# COMMISSION OF THE EUROPEAN COMMUNITIES

COM(81) 517 final.
Brussels, 21 September 1981

Proposal for a Council Decision

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

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(submitted to the Council by the Commission)

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## A. SUMMARY

The present proposal deals with a new sectoral research and development programme (1982 - 1986) of the EEC in the field of medical and public health research, to be carried out by means of the concerted action method.

It aims at increasing the efficiency of the relevant R & D efforts in the Member States through the mobilization of the available research potential of parts of national programmes and its gradual coordination at Community level.
Particular attention is devoted to the potential economic and industrial development within the fields covered by the research actions of this programme, in conformity with Article 235 of the Treaty establishing the European Economic Community and in accordance with the objectives and means of action described in Article 2 of the Treaty.

This proposal constitutes a step towards the sectoral grouping of Community research actions in the field of medical and public health research and towards the rationalization of structures and procedures for the "preparation, examination and implementation of Community R & D programmes".

The programme proposal, by presenting a coherent scheme of Community concerted research, provides for the continuation of the first medical research programme (1978 - 1981) and the integration of the second one (1980 - 1984) as well as for new activities in critical areas of common interest. It is subdivided into three subprogrammes :

Subprogramme 1 : Health problems
Subprogramme 2 : Health resources
Subprogramme 3 : Personal environment (diet and drugs).

Each one is further detailed in research areas grouping several projects.

Overall programme implementation will be ensured by one "General Concerted Action Committee" assisted in its tasks by four "Concerted Action Committees" with defined scientific-technical competences, each responsible for the optimal execution of several projects entrusted to it.

The Member States intend, according to the rules and procedures applicable to their national programmes, to carry out the research work estimated to involve global financial contributions of about 300 million ECU over the programme period of 5 years (1982 - 86).

The Commission is responsible for the coordination of the national research contributions to the programme at Community level. The appropriations necessary to finance the Community contribution to such coordination are evaluated to be in the order of 20 million ECU for the duration of the programme. This figure includes staff expenditures for a total of 10 officials (4 of them were already allocated to the 2nd medical research programme).

Interested non-Member States participating in European Cooperation in the field of Scientific and Technical Research (COST) will be invited to associate wholly or partly with this programme.

In order to ensure continuity, the programme is foreseen to start on 1 January 1982.

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## B. INTRODUCTION

The Council Decisions of 13 February 1978, adopting three concerted actions as a first Community research programme in the field of medical and public health research, gave a new dimension to the task of the Commission, namely to extend its efforts of "gradually coordinating national research activities" to a further area of increasing importance for the Community.

The first programme was followed by the Council Decision of 18 March 1980 (80/344/EEC [4]), adopting a second medical research programme consisting of four multiannual concerted actions.

The latter Decision was of crucial importance to the Commission since it confirmed the option taken by the Council, and furthermore settled the institutional problem of using under certain conditions the Article 235 of the EEC Treaty for undertaking medical and public health research.

The following concerted actions are presently implemented :

| | |
|---|---|
| 1. Registration of congenital abnormalities [1, 5] | 1st programme (1.1.1978 - 31.12.1981) |
| 2. Cellular ageing [2] | |
| 3. Extracorporeal oxygenation [3] | |
| 4. Detection of tendency to thrombosis | 2nd programme [4] (1.6.1980 - 31.5.1984) |
| 5. Hearing impairment | |
| 6. Perinatal monitoring | |
| 7. Quantitative electrocardiography | |

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(1) OJ No L 52, 23.2.78, p. 20
(2) OJ No L 52, 23.2.78, p. 24
(3) OJ No L 52, 23.2.78, p. 28
(4) OJ No L 78, 25.3.80, p. 24
(5) OJ No L 43, 14.2.81, p. 12

The concerted action method for initiating Community activities in the medical and public health field in a number of well defined topics has been preferred at the time of their proposal.
Two main reasons led to this choice, namely the existing dicrepancies between national research policies and strategies, as stated at an earlier confrontation exercise (CREST/22/76), as well as the existence of many scattered and relatively small research teams at national level. The validity of this choice has been proven and at present more than 400 national projects are coordinated by the ongoing seven EC actions. The number of institutes wishing to join this venture is in fact steadily increasing.

The close collaboration evolved over ten years between the Committee on Medical and Public Health Research CRM/CREST and the Commission has facilitated considerably this coordination.

The achievements in coordination and the recognized scientific and technical enhancement of results of the actions of the first programme confirm the :

- remarkably improved efficiency of national efforts in the respective fields,
- favourable cost/benefit ratio of the Community funds spent for coordination purposes, and
- strengthened confidence and interest of the Member States in this form of Community action for its contribution to economic returns in the biomedical and industrial fields.

CRM, assisted by its Specialized Working Groups, also advised the Commission to promote a wide range of exploratory activities in the form of studies, seminars, workshops etc. Thus, a coherent scheme has been set up, where 3 broad subprogrammes have been defined. Each of them is divided in research areas where the ongoing concerted actions and a number of new projects are integrated.

