II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 17 August 1982

adopting a sectoral research and development programme of the European Economic Community in the field of medical and public health research — concerted action — (1982 to 1986)

(82/616/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 *inter alia* the task of promoting throughout the Community the harmonious development of economic activities, a continuous and balanced expansion and an accelerated raising of the standard of living;

Whereas, by Decision 78/167/EEC (4), as amended by Decision 81/21/EEC (5), and Decisions 78/168/EEC (6) and 78/169/EEC (7), the Council has adopted three concerted projects as a first programme in the field of medical and public health research;

Whereas by Decision 80/344/EEC (8) the Council adopted a second research programme in the field of medical and public health research, consisting of four multiannual concerted projects;

Whereas, in its resolution of 14 January 1974 on an initial outline programme of the European Communities in the field of science and technology (9), the Council stressed that an appropriate approach should be adopted towards the whole range of available ways and means, including concerted action, 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 (10) 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 sectoral research and development programme dealt with by this Decision appears 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 areas;

(1) OJ No C 291, 12. 11. 1981, p. 13.
(2) Opinion delivered on 9 July 1982 (not yet published in the Official Journal).
(3) OJ No C 64, 15. 3. 1982, p. 20.
(4) OJ No L 52, 23. 2. 1978, p. 20.
(5) OJ No L 43, 13. 2. 1981, p. 12.
(6) OJ No L 52, 23. 2. 1978, p. 24.
(7) OJ No L 52, 23. 2. 1978, p. 28.
(8) OJ No L 78, 25. 3. 1980, p. 24.
(9) OJ No C 7, 29. 1. 1974, p. 6.
(10) OJ No C 7, 29. 1. 1974, p. 2.

Whereas the Treaty does not provide the specific powers of action required for these ends;

Whereas the Member States intend, in accordance with the rules and procedures applicable to their national programmes, to carry out all or part of the research indicated in Annex I, and are prepared to integrate such research into a process of coordination at Community level until 31 December 1986;

Whereas the cost of the research indicated in Annex I, performed in the Member States, is estimated at 300 million ECU;

Whereas in its conclusions of 20 December 1979 the Council invited the Commission to submit proposals aimed at the rationalization of structures for the preparation, examination and implementation of Community research and development programmes; whereas a grouping together of concerted action projects in the field of medical and public health research would constitute a first contribution towards meeting these objectives;

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), wholly or partly with the programme 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 Council has concluded such an agreement between the European Economic Community and the Swiss Confderation on concerted projects [1] [2];

Whereas CREST has given its opinion on the Commission proposal,

HAS DECIDED AS FOLLOWS:

Article 1

A concerted research and development programme of the European Economic Community in the field of medical and public health research is hereby adopted for a period of five years commencing on 1 January 1982.

The programme shall consist in coordination at Community level, within the research areas described in Annex I, of those activities which form part of the research programmes of the Member States.

Article 2

The Commission shall be responsible for such coordination.

Article 3

The funds estimated as necessary for the Community contribution to the coordination should be 13·3 million ECU, including expenditure on a staff of nine.

The internal and indicative allocation of these funds and the timetable for the implementation of the measures are set out in Annex II.

Article 4

At the beginning of the third year the Commission shall submit to the Council an interim report on the results of the programme. On the basis of this report, the programme shall be evaluated before the end of the third year. This evaluation shall be carried out by experts not involved in the Committees referred to in Article 5 and who have themselves not received any appropriations under the research programme. A report on this evaluation shall be sent to the Council and to the European Parliament.

This evaluation may lead to the submission by the Commission, after the Committee referred to in Article 5 point (a) has been consulted, of a proposal for a revision of the programme in accordance with the appropriate procedures.

Article 5

To facilitate the execution of the programme:

(a) one General Concerted Action Committee, hereinafter referred to as 'the General Committee', and

(b) four Concerted Action Committees assisting the General Committee in its management tasks,

shall be established.

The terms of reference and the composition of these committees are defined in Annex III.

The Commission shall be assisted in its coordinating action by project leaders appointed by the Commission, after having consulted the General Committee.

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

Implementation and coordination of the national contributions to the programme shall be carried out by the national bodies in the list given for guidance in Annex IV.

[1] OJ No L 113, 25. 4. 1981, p. 44.
[2] OJ No L 83, 29. 3. 1982, p. 1.

