COMMISSION OF THE EUROPEAN GOMMUNITIES

COM(81) 604 FEBL1 Brussels, 30 October '1984

Draft <u>COUNCIL DECISION</u>

on the conclusion of the Agreement between the European Economic Community and Switzerland on a concerted action project in the field of the detection of the tendency to thrombosis

(submitted to the Council by the Commission)

COM(81) 604 final

COMMUNICATION FROM THE COMMISSION TO THE COUNCIL

<u>Subject</u>: Agreement between the European Economic Community and Switzerland on a concerted project relating to the detection of the tendency to thrombosis

A second research programme in the field of medical and public health research consisting of four multiannual concerted action projects, one of which concerns the detection of the tendency to thrombosis, was adopted by the Council on 18 March 1980¹.

Article 6 of the aforesaid Decision provides for the conclusion of international agreements between the Community and non-member States participating in COST (European Co-operation in the field of Scientific and Technical Research) with a view to associating them with the said projects. Under the terms of the same provision, the Commission was authorized to enter into negotiations to that end.

On 16 July 1981 Switzerland expressed its willingness to participate in the concerted action project relating to the detection of the tendency to thrombosis. The negotiations with Switzerland resulted in the draft agreement appended to the attached draft Council decision.

This agreement provides that:

- the person responsible for coordinating the Swiss national contribution to the concerted project shall be a member of the Concerted Action Committee on the Detection of the Tendency to Thrombosis.
- the Swiss financial contribution to the co-ordination costs shall be
 38 000 ECU for the period referred to in Article 1 of the agreement.

The Commission requests the Council to adopt the draft decision concluding the aforesaid agreement.

¹0J No L 78 of 25 March 1980, p. 24.

DRAFT COUNCIL DECISION

• on the conclusion of the Agreement between the European Economic Community and Switzerland on a concerted action project in the field of the detection , of the tendency to thrombosis

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Decision 80/344/EEC of 18 March 1980 adopting a second research programme in the field of medical and public health research, consisting of four multiannual concerted action projects¹, and in part-icular Article 6(1) thereof,

Having regard to the draft Decision submitted by the Commission,

Whereas, pursuant to Article 6(2) of Decision 80/344/EEC, the Commission has negotiated an Agreement with Sw tzerland with a view to associating it with the concerted action project in the field of the detection of the tendency to thrombosis;

Whereas that Agreement should be approved,

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement between the European Economic Community on a concerted action project in the field of the detection of the tendency to thrombosis is hereby approved on behalf of the Community.

The text of the Agreement is annexed to this Decision.

¹0J No L 78, 25.3.1980, p.25

Article 2

The President of the Council is hereby authorized to designate the persons empowered to sign the Agreement in order to bind the Community.

Done at Brussels,

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The President

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DRAFT AGREEMENT

between the European Economic Community and Switzerland on a concerted action project in the field of the detection of the tendency to thrombosis

THE EUROPEAN ECONOMIC COMMUNITY

and

SWITZERLAND,

Whereas a European concerted research action project in the field of the detection of the tendency to thrombosis is likely to contribute eff ctively to ensuring an optimum level of health in individuals and in society;

Whereas, by its Decision of 18 March 1980, the Council of the European Communities adopted a second research programme in the field of medical and public health research consisting of four multiannual concerted projects, one of which relates to the detection of the tendency to thrombosis;

Whereas, the Member States of the Community and Switzerland, hereinafter referred to as "the States", intend, subject to the rules and procedures applicable to their national programmes, to carry out the research described in Annex A and are prepared to integrate such research into a process of co-ordination which they consider will be of mutual benefit;

Whereas the implementation of the research covered by the concerted action project will require a financial contribution of approximately 10 million ECU from the States,

HAVE AGREED AS FOLLOWS:

<u>Article 1</u>

- 2 -

The Community and Switzerland, hereinafter referred to as "the con_racting parties", shall participate for a period extending until 31 May 1984 in a concerted action project in the field of the detection of the tendency to thrombosis.

This project shall consist in co-ordinating the Community concerted action programme with the corresponding programme of Switzerland. The programmes covered by this Agreement are listed in Annex A.

The States shall remain entirely responsible for the research executed by their national institutions or bodies.

Article 2

The Commission of the European Communities shall be responsible for the co-ordination.

It shall be assisted in this task by a project leader.

Article 3

In order to facilitate the execution of the project, the Concerted Action Committee on the Detection of the Tendency to Thrombosis, hereinafter referred to as "the Committee", set up by the Decision of the Council of the European Communities of 18 March 1980, shall be enlarged to include Switzerland.

The secretariat of the Committee shall be provided by the Commission.

The terms of reference and the composition of the Committee shall be as :set out in Annex B.