Considering the above, the Commission advised by CRM prepared its present proposal for a sectoral R & D programme of the EC in the field of medical and public health research.

This proposal provides for the following specific requirements :

- continuation of the concerted actions of the first programme enabling their extension and/or expansion, as already foreseen at the time of their proposal (COM(77) 282 final);

- integration of the concerted actions of the second programme considering their present state of evolution and plans for extension and continuation (COM(78) 377 final);

- implementation of new actions in critical fields of common interest;

- support of centralized coordination facilities, whenever required.

The proposal presents a coherent scheme of Community actions as shown in tables I - III. It constitutes a step towards the sectoral grouping of Community medical research actions of the Member States conducted under the EEC Treaty, and the rationalization of structures and procedures for the "preparation, examination and implementation of Community R & D programmes" in conformity with the Council conclusions of 20 December 1979.

Relevant activities in progress in other countries as well as those of appropriate international organizations such as WHO, OECD, Council of Europe, European Medical Research Councils of the European Science Foundation, etc. were taken into consideration when preparing the project proposals.

The conclusions of the meetings of the Ministers of Public Health (13.12.1977 and 16.11.1978) have also been considered.

In the implementation of the present programme, close coordination is envisaged with other research programmes of the EC which include or are related to medical and/or public health research components. At present these include :

- parts of the research programme of the EC in the field of reference materials and methods (Community Bureau of Reference) [1] related to the production of standards for materials which are of biomedical interest;

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(1) OJ No L 258, 13.10.79, p. 32

- the sectoral R & D programme of the EEC in the field of environment[2], in particular for the part relating to man-environment interaction;

- the plan of action of the EEC in the field of scientific and technical information and documentation [3] for its part concerning "Biomedical Information";

- the research and training programme of the EAEC in the field of biology - health protection (Radiation Protection Programme) [4] in its medical and public health aspects;

- the current four ECSC research programmes [5-8] related to occupational health;

- the action programme of the European Communities on safety and health at work [9].

- **Finally, important areas of this proposal, namely areas I.1. (Pre-, peri-, and postnatal care) and I.2. (Ageing, Disabled and Handicapped) can be seen in the perspective of the International Year of Disabled Persons and of the opinions of the European Parliament and the Economic and Social Committee pertaining to it.**

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(2) OJ No L 101, 11.4.81, p. 1
(3) OJ No L 311, 4.11.78, p. 1
(4) OJ No L 78, 25.3.80, p.19
(5) OJ No C 10, 14.1.77, p. 2
(6) OJ No C 159, 5.7.78, p. 2
(7) OJ No C 161, 1.7.80, p. 4
(8) OJ No C
(9) OJ No C 165, 11.7.78, p. 1

## C. OBJECTIVES, JUSTIFICATION AND ORIENTATIONS

The diseases of modern society with their incidence on industrial development and the steadily mounting costs of health care are among the most important economic problems confronting all Member States.

National efforts to solve them are in progress. Thus, within the Community, there exists a considerable potential for scientific research and industrial development. If mobilized within the frame of a coherent Community medical research programme it would allow the realization of evident scientific progress, giving adequate and more effective information.

### 1. Objectives

The main objectives of European cooperation in the sector of medical and public health research are prevention, early detection of disease and rehabilitation. More specifically they aim at the following, namely to :

a) optimize the capacity and economic efficiency of health care efforts by initiating or implementing common actions in defined fields considered as critically relevant to the solution of major health problems and their incidence on occupational health;

b) improve efficiency of ongoing national R & D through the encouragement of concerted actions thus making a better use of the available research potential;

c) promote through coordinated efforts an active interaction of the National Research Agencies, of the Health Authorities and of the Biomedical Industries, leading to an accelerated raising of the social and economic welfare of the Community;

d) gradually coordinate, at Community level, the national research programmes in the fields of common interest. The implementation of the research work is the remit of competent research organizations of the Member States;

e) provide a systematic template for medical and public health research in the Community R & D policy by bringing under it an increasing proportion of national research activities in this sector.

2. Justification

The legal basis for this programme is Article 235 of the Treaty establishing the European Economic Community and the Council Decision of 18 March 1980 (80/344/CEE [1]) adopting the second medical research programme.

On this basis, and in line with the conclusions of the 619th meeting of the Council on 20 December 1979 (doc. 4230/80/RECH. 1), the Commission prepared the present proposal for a new "sectoral" R & D programme in which an attempt is made to group several ongoing and new research actions pertaining to the field of medical and public health research.
Although this research field is not mentioned among the areas of foremost priority, the Commission proposes to devote to it a certain proportion of its R & D efforts, in conformity with the Council conclusion "not to exclude a priori other areas where a Community contribution could be of particular value for the Community" (see : COM(80) 412 final).

