法規名稱：AGREEMENT BETWEEN NATIONAL INSTITUTE OF PREVENTIVE MEDICINE, DEPATRMENT OF HEALTH, EXECUTIVE YUAN, REPUBLIC OF CHINA AND STATENS SERUMINSTITUT, DENMARK (AD.1994.02.16)

簽訂日期：民國 83 年 02 月 16 日

生效日期：民國 83 年 01 月 01 日

AGREEMENT

PREAMBLE

This Agreement between National Institute of Preventive Medicine , Department of Health, Executive Yuan, Republic of China (hereinafter referred to as Party A) and Statens Seruminstitut, Denmark (hereinafter referred to as Party B) is based on agreements made during meetings at Statens Seruminstitut July 1992 and discussed in detail during meetings at National Institute of Preventive Medicine February 1993.

RECITALS

WHEREAS, The parties in the Memorandum of Understanding of 31 July 1992 stipulate that a broad collaboration will be established between the Parties for the benefits of the populations in the Republic of China and Denmark as well as other relevant countries.

WHEREAS, Party B as a gesture of good faith is willing to provide to Party A tuberculin bulk solutions for the purpose of preparations of finished tuberculin products by Party A at its facilities to fulfill the needs of the products in the Republic of China.

WHEREAS, This agreement is the first step of the action plan agreed by the parties to develop said broad collaboration.

WHEREAS, Party A desires to receive from Party B the tuberculin bulk solution, and Party B is willing to provide to Party A said product.

THEREFORE Party A and Party B agree as follows:

1.Tuberculin bulk soltions: Tuberculin PPD RT23 1TU/O.lml (hereinafter referred to as the PPD).

2.Quantity: Party B agrees to sell to Party A, on a long-term a-

nd steady basis, the PPD in quantities from 500,000 to 1,000,000 doses each time and twice a year , for Party A to produce the final products to be distributed only within the Republic of China. The procedure for ordering the PPD is described in Annex A.

3.Price: Party B shall sell the PPD to Party A at a price of DKK 0.35 per dose (1TU/0.1ml) delivered CIP Taipei C.K.S. International Airport (Incoterms 1990). To compensate for Party A's wastage and necessary overfilling, each shipment shall contain 20% more than the quantity actually ordered and the extra part shall be free of charge to Party A. The selling price of the PPD shall not be changed within the first two years of this agreement. Any price increase following this period shall be reasonably and should be based on exchange rates developments, market conditions, and actual increases in productions costs by Party B.

4.Date of Delivery: Party B shall deliver the PPD to Party A in accordance with the procedure set forth in Annex A.

5.Terms of Payment: Party A shall pay 50% of the total price of the PPD upon ordering and pay the rest within two months after the PPD are delivered by Party B and pass the inspection arranged by Party A.

6.Guaranty: Party B warrants that the PPD delivered to Party A meets the specifications set forth by Party B and agreed upon by party A.

1) If non-conformity should exist, either because the temperature monitoring at the time of delivery does not meet the specifications or the PPD does not pass the inspection and analysis arranged by Party A, Party A shall immediately inform Party B to solve the problems.

2) In any case of non-conformity caused by Party B, Party B shall refund the payment for the PPD made by Party A, and Party A shall return the PPD to Party B.

3) In any case of non-conformity, whether or not it is caused by Party B, Party A shall have the right to order for new PPD to

be delivered within 4 months to ensure that Party A at all time will be in a position to cover the needs for the finished products in R.O.C.

7.Penal Provisions:

1) If Party B can not deliver the PPD on the date of delivery, it has to pay 0.3% of the total price for each day past the agreed due date. It is agreed, however, that the maximum penalty is 50% of the total price.

2) The above penalty provision shall also apply to orders for PPD as a result of non-conformity as set forth in section 6 above.

3) Party B shall not be liable for the delay of the delivery of goods as a result of failing to fulfill the entire or part of the Agreement because of force majeure, including Act of God, earthquake, war, blockades, rebellions, storms, fire, flood, strike (excluding internal strikes within an individual factory), embargo, explosion, government or international organizations orders or restrictions, etc. Nonetheless, any party affected by any event resulted from the above mentioned force majeure shall do its best to eliminate, recover and overcome the hardships and fulfill its obligations in the Agreement in due course.

