

DENMARK, KINGDOM OF*
 MEMORANDUM OF UNDERSTANDING
 [BETWEEN
 NATIONAL INSTITUTE OF PREVENTIVE
 MEDICINE DEPARTMENT OF HEALTH
 REPUBLIC OF CHINA
 AND
 STATENS SERUMINSTITUT MINISTRY OF
 HEALTH DENMARK]

Signed on July 31, 1992
 Entered into force on July 31, 1992

丹麥王國*

[行政院衛生署預防醫學研
 究所與丹麥國立血清研究所
 間] 備忘錄

八十一年七月三十一日簽訂
 八十一年七月三十一日生效

Preamble

The purpose of this Memorandum of Understanding is to sum up the conversations held in Copenhagen 30th - 31st of July 1992 between representatives of the National Institute of Preventive Medicine, Department of Health, Taiwan, Republic of China, and Statens Serum Institut, a public enterprise owned by the Ministry of Health, Denmark, with the aim to identify areas of future cooperation.

The Delegations

The delegation from the National Institute of Preventive Medicine:

Led by Dr. Chi-Byi Horng, Director, Nationale Institute of Preventive Medicine,

Mr. Pen-Tui Lai, President, Lifeguard Pharmaceutical Inc.

Dr. Ming-Yi Liao, Head, Division of Biologics Production, National Institute of Preventive Medicine

Representatives from Statens Serum Institut:

Mr. Lars Pallesen, Executive Director, CEO

Mr. Jesper Kongstad, Head, Department of Corporate Planning

Mr. Michael Olsen, Analyst, Department of Corporate Planning

Summary of Discussions

1. Presentations of the National Institute of Preventive Medicine and Lifeguard Pharmaceuticals Inc.
2. Presentation of Statens Serum Institut.

[譯文]
 導言：

此備忘錄目的在於記錄一九九二年七月三十及三十一日，中華民國衛生署預防醫學研究所代表與丹麥衛生部所屬公營事業之Statens Serum Institut代表在哥本哈根舉行的會談，此會談著重在雙方討論對未來合作範圍的確認。

代表團：

預防醫學研究所代表：

洪其璧博士：預防醫學研究所所長

廖明一博士：預防醫學研究所生物製劑製造組組長

丹麥Statens Serum Institut代表：

Mr. Lars Pallesen：執行長

Mr. Jesper Kongstad：合作企劃組組長

Mr. Michael Olsen：合作企劃組分析師

討論結果：

1. 介紹預防醫學研究所。
2. 介紹丹麥血清研究所。

3. Discussion on the future possibilities and limitations for not-for-profit organizations within the international vaccine industry. Focus: Increasing scale economies within the production of vaccines, the necessity to specialize within competences already present, priority to R&D, etc.
 4. Discussion of the role of not-for-profit organizations to support and deliver products for third world countries.
 5. Statens Seruminstitut has expressed its interests in the Japanese Encephalitis vaccine and the venum antisera produced by the National Institute of Preventive Medicine and will investigate possible future distribution channels for products representing the National Institute of Preventive Medicine's core competences.
 6. The National Institute of Preventive Medicine has expressed an interest in Statens Seruminstitut's products within the diagnosis and preventions of tuberculosis especially Tuberculin PPD and BCG vaccine.
 7. In the near future, the parties will investigate whether other products might be of mutual interest to exchange and have in this respect discussed the possibility of exchange of products on a bulk basis .
 8. In the near future, the parties will investigate how the two institutions can contribute to and strengthen the prevention and control of infectious diseases within third world countries situated in the Pacific Rim.
 9. Statens Seruminstitut will shortly forward information to the National Institute of Preventive Medicine concerning Tuberculin PPD:
 - Necessary overfilling of bulk shipments;
 - Registration material including descriptions of QA/QC and stability testing;
 - Information of procedures to be followed in terms of QA/QC as part of filling and preparation of final products, etc.
3. 探討國際上疫苗工業中，未來非營利事業之可行性及其限制。重點：增進疫苗產品的經濟效益，就現有有能力專業化，及研究發展之優先性等。
4. 討論以非營利機構，扮演對第三國家支援及提供產品的角色。
5. 丹麥血清研究所對預防醫學研究所的產品：日本腦炎疫苗、抗蛇毒血清表示興趣，同意研究未來預防醫學研究所產品銷售管道。
6. 預防醫學研究所對丹麥血清研究所的結核菌淨素及卡介苗表示興趣。
7. 討論雙方對產品或原液 (final bulk) 互換的可行性。
8. 雙方將研究對太平洋區的第三世界國家如何貢獻於加強傳染性疾病的預防及控制。
9. 丹麥血清研究所不久將給預防醫學研究所下列有關結核菌淨素 (PPD) 之訊息：
- (1) 供應足夠分裝量的PPD原液。
 - (2) 有關PPD QA/QC說明書及安定性試驗。
 - (3) 有關PPD分裝、包裝的QA/QC的製程記錄。

10. Statens Seruminstitut will be happy to receive a guest from the National Institute of Preventive Medicine to be trained in QA/QC in conjunction with filling and final preparation of Tuberculin PPD products.
11. In order to guarantee a good final product of Tuberculin PPD, the National Institute of Preventive Medicine can send to Statens Seruminstitut samples of the final products for confirmation testing of the quality.

Future Initiatives

- Dr. Liau and Mr. Olsen will be in contact in order to prepare for the final decisions concerning future cooperation within the areas of Japanese Encephalitis vaccine, venom antisera, Tuberculin PPD, and BCG vaccine.
- The first shipment of Tuberculin PPD in final bulk to the National Institute of Preventive Medicine will take place within two months of the date of the signing this Memorandum of Understanding.
- The parties envisage to meet in October 1992 to discuss in detail the future cooperation and to finalize agreements, including a long term agreement on supplies of Tuberculin PPD. The parties will also discuss the future possibilities for expanding the cooperation, including exchange of other products and scientific collaboration.

This Memorandum of Understanding has been executed in two identical copies and signed after approval by the parties. Each party has received one original copy bearing the following signatures.

The National Institute
of Preventive Medicine

Date: 31/7/92

[Signed]
Dr. Chi-Byi Horng
Director

Statens Seruminstitut

Date: 31/7/92

10. 丹麥血清研究所願意接受一名預防醫學研究所人員，訓練其對PPD的分裝、包裝依QA/QC的作業程序。

11. 為保證PPD產品優良，預防醫學研究所可將PPD產品樣本送丹麥血清所檢驗以確認PPD之品質。

未來計劃：

1. 廖博士與Mr. Olsen將保持連繫，以應未來雙方合作的最後決定做準備，此合作項目包括日本腦炎疫苗、抗蛇毒血清、結核菌淨素及卡介苗等。

2. 第一批結核菌淨素原液將於簽此備忘錄後2個月內送達預防醫學研究所。

3. 雙方將於1992年10月再開會討論未來合作的細節，並完成合約書，此合約書包括同意長期供應結核菌淨素。雙方也將討論擴展合作事項，包括互換其他產品及科學上的合作。

此備忘錄相同者兩份，經雙方認可及簽名。雙方各保存一份具有如下簽字原件。

簽名者：雙方代表 [簽字]

[Signed]
Mr. Lars Pallesen
Executive Director, CEO

Witnessed by:

[Signed]
Dr. Stephan Hsu
Representative,
Republic of China on Taiwan

見證者：許智偉 [簽字]
(中華民國駐丹麥代表)