Article 4

The maximum financial contribution by the contracting parties to the coordination costs shall be:

- 616 000 ECU from the Community for a four-year period beginning on 1 June 1980,
- 38 000 ECU from Switzerland for the period referred to in the first paragraph of Article 1.

The ECU is defined in the Financial Regulation applicable to the general budget of the European Communities and in the financial provisions adopted pursuant to that Regulation.

The rules governing the financing of the Agreement are set out in Annex C.

Article 5

In accordance with the procedure laid down by the Commission after consulting the Committee, the States shall exchange regularly all relevant information concerning the execution of the research covered by the concerted action project and shall forward to the Commission all information which will assist co-ordination. They shall also endeavour to provide the Commission with information on research in the field in question planned or carried out by bodies not subject to their authority. Any information shall be treated as confidential if the State which provides it so requests.

The Commission shall prepare yearly progress reports on the basis of the information supplied and shall forward them to the States.

At the end of the period of the concerted action project, the Commission, after consulting the Committee, shall forward to the States a general report on its execution and on the results obtained, in particular so that these results are made accessible as quickly and as fully as possible to undertakings, institutions and other parties concerned, in particular in memthe social field. This report shall be published by the Commission six months after it is 'forwarded to the States, unless a State objects. In the latter case, the report shall be forwarded, on request, solely to the institutions and undertakings the research or production activities of which justify access to the results of the research covered by the concerted action project.

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Article 6

1. As soon as possible after signing this Agreement, each of the contracting parties shall notify the Secretary-General of the Council of the European Communities of the completion of the procedures necessary under its internal provisions for the implementation of this Agreement.

2. This Agreement shall enter into force on the day on which the second of the contracting parties forwards this notification.

Prior to entry into force of this Agreement and for a maximum period of nine months after it is signed, Switzerland may take part without voting rights in the work of the Committee.

3. For a period of six months following its entry into force, this Agreement shall be open for accession by other European States which took part in the Ministerial Conference held in Brussels on 22 and 23 November 1971. The instruments of accession shall be deposited with the General Secretariat of the Council of the European Communities.

A State which accedes to this Agreement shall become a contracting party within the meaning of Article 1 on the date on which the instrument of accession is deposited. It shall contribute to the co-ordination costs under the conditions laid down in Article 4 concerning Switzerland. 4. The Secretary-General of the Council of the European Communities shall notify each of the contracting parties of the lodging of the rotifications referred to in paragraph 1, of the date of entry into force of this Agreement and of the deposition of the instruments of accession referred to in paragraph 3.

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Article 7

This Agreement, drawn up in a single original in the Danish, German, Greek English, French, Italian and Dutch languages, each text being equally authentic, shall be deposited in the archives of the General Secretariat of the Council of the European Communities, which shall transmit a certified copy to each of the contracting parties.

ANNEX A

PROGRAMMES COVERED BY THE AGREEMENT

I. Implementation and co-ordination of the national contributions to the project

The following authorities carrying out medical research in the States will ensure the implementation of the national contributions to the project and their co-ordination at national level:

| Belgium: | FRSM, Fonds de la recherche scientifique médicale, Bruxelles/Fonds voor Geneeskundig Wetenschappelijk Onderzoek, Brussel |
|-----------------|--|
| Denmark: | Statens laegevidenskabelige Forskningsråd, København |
| Germany: | - Zentrum für Innere Medizin der Universität Giessen |
| <i>.</i> | – Department für Innere Medizin der Universität Ulm |
| Greece: | - Ipiresia Epistimonikis Erevnis ke Technologhias, Athens |
| | - Simvoulion Iatrikon Erevnon, Athens |
| France: | INSERM, Institut national de la santé et de la recherche médicale, Paris |
| Ireland: | Medical Research Council of Ireland, Dublin |
| Italy: | CNR, Consiglio nazionale della ricerca, Roma, and Istituto superiore di sanità, Roma |
| Netherlands: | Gezondheidsorganisatie TNO and Stichting Medisch Wetenschappelijk Onderzoek FUNGO, Den Haag |
| United Kingdom: | MCR, Medical Research Council, London |
| Switzerland: | Theodor Kocher Institut, Universität, Bern |

II. Project relating to the detection of the tendency to thrombosis

The research will be carried out with the purpose of acquiring scientific and technical knowledge in this field, selected for its importance at Community level.

The research is expected to cover the following topics:

- 1. Detection of activated clotting factors and their reaction products
- 2. Quantitative analysis of the inhibitors of the clotting system
- 3. Studies of the active and inhibitory components of the fibrinolytic system
- 4. Studies of blood platelets
- Pilot studies in well-defined populations following standardization of materials and methodology

Belgium, Denmark, Germany, Greece, France, Ireland, Italy, the Netherlands, the United Kingdom and Switzerland will contribute research under the topics mentioned above.

