COUNCIL DECISION

of 13 February 1978

adopting a concerted project of the European Economic Community in the field of extracorporeal oxygenation (medical and public health research)

(78/169/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 235 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas, by virtue of Article 2 of the Treaty establishing the European Economic Community, the Community has been assigned the task of promoting throughout the Community a harmonious development of economic activities, a continuous and balanced expansion and an accelerated raising of the standards of living ;

Whereas, in its resolution of 14 January 1974 on an initial outline programme of the European Communities in the field of science and technology (3), the Council stressed that an appropriate approach should be adopted towards the whole range of available ways and means, including concerted projects and that whenever it proves desirable that third countries, particularly European ones, should be associated in these projects, steps should be taken to make this possible ;

Whereas, in its resolution of 14 January 1974 relating in particular to the coordination of national policies in the field of science and technology (4), the Council entrusted the Community institutions with the task of gradually ensuring such coordination, aided by the Scientific and Technical Research Committee (CREST) ;

Whereas a concerted Community research action in the field of extracorporeal oxygenation is likely to contribute effectively to the achievement of the above-mentioned aims ;

Whereas the Member States intend, as part of the rules and procedures applicable to their national programmes, to carry out the research described in Annex I, and are prepared to integrate such research into a process of coordination at Community level over a period of four years ;

Whereas the execution of such research as described in Annex I will require a financial contribution of about 4·1 million units of account from the Member States ;

Whereas the Community is empowered to conclude Agreements with third countries in the fields covered by this Decision ; whereas it may prove advisable to extend the coordination established by this Decision to third countries participating in European cooperation in the field of scientific and technical research (COST) ; whereas, on the one hand, procedural conditions should be determined so as to lead to a rapid conclusion of these agreements and, on the other, negotiations should be opened with the countries referred to as soon as this Decision is adopted ;

Whereas the Treaty has not provided the specific powers for this purpose ;

Whereas the Scientific and Technical Research Committee (CREST) has given its opinion on the Commission proposal,

HAS DECIDED AS FOLLOWS :

Article 1

The Community shall implement for a period of four years a concerted project in the field of extracorporeal oxygenation, hereinafter referred to as 'the project'.

The project shall consist in coordination at Community level of the research described in Annex I, which forms part of the research programmes of the Member States.

Article 2

The Commission shall be responsible for such coordination.

(1) OJ No C 299, 12. 12. 1977, p. 47.
(2) Opinion delivered 23 and 24 November 1977 (not yet published in the Official Journal).
(3) OJ No C 7, 29. 1. 1974, p. 6.
(4) OJ No C 7, 29. 1. 1974, p. 2.

Article 3

The maximum financial contribution by the Community to such a project will be 360 000 units of account, the unit of account being defined by the relevant Financial Regulations.

Article 4

To facilitate the execution of the project, a concerted action Committee on Extracorporeal Oxygenation, hereinafter referred to as 'the Committee', shall be established.

A project leader shall be appointed by the Commission in agreement with the Committee. He shall, in particular, assist the Commission in its coordinating action.

The terms of reference and the composition of this Committee are defined in Annex II.

The Committee shall draw up its rules of procedure. Its secretariat will be provided by the Commission.

Article 5

In accordance with a procedure to be adopted by the Commission in agreement with the Committee, the Member State participating in the project shall exchange regularly all useful information concerning the execution of the research covered by the project and forward to the Commission all information that may be useful for coordination purposes. They shall also endeavour to provide the Commission with information on similar research planned or carried out by bodies for which they are not responsible. This information shall be treated as confidential if so requested by the Member State which provides it.

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

At the end of the coordintion period, the Commission shall, in agreement with the Committee, forward to the Member States and to the European Parliament a general report on the execution and results of the coordination action. The Commission shall publish this report six months after it has been forwarded to the Member States unless a Member State objects. In this case the report shall be distributed, at their request, solely to institutions and undertakings whose research and production activities justify access to the results of the research carried out under the project. The Commission may make provision that the report remains confidential and is not disclosed to third parties.

Article 6

1. In accordance with the provisions laid down in Article 228 of the Treaty establishing the EEC, the Community may conclude Agreements with other States involved in European Cooperation in the field of scientific and technical research (COST) with a view to extending the coordination which is the subject of this Decision to research undertaken in these States.

2. The Commission is hereby authorized to open negotiations for the conclusion of Agreements of the type referred to in the preceding paragraph.

Article 7

This Decision shall come into force on 1 January 1978.

Done at Brussels, 13 February 1978.

For the Council

The President

P. DALSAGER

ANNEX I

RESEARCH PROGRAMME RELATING TO EXTRACORPOREAL OXYGENATION

(Concerted project)

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. Continuous improvement in performance of present oxygenator principles with respect to the limitations set by diffusion resistance and blood trauma :
   (a) clinical applicability of introduction of a controlled secondary flow (blood mixing) into present oxygenator principles ;
   (b) studies of the effects of blood flow shear stress on the aggregation and adhesion of platelets, of the interaction of red cells and platelets, and of pharmacologic methods of intervention.
2. Continuous development of alternative oxygenation principles and testing for their clinical applicability.

   Here, research is aiming in particular at further development and joint evaluation of the principle of :
   (a) hyperbaric oxygenation ;
   (b) physico-chemical release of oxygen (from H_2O_2) through membranes containing catalytic activity ;
   (c) liquid oxygenation by using inert liquids (fluorocarbons) for direct gas transfer to the blood.
3. Development of methods for continuous control and dynamic compensation of the patient's respiratory, circulatory and metabolic deficiencies.
   (a) dynamic control system, based on oxygen consumption and carbon dioxide production in the patient, for the regulation of the gas transfer rate in oxygenators ;
   (b) regulation of blood electrolytes and pH in the perfused patient.

The coordination will be carried out by the following medical research organizations or institutes of the participating Member States :

Belgium : FNMR — Fonds national de la recherche médicale, Bruxelles.

Denmark : Danish Medical Research Council, Copenhagen.

France : INSERM — Institut national de la santé et de la recherche médicale, Paris

Germany : — German Heart Centre, Munich ;
— Department of Physiologiy, Technical University, Aachen ;
— MPI, System-Physiology, Dortmund ;
— Department of Physiology, University of Mainz.

Ireland : Medical Research Council of Ireland, Dublin.

Italy : CNR — Consiglio Nazionale della Ricerca, Roma.

Netherlands : — University of Groningen ;
— Eindhoven University of Technology ;
— Department of Physiology, University of Nijmegen ;
— Department of Appl. Physiology and Cryobiology, Central Red Cross Blood Transfusion Services, Amsterdam.

United Kingdom : MRC — Medical Research Council, London.

These countries will contribute research under the three topics mentioned above.

ANNEX II

TERMS OF REFERENCE AND COMPOSITION OF THE CONCERTED ACTION COMMITTEE ON EXTRACORPOREAL OXYGENATION

1. The Committee shall :

   1.1 contribute to the optimum execution of the programme 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 subparagraph of Article 5 ;

   1.4 keep abreast of national research being done in the fields covered by the concerted 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.

2. The Committee's reports and opinions shall be forwarded to the Commission and to the Member States participating in the project. The Commission shall forward these opinions to the CREST.

3. The Committee shall be composed of persons responsible for coordinating the national contributions to the programme, and the project leader. Each member may be accompanied by experts.