Article 6

In accordance with a procedure to be laid down by the Commission after havng consulted the General Committee, the participating Member States and the Commission shall regularly exchange all useful information concerning the execution of the research covered by this Decision. The participating Member States shall provide the Commission with all information relevant for coordination purposes. They shall also endeavour to provide the Commission with information on similar research planned or carried out by bodies which are not under their authority. Any information shall be treated as confidential if so requested by the Member State which provides it.

On completion of the programme, the Commission, in agreement with the General Committee, shall send to the Member States and the European Parliament a summary report on the implementation and results of the programme, particularly so that the results obtained may be accessible as rapidly as possible to the enterprises, institutions and other parties concerned, especially in the social area.

Article 7

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 wholly or partly with this programme.

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

Article 8

Decision 80/344/EEC is hereby repealed with effect from 1 January 1982.

However, the amounts which have been authorized in the corresponding items of the 1980, 1981 and 1982 budgets and which, on 1 January 1982, have not been committed or which have been committed but not yet settled, will be used in implementing this Decision over and above the amount referred to in Article 3.

Done at Brussels, 17 August 1982.

For the Council

The President

O. MØLLER

ANNEX I

SCIENTIFIC AND TECHNICAL CONTENT

(Concerted action programme)

The aim of this European collaboration in the sector of medical and public health research is to :

— increase the efficiency of relevant R and D efforts in the Member States through the mobilization of the available research potential of national programmes and through their gradual coordination at Community level,

— improve scientific and technical knowledge in the R and D areas selected for their importance by all the Member States, taking particular account of potential industrial and economic development in the areas concerned,

— provide for the continuation of the three concerted action projects of the first medical research programme (1978 to 1981), the integration of the four projects of the second programme (1980 to 1984) as well as for new projects of common interest.

SUB-PROGRAMME I : HEALTH PROBLEMS

Research area 1 : Pre-, peri- and postnatal care

— Continuation of the project relating to criteria for perinatal monitoring (1), with emphasis on technological development and assessment of devices and procedures for non-invasive monitoring, and extension to prevention of mothers' distress and risk as well as of foetal loss.

— Improvement of techniques needed for automated chromosome analysis as well as for biochemical and genetical studies to increase possibilities of application.

— Screening of inborn metabolic diseases, including cystic fibrosis, hemoglobinopathies and hyperlipoproteinaemia, by standardization or improvement of existing methodologies and developing new ones, as well as studies on early detection and treatment.

— Continuation of the project relating to the registration of congenital abnormalities (2) with extension to improvement of intra-uterine diagnosis and studies on early foetal loss, death in early childhood and foetal growth disturbances.

— Examination of current practices regarding care delivery systems, and in particular the application of technical devices and procedures to perinatal medicine, including cost/effectiveness evaluations.

Research area 2 : Ageing, disabilities and handicaps

— Continuation of the project relating to cellular ageing (3) with extension on its immunological sub-project to the understanding of arthritic diseases and of its sub-project concerning organs to studies of the brain and senile dementia.

— Continuation of the project relating to hearing impairment (1) and of the sub-project, on ageing of the crystalline lens, of the project mentioned in the first indent ; development of adequate aids for visual and auditory sensorial impairment including biomaterial compatibility studies.

— Continuation of the project relating to the detection of tendency to thrombosis (1) with extension to population studies following development of suitable methodology.

— Evaluation of selected aids for the disabled, including the technological development thereof, and identification of specific needs.

— Examination of care pattern for the chronic patient with several functional disabilities and for the impaired elderly, including epidemiological aspects.

(1) For programme description see : OJ No L 78, 25. 3. 1980, p. 24.
(2) For programme description see : OJ No L 52, 23. 2. 1978, p. 20.
(3) For programme description see : OJ No L 52, 23. 2 1978, p. 24.

Research area 3 : Breakdown in adaptation

— Evaluation, improvment, standardization and/or development of quantitative measurements of hormonal, psychological and sociological parameters involved in the adaptive process.

— Investigation of performance decrement in workers under various environmental conditions, using the abovementioned methodology.

— Comparative studies, through monitoring the relevant physiological variables, in selected groups suffering from cardiovascular symptoms, with particular reference to hypertension and ischaemic heart diseases.

— Comparative studies, through determination of the relevant psychobiological and psychosocial parameters, in selected groups suffering from gastro-intestinal diseases.

— Biological and epidemiological studies in workers on the effects of alcohol abuse and the mechanisms involved in the proneness to it, of tobacco or products associated with its consumption, as well as of the effects of potential opiate intake on the central nervous system and the general metabolism.

SUB-PROGRAMME II : HEALTH RESOURCES

Research area 1 : Health services research

— Assessment of the present state of the art of research on health services in the Member States following development of a common methodology for comparative evaluation, and elaboration, of joint projects.