8.The Parties shall have the right to terminate this agreement with 9 months notice to expire by the end of a calendar year. However, termination of this agreement can take effect no earlier than by the end of the calendar year of 1995. It is stipulated by the parties that this agreement shall be in force on a long-term basis as part of the expected broad collaboration between the parties.

9.If any dispute should arise between the Parties concerning the subject matters of this agreement, the Parties shall settle the dispute amicably through good faith negotiations. If the dispute can not be settled amicably, it shall be finally settled arbitrally under the rules of The International Chamber of Commerce. The arbitral procedure shall take place in Singapore

. The language to be used shall be English. The English version of the agreement is the governing version.

10.This Agreement is made in duplicate, with four identical copies, signed by both parties. Party A shall hold one original together with four copies and Party B shall hold the other original for reference and filing respectively.

IN WITNESS WHEREOF, this Agreement is signed on , 1994.

National Institute of Preventive Medicine,

Department of Health, Executive Yuan, Republic of China (Party A)

[Signed]

Name : Dr. Chi-Byi Horng

Title :Director

Jan.14,1994

Statens Seruminstitut, Denmark (Party B)

[Signed]

Name : Dr. Lars Pallesen

Title : Executive Director, CEO

Feb. 16, 1994

Witness

[Signed]

Name :Prof. Stephan Hus

Title :Representative, Republic of China on Taiwan

Feb.23, 1994

ANNEX A

General and commercial specifications:

1) The Parties have appointed the following two persons to be inch arge of and act as liaison officers on matters of general and commercial nature:

Party A:

Dr. M. Y. Liau

Head, Division of Biological Products

Party B:

Mr. Michael A. Olsen

Department of Corporate Planning

2) Ordering:

The procedure for submitting orders for the PPD shall be as follows:

(1) Party A shall inform Party B about its intentions for purchase the PPD in each calendar year no later than November the foregoing year.

(2) The first delivery in each calendar year shall be no earlier than March, unless Party A has notified Party B 4 months before delivery date.

(3) Submission ofdnal orders shall be made no later than 3 month before delivery date.

Technical Specifications:

1) The Parties have appointed the fellowing two persons to be incharge of and to act as liaison omcers on matters concerning quality control/quality assurance.

Party A:

Dr. Cheng-hasiung Lu

Head, Division of Biological Quality Control.

Party B:

Mrs. Birgitte W. Knudsen

Head, Department of Quality Assurance

2) There should be a temperature monitor card and ice-packs installed in each packed box.

3) There should be information regarding the manufacturing date, the delivering batch code, the valid period and the producer's name on the outer surface of each packed box.

4) The valid period shall not be less than one year and three months starting from the date of delivery.

5) Party B shall provide Party A with all reasonably necessary information for the application of the production license for the PPD.

6) Party B shall provide Party A 6 weeks in advance with enough quantity of reference standard and sensitizing agent (the vald period shall be more than 6 months) to facilitate

the measurement oft;he potency of the PPD. For each batch of bulk solution, the following reagents are requested:

1.Sensitizer 20mg

2.Reference PPD

A) 5 TU/O.1ml 30ml

B) 0.5 TU/O.1ml 30ml

7) Party B shall provide Party A with the reference standard in testing the additive of the PPD, Potassium hydroxychinoline sulphate.

8) Party B shall provide Party A with the complete protocol of batch file and the testing report for each shipment of the PPD.

9) To ensure the quality of the end products made from the PPD hulk solution produced by Party A, if it is necessary, Party A may Bend the final products to Party B for testing . Party B shall conduct the said testing in due course and free of charge.

10) Party B shall be responsible for the training of Party A's personnels to enable then to understand the standard operation procedure of dispensing and packing the PPD, the quality control and the quality assurance at Party B's expense. However , Party B shall be responsible for the travelling, lodging and boarding expenses of the trainees.