立交流平台，積極舉辦交流活動，促進中醫藥發展。

第五章　緊急救治

二十、合作範圍

雙方同意就兩岸重大意外事件所致傷病者的緊急救治措施、資訊交換及傷病者轉送等事項，進行交流與合作。

二十一、緊急救治措施

雙方同意對在己方因重大意外事件所致傷病的對方人民，提供緊急救治，協助安排收治醫院，並採取其他適當醫療措施。

二十二、緊急救治資訊交換

雙方同意重大意外事件發生方，應儘速提供對方傷病者名冊、傷病情形、收治醫院和聯繫方式，以及其他相關資訊。

二十三、緊急傷病者轉送協助

雙方同意重大意外事件發生方，於對方請求時，應積極協助辦理傷病者轉送事宜。

第六章 附則

二十四、保密義務

雙方同意對於執行本協議相關活動所獲個人資料、營業秘密及其他資訊予以保密。但依請求目的使用者，不在此限。

二十五、限制用途

雙方同意僅依請求目的使用對方提供的資料。但雙方另有規定者，不在此限。

二十六、文書格式

雙方同意資訊交換、通報、查詢及業務聯繫等，使用商定的文書格式。

二十七、協議履行與變更

雙方應遵守協議。

本協議變更，應經雙方協商同意，並以書面形式確認。

二十八、爭議解決

因適用本協議所生爭議，雙方應儘速協商解決。除另有約定外，協商應於請求提出後十五個工作日內舉行。

二十九、未盡事宜

本協議如有未盡事宜，雙方得以適當方式另行商定。

三十、簽署生效

本協議簽署後，雙方應各自完成相關程序並以書面通知對方。本協議自雙方均收到對方通知後次日起生效。

本協議於十二月二十一日簽署，一式四份，雙方各執兩份。

財團法人海峽交流基金會	海峽兩岸關係協會
董事長 江丙坤	會長 陳雲林

附註

（本附註非協議內容，僅係供瞭解之參考）

一、GLP：非臨床試驗管理規範（Good Laboratory Practice），係用於規範藥物（藥品及醫療器材）研發過程中的非臨床安全性、有效性試驗（包括動物試驗及細胞試驗），以確保試驗數據的品質與可信度。

二、GCP：臨床試驗管理規範（Good Clinical Practice），係用於規範藥物研發過程中的人體安全性、有效性試驗，能確實遵守研究倫理，以確保受試者之權益，且執行所得的資料能符合科學要求。

三、GMP：生產管理規範（Good Manufacturing Practice），係用於確保醫藥品的生產及品質管制等作業上，皆能持續達到適合其預定效用及上市許可或產品規格所要求的品質標準。

四、ICH：國際醫藥法規協和會（International Conference on Harmonization），為美國、歐盟及日本於1990年所設立的國際平台，透過會議討論，目的在於發展及制訂國際一致化之規範及準則，促進新藥研發，提昇審查品質。

五、GHTF：全球醫療器材法規協和會（Global Harmonization Task Force），為美國、歐盟、日本、加拿大與澳洲的醫療器材主管機關與製造業者於1992年所成立的國際平台，目的在於促使國際間醫療器材安全、有效及品質管理法規的協合、以提倡技術革新並增進新器材使用。

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

Notes:

(These notes are included for the purpose of understanding the Agreement. They are not part of the Agreement)

1. GLP is the acronym of "Good Laboratory Practice". It refers to a system to govern the non-clinical safety and efficacy trial (including trials in animal and cell) in the research and development process of medicines and medical devices to ensure the quality and reliability of trial data.
2. GCP is the acronym of "Good Clinical Practice". It refers to a standard to be applied in governing the safety and efficacy trial during the process of research and development of medicines so that the clinical trial will be conducted in accordance with ethical requirements to ensure the proper protection of rights and interests of the human subjects, and that the data arising from the clinical trial will meet the scientific requirements.
3. GMP is the acronym of "Good Manufacturing Practice". It refers to a system to ensure that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing approval or product specification.
4. ICH is the acronym of the "International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use". It is an international platform jointly established by the European Community (now the European Union), Japan and the United States in 1990 for the purpose of developing and enacting harmonized rules and guidelines, through discussions and deliberations at conferences, to enhance the research and development of new medicines and the quality of reviewing them.
5. GHTF is the acronym of "Global Harmonization Task Force". It is an international platform jointly established by the regulators and the manufacturers of medical devices from the United States, the European Union, Japan, Canada and Australia in 1992 for the purposes of enhancing the international harmonization of regulations concerning safety, efficacy, and quality of medical devices so as to promote technical renovation and to enhance the use of new medical devices.

海峽兩岸醫藥衛生合作協議
Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs

行政院衛生署

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