— Development of health indicators and subsequent assessment of the health status of the working population in the Community.

— Studies of health risk factors, influence of the working environment on health, as well as the use of medical services, sick leave, accidents at work and drug consumption ; evaluation of relevant national activities and elaboration of a concerted approach towards prevention.

— Assessment of the feasibility, by considering, in particular, relevant technological progress, and of potential importance, of community care in the home and occupational environment, as compared with hospitalization.

Research area 2 : Health technology

— Continuation of the project relating to extracorporeal oxygenation [1] with extension to advanced technological developments for the replacement of further body functions, including research on biomaterials.

— Continuation of the project relating to common standards in quantitative electrocardiography [2] with extension to standardization and improvement of diagnostic criteria ; the same approach will be used for computerized analysis of other diagnostic functional parameters.

— *In vitro* and *in vivo* development of imaging techniques following pilot studies to define common multipurpose packages for application.

— Development of devices and procedures for ambulatory monitoring of physiological variables of major diagnostic importance to rehabilitation, therapeutic needs, drug use and occupational health.

— Clinical and technical evaluation of new medical devices and procedures, including cost/efficiency aspects, through coordination of existing facilities, for both comparative technical testing and user trials, considering in particular : ultrasonic tissue characterization, accelerated bone fracture healing, blood flow measurements, automated cell identification and medical telemetry.

[1] For programme description see : OJ No L 52, 23. 2. 1978, p. 28.
[2] For programme description see : OJ No L 78, 25. 3. 1980, p. 24.

Research area 3 : Human resources

— Methodological research on ways and means of providing industry as well as public and private institutes with highly qualified research scientists in need-areas such as toxicology, occupational health, advanced health technology, clinical investigation, health services management and epidemiology.

— Evaluation of present and future needs, comparison of national measures taken and identification of suitable upgrading facilities ; subsequently, development of coordinated procedures and assessment of their efficiency through test cases in toxicology and clinical investigation.

SUB-PROGRAMME III : PERSONAL ENVIRONMENT (Nutrition and pharmaceuticals)

Research area 1 : Nutrition

— Development and improvement of specific methologies for the study of food and the detection of individual predisposition to arterial hyptertension and digestive tract diseases ; biological and/or epidemiological studies on the prevalence of such diseases and on the environmental factors involved, as well as on preventive measures.

Research area 2 : Pharmaceuticals

— Controlled post-marketing clinical trials on a large scale through mobilization and coordination of existing facilities ; appropriate collection, storage and dissemination of information on the efficacy of some specific effects of selected old and new drugs.

— Development of a post-marketing drug surveillance project on a large scale through the coordination of existing facilities in the Member States ; collection, storage and early dissemination of information on adverse drug effects of low incidence or late occurence, including case control surveillance as well as record linkage drug surveillance.

ANNEX II

INDICATIVE INTERNAL DISTRIBUTION OF FUNDS
(1982 to 1986)

Sub-programme I:	48 %
Sub-programme II:	39 %
Sub-programme III:	13 %

TIMETABLE FOR IMPLEMENTATION OF THE PROJECTS

			Ia	Ib	II	III
SUB-PROGRAMME I: HEALTH PROBLEMS						
Area I.1.	**Pre-, peri- and postnatal care**					
Project	I.1.1.	Perinatal monitoring	×			
	I.1.2.	Chromosome analysis				×
	I.1.3.	Inborn metabolic diseases			×	
	I.1.4.	Congenital abnormalities	×			
	I.1.5.	Care delivery systems				×
Area I.2.	**Ageing, disabilities and handicaps**					
Project	I.2.1.	Cellular ageing and diseases	×			
	I.2.2.	Sensorial impairment	×			
	I.2.3.	Thrombosis and disabilities	×			
	I.2.4.	Aids to the disabled			×	
	I.2.5.	Care delivery systems		×		
Area I.3.	**Breakdown in adaptation**					
Project	I.3.1.	Quantification of parameters		×		
	I.3.2.	Performance decrement			×	
	I.3.3.	Cardiovascular diseases			×	
	I.3.4.	Gastro-intestinal diseases			×	
	I.3.5.	Abuse of stimulants and drugs		×		
SUB-PROGRAMME II: HEALTH RESOURCES						
Area II.1.	**Health services research**					
Project	II.1.1.	Coordination of health services research				×
	II.1.2.	Health status assessment				×
	II.1.3.	Research on prevention			×	
	II.1.4.	Community v. hospital care				×
Area II.2.	**Health technology**					
Project	II.2.1.	Replacement of body functions and biomaterial research	×			
	II.2.2.	Quantitative functional assessment	×			
	II.2.3.	Imaging techniques			×	
	II.2.4.	Ambulatory monitoring		×		
	II.2.5.	Clinical and technical evaluation		×		
Area II.3.	**Human resources**					
Project	II.3.1.	Upgrading in toxicology		×		
	II.3.2.	Upgrading in health service management				×
	II.3.3.	Upgrading in occupational health				×
	II.3.4.	Upgrading in advanced technology				×
	II.3.5.	Upgrading in epidemiology				×
	II.3.6.	Upgrading in clinical investigation		×		
SUB-PROGRAMME III: PERSONAL ENVIRONMENT (nutrition and pharmaceuticals)						
Area III.1.	**Nutrition**					
Project	III.1.1.	Diet, hypertension and digestive tract diseases		×		
Area III.2.	**Pharmaceuticals**					
Project	III.2.1.	Clinical trials				×
	III.2.2.	Drug surveillance				×