ANNEX B

TERMS OF REFERENCE AND COMPOSITION OF THE COMMITTEE

1. The Committee shall:

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- 1.1 contribute to the optimum execution of the project by giving its opinion on all of its aspects;
- 1.2 evaluate the results and draw conclusions as regards their application;
- 1.3 be responsible for the exchange of information referred to in the first sub-paragraph of Article 5;
- 1.4 keep abreast of national research being done in the fields covered by the project and more especially of scientific and technical developments likely to affect the execution of the project;
- 1.5 suggest guidelines to the project leader.
- The Committee's reports and opinions shall be forwarded to the Commission and to the States. The Commission shall forward these opinions to CREST.
- 3. The Committee shall be composed of persons responsible for co-ordinating the national contributions to the project and the project leader. Each member may be accompanied by experts.

ANNEX C

FINANCING RULES

Article 1

These provisions lay down the financing rules referred to in Article 4 of the Agreement on a concerted action project in the field of the detection of the tendency to thrombosis.

Article 2

At the beginning of each financial year, the Commission shall send to Switzerland a call for funds corresponding to its share of the annual co-ordination costs under the Agreement, calculated in proportion to the maximum amounts laid down in Article 4 of the Agreement.

This contribution shall be expressed both in ECU and in the currency of the State concerned, the value of the ECU being defined in the Financial Regulation applicable to the general budget of the European Communities and determined on the date of the call for funds.

The total contributions shall cover the travel and subsistence costs of the delegates to the Committee, in addition to the co-ordination costs proper.

Switzerland shall pay its annual contribution to the co-ordination costs under the Agreement at the beginning of each year and by 31 March at the latest. Any delay in the payment of the annual contribution shall give rise to the payment of interest by Switzerland at a rate equal to the highest discount rate ruling in the States on the due date. The rate shall be increasing by 0.25 of a percentage point for each month of delay. This increased rate shall be applied to the entire period of delay. However, this interest shall be recoverable only if payment is made more than three months after the Commission has sent a call for funds.

ANNEX C

Article 3

The funds paid by Switzerland shall be credited to the concerted action project as budget receipts allocated to a heading in the statement of revenue of the budget of the Commission.

Article 4

The provisional timetable for the co-ordination costs referred to in Article 4 of the Agreement is annexed hereto.

Article 5

The Financial Regulation in force applicable to the general budget of the European Communities shall apply to the management of the appropriations.

Article 6

At the end of each financial year, a statement of appropriations for the concerted action project shall be prepared and transmitted to Switzerland for information.

Annex to Annexe O

PHOVISIONAL TINETABLES FOR THE CONCERTED ACTION PROJECT : DETECTION OF THE TENDENCT TO THROMBOSIS

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| | 1980 | | 1981 | | 1982 | | 1983 | 3 | 1984 | 34 | TOTAL | |
|--|-------------------|------------------|----------------------------|----------------------------|--|----------------------------|---------|---------------|--------|--------|---------|--------------------------------|
| ne (de delarma mundade) za del ante de la preziona fonde (ante de la concepta de mais e concepta de mais e co | AC | AP | AC | AP | AC | AP | AC | AP | AC | AP | AC | AP |
| Initial estimate of overall requirements figures on the commitments and payments echedule and in the table of equivalence 'n Annex II to the budget of the dommission) | | | | | <u>a, e e a la citada de anticidada de anticidada de anticidada de anticidada de anticidada de anticidada de antic</u> | | | · | • | | | a, i gernoù, ' ∠annen farnet r |
| - Staff - Administrative operating expenditure - Contracts | 27.000 | 77.000 \$154.000 | | 154.000 | 47.500 31.500 75.000 | 47.500 31.500 75.000 | 154.000 | 154.000 | 11.000 | 21.000 | 616.000 | 616.000 |
| TOTAL | 77.000 | 77.000 | 154.000 | 154.000 | 154.000 | 154.000 | 154.000 | 154.000 | 000°LL | 77.000 | 616.000 | 616.000 |
| . Revised estimate of expenditure taking into account additional requirements arising from the accession of Switzerland | | | | | | | | | | | | |
| - Staff - Administrative perating expenditure - Contracts | 1 | 1 | 47.500 34.500 81.500 | 47.500 34.500 81.500 | 163.500 | 163.500 | 163.500 | 163.500 | 86.500 | 86.500 | 654.000 | 654.000 |
| NEW TOTAL | (000-12) (000-12) | (000-17) | 163.500 | 163.500 | 163.500 | 163.500 | 163.500 | 163.500 | 86.500 | 86.500 | 654.002 | 654.000 |
| 3. Difference between 1 and 2 to be covired by the contribution from Switzerland | l | j | 9•500 | 9•500 | 9.500 | 9. 500 | 9.500 | 9 •500 | 9•500 | 9.500 | 38,000 | 38.000 |

AC = Account credited AP = Account paid