COUNCIL DECISION

of 18 March 1980

adopting a second research programme in the field of medical and public health research, consisting of four multiannual concerted projects

(80/344/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 (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas pursuant to Article 2 of the Treaty, 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 standard of living;

Whereas by Decisions 78/167/EEC (4), 78/168/EEC (5) and 78/169/EEC (6), the Council has adopted three concerted projects as a first research programme in the field of medical and public health research;

Whereas in its resolution of 14 January 1974 on an initial outline programme of the European Communities in the field of science and technology (7) 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 necessary or desirable that non-Member States, 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 (8) relating in particular to the coordination of national policies in the field of science and technology, the Council entrusted the Community institutions with the task of gradually ensuring such coordination, aided by the Scientific and Technical Research Committee (Crest);

Whereas the Community concerted projects in the sector of medical and public health research are necessary to attain in the course of the operation of the common market the objectives of the Community as regards the harmonious development of economic activities, a continuous and balanced expansion and an accelerated raising of the standard of living, account being taken in particular of potential economic and industrial development within the fields covered by the research projects;

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 periods of three or four years;

Whereas the execution of such research as described in the aforesaid Annex will require a financial contribution of about 35 million European units of account from the Member States;

Whereas the Community is empowered to conclude Agreements with non-member States in the fields covered by this Decision; whereas it may prove advisable to associate the non-member States participating in European Cooperation in the Field of Scientific and Technical Research (COST) within the concerted projects covered by this Decision, in accordance with the conclusions approved by the Council on 18 July 1978 in connection with such cooperation; whereas, on the one hand, procedural conditions should be determined so as to lead to a rapid conclusion of such Agreements, and on the other hand, negotiations should be opened with the non-member States, as soon as this Decision is adopted;

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

Whereas Crest has given its opinion on the Commission proposal,

(1) OJ No C 213, 7. 9. 1978, p. 3.
(2) OJ No C 296, 11. 12. 1978, p. 33.
(3) OJ No C 105, 26. 4. 1979, p. 22.
(4) OJ No L 52, 23. 2. 1978, p. 20.
(5) OJ No L 52, 23. 2. 1978, p. 24.
(6) OJ No L 52, 23. 2. 1978, p. 28.
(7) OJ No C 7, 29. 1. 1974, p. 6.
(8) OJ No C 7, 29. 1. 1974, p. 2.

HAS DECIDED AS FOLLOWS:

Article 1

In the field of medical and public health research, the Community shall implement four concerted projects, hereinafter referred to as 'the projects', for the periods indicated, in the fields of:

1. The detection of the tendency to thrombosis	4 years
2. The understanding, evaluation and treatment of hearing impairment	3 years
3. Criteria for perinatal monitoring	4 years
4. Common standards for quantitative electrocardiography	4 years

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

Article 2

The Commission shall be responsible for such coordination.

Article 3

The appropriations necessary to finance the Community contribution to the coordination, the amount of which shall be fixed at 2·32 million European units of account, including the expenditure relating to a staff of four officials, shall be entered in the budget of the European Communities.

The European unit of account is defined in Article 10 of the Financial Regulation of 21 December 1977 applicable to the general budget of the European Communities (1).

Article 4

To facilitate the execution of the four projects, a Concerted Action Committee, hereinafter referred to as 'the Committee', shall be established for each project.

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

The terms of reference and the composition of these Committees are defined in Annex II.

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

Article 5

In accordance with a procedure to be adopted by the Commission by agreement with the respective Committees, the Member States participating in the projects shall regularly exchange all useful information concerning the execution of the research covered by each project and forward to the Commission all information which 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 coordination period, the Commission shall, by agreement with the respective Committees, forward to the Member States and to the European Parliament a general report on the execution and results of the projects particularly so that the results obtained may be accessible as completely and rapidly as possible to the enterprises, institutions and other parties particularly concerned at the social level. 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 enterprises whose research and production activities justify access to the results of the research carried out under each project. The Commission may make provision that the report remains confidential and is not disclosed to third parties.

Article 6

1. In accordance with Article 228 of the Treaty, the Community may conclude Agreements with the non-Member States participating in European Cooperation in the field of Scientific and Technical Research (COST) with a view to associating them with the projects.

2. The Commission is hereby authorized to negotiate the Agreements referred to in paragraph 1.

Article 7

This Decision shall take effect on 1 June 1980.

Done at Brussels, 18 March 1980.

For the Council

The President

A. RUFFINI

(1) OJ No L 356, 31. 12. 1977, p. 1.

ANNEX I

PROJECTS IN THE FIELD OF MEDICAL AND PUBLIC HEALTH RESEARCH

I. Implementation and coordination of the national contributions to the projects

The following authorities carrying out medical research in the participating Member States will ensure the implementation of the national contributions to the projects indicated in Sections II to V, as well as their coordination at national level :

Belgium :	FRSM — Fonds de la recherche scientifique médicale, Bruxelles FGWO — Fonds voor Geneeskundig Wetenschappelijk Onderzoek, Brussel
Denmark :	Statens lægevidenskabelige Forskningsråd, København
Germany :	The abovementioned projects will be provisionally carried out by the following institutes until the appointment of the national coordinator responsible : Project No 1 : — Zentrum für Innere Medizin der Universität Gießen — Department für Innere Medizin der Universität Ulm Project No 2 : — Institut für Physiologie u. Biokybernetik der Universität Erlangen-Nürnberg — Hals-, Nasen und Ohrenklinik der Universität Münster Project No 3 : — Frauenklinik der Universität Düsseldorf Project No 4 : — Abtlg. Innere Medizin I der RWTH Aachen — Department für Biometrie u. med. Informatik der Mediz. Hochschule Hannover
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 :	MRC — Medical Research Council, London

II. Project relating to the detection of the tendency to thrombosis (project No 1, four years)

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 of 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.
5. Pilot studies in well-defined populations following standardization of materials and methodology.

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

III. **Project relating to the understanding, evaluation and treatment of hearing impairment (Project No 2, three years)**

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. Comparative studies of the relationships between histopathological, functional and clinical data in cases of perceptive hearing losses.
2. Development and/or improvement of electrophysiological auditory function tests.
3. Improvement of artificial auditory stimulation.
4. Mathematical modelling of normal and impaired auditory systems.

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

IV. **Project relating to criteria for perinatal monitoring (project No 3, four years)**

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. Definition of specific high-risk groups for perinatal monitoring.
2. Evaluation and improvement of existing processing techniques and methods for monitoring.
3. Drawing up common quantitative methods to define the neonatal condition.
4. Studies of the correlations between neonatal conditions and relevant perinatal parameters obtained during labour ; establishment of common criteria for perinatal monitoring.

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

V. **Project relating to common standards for quantitative electrocardiography (project No 4, four years)**

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. Standardization of ECG measuring procedures in quantitative (computer) terms ; comparative studies of measurements performed by different programmes ; drawing up of guidelines and definition of common standards for measurement.
2. Standardization of the diagnostic criteria and of the algorhythmic documentation of their operation.
3. Establishment of a modest pilot library of ECG's.

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

ANNEX II

TERMS OF REFERENCE AND COMPOSITION OF THE COMMITTEE

1. The Committee shall :

   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 subparagraph 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.

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 Crest.

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