Categories

Ia: Continuation and new developments of concerted actions from the first and second programmes.

Ib: New concerted actions ready to start on 1 January 1983.

II: Concerted actions to start on 1 July 1983 with progressive attainment of full-scale operation.

III: No concerted action, but studies, seminars, workshops.

ANNEX III

TERMS OF REFERENCE AND COMPOSITION OF THE COMMITTEE

I. General Concerted Action Committee

1. The General Committee shall :
   - contribute to the best possible implementation of the programme by giving its opinion on all of its aspects,
   - endeavour to integrate those parts of national research activities covered by this programme into a process of coordination at Community level,
   - within the programme as defined in Annex I of this Decision, coordinate the activities, duration and possibly early termination of the projects forming the research areas of this programme, according to emerging needs or results of periodical evaluations,
   - indicate guidelines to the Concerted Action Committees,
   - advise the Commission on allocation of funds for coordination purposes, supporting centralized facilities, meeting urgent needs in critical areas, and undertaking exploratory activities in view of the preparation of future programmes.
2. The General Committee's reports and opinions shall be forwarded to the Commission and to the Member States participating in the programme. The Commission shall forward these opinions to CREST.
3. The General Committee shall be composed of representatives of the Member States responsible for science and technology in the field of medical and public health research and, in particular, for coordinating the national contributions to the programme.

II. Concerted Action Committee

1. Each committee shall :
   - assist the General Committee in its management tasks by ensuring the scientific and technical execution of all those projects allocated to it in accordance with its competence,
   - evaluate the results and draw conclusions as regards their application,
   - be responsible for the exchange of information referred to in the first subparagraph of Article 6,
   - keep abreast of national research being done in the field of the projects, and more especially of scientific and technical developments likely to affect their execution,
   - suggest guidelines to the project leaders.
2. The Committee's reports and opinions shall be forwarded to the General Committee and to the Commission.
3. The Committee shall be composed of experts nominated by the competent authorities of the Member States.
4. The project leaders shall attend the meetings of the Committee but shall not have the right to vote.

ANNEX IV

IMPLEMENTATION AND COORDINATION OF THE NATIONAL CONTRIBUTIONS TO THE PROGRAMME

The authorities of the participating Member States, listed below for guidance, will endeavour to ensure the implementation of the national contributions to the research areas of the three sub-programmes indicated in Annex I, 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
France :	INSERM — Institut national de la santé et de la recherche médicale, Paris
Federal Republic of Germany :	Bundesminister für Forschung und Technologie, Bonn Bundesminister für Jugend, Familie und Gesundheit, Bonn Bundesminister für Arbeit und Sozialordnung, Bonn
Greece :	Ὑπουργεῖο Ἔρευνας καί Τεχνολογίας, Ἀθήνα Συμβούλιο Ἰατρικῶν Ἐρευνῶν, Ἀθήνα
Ireland :	Medical Research Council of Ireland, Dublin Medico-Social Research Board, Dublin
Italy :	CNR — Consiglio nazionale della ricerca, Roma, and Istituto superiore di sanità, Roma
Luxembourg :	Ministère de la santé, Luxembourg
Netherlands :	— Hoofdgroep Gezondheidsonderzoek TNO, Den Haag — Stichting Medisch Wetenschappelijk Onderzoek FUNGO, Den Haag
United Kingdom :	MRC — Medical Research Council, London, and DHSS — Department of Health and Social Security, London