Similarly, this programme proposal corresponds to the Resolution of the European Parliament embodying its opinion on both earlier programmes, in which "the Commission is expected, in accordance with the traditionally universal nature of medical knowledge, to continue to promote such research at European level and to ensure that it is coordinated and, where possible, integrated with similar research being carried out in other parts of the world".

Moreover, the Council Decision of 9 April 1981 [2] on the conclusion of the Agreement between the EEC and the Swiss Confederation on a concerted action, should be considered as a beginning of associating non Member States, participating in COST, wholly or partly with this programme.

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(1) JO No L 78, 25.3.80, p. 24

(2) JO No L 113, 25.4.81, p. 44

3. Orientations

Current national programmes in the field of medical and public health research are predominantly oriented to disease-related targets such as : cardiovascular disorders, mental illnesses, congenital abnormalities, geriatric diseases, etc. Here, progress derives largely from individual efforts and dissemination of information is assured by scientific societies. Development as well as coordination at national level is mainly or partially done by making available purpose-linked public research funds. The Commission in line with the advise of CRM does not feel that additional coordination efforts along these targets are considered opportune or necessary at Community level.

In compliance with its mandate and on advice of the CRM, the Commission proposes to orient its sectoral R & D programme towards more comprehensive targets of common interest.

The present R & D programme proposal will allow for more effective research through collaboration and coordination at EC level making use of a multidisciplinary research potential beyond the possibilities of any single country. It focuses on the following three key areas, hereinafter referred to as subprogrammes, relating to :

1. Health Problems
2. Health Resources
3. Personal environment (Diet and Drugs).

The first R & D subprogramme is essentially oriented to the solution of those health problems involving the critical phases of human life, namely birth and old age, to the effects of the life-style related stress of the industrial environment and the ability to cope with it, and to the improvement of rehabilitation of the disabled and handicapped.

It would thus promote the identification of ways and means likely to maximize the results of scientific and technological progress, and to minimize the negative economic and social consequences related to inappropriate intervention in these areas.

The second R & D subprogramme is oriented to the improvement and appropriate use of those health resources required to ensure optimization of the cost-effectiveness ratio in the health care field. Particular attention is given to coordination of efforts to develop health services research, improve health technology and promote upgrading and qualification of human resources.

The third R & D subprogramme focuses on the need for a better understanding of the effects on the individual's health resulting from its diet and the intake of pharmaceuticals, as part of its personal environment.

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D. PROGRAMME CONTENT

## I. HEALTH PROBLEMS

This subprogramme covers research aimed at establishing the biological, physiological, technological, epidemiological and organizational data required for improving the medical intervention at birth, during development and in old age, as well as the effective prevention, better handling and reduced dependence of unfitness, be it the consequence of congenital or acquired handicaps. Results from these investigations are expected to have an important fall-out for the European biomedical and pharmaceutical industries.

The subprogramme also includes studies on the quantification of risk potential and adaptive responses to psychological and social stresses, of particular importance to the area of occupational health.

Part of the research included in this subprogramme is already coordinated in ongoing "Concerted Actions" of the 1st and 2nd medical and public health research programmes. It is proposed to continue these actions.

### Area 1 : Pre-, peri-, and post-natal care

- Technological development and assessment for perinatal monitoring procedures with emphasis on non-invasive techniques. Particular attention will be given to their reliability, to the relevance of information obtained, to mother distress and risks, as well as to foetal loss.

- Research in laboratories equipped to carry out chromosome analysis will endeavour to solve technical problems needed to reach partially automated measurements. Simultaneous parallel biochemical and genetical studies are envisaged.

- The determination of inborn metabolic errors through a uniform methodic approach to different screening programmes aims at defining the criteria for monitoring their incidence and prevalence in the Member States, at diagnosis and at development of treatment.

  Particular attention will be given to treatable errors, and the project will include studies on cystic fibrosis, hemoglobinopathies and hyperlipoproteinemia.

- The congenital anomalies registry in progress will be complemented by investigations on intrauterine diagnosis and studies on early foetal loss, death in early childhood and foetal growth disturbances.

- Current practices in Member States regarding care delivery systems, and in particular the application of technical devices and procedures to perinatal medicine, including cost/effectiveness evaluations,will be examined.

Area 2 : Ageing, disabled and handicapped

- The continuation and further development of the concerted action on cellular ageing will involve studies at organ, cellular and sub-cellular level. It is proposed to include also further investigations of the immune response during ageing including studies contributing to the understanding of arthritic diseases, and of ageing of the brain and senile dementia. The problem of premature, as opposed to normal, ageing will be considered.

- Ageing of the lens and hearing impairment form the crux of the action on sensorial impairment partly covered by ongoing concerted actions. The development of adequate aids to vision and hearing deterioration or loss due to a metabolic or occupational origin will be considered. Biomaterial compatibility studies, closely associated with technological developments, will form the basis of this research.

- The continuation and development of the concerted action on detection of thrombosis and prevention of its resulting disabilities are expected to lead to a better understanding of the pathogenesis of thrombosis as well as to the availability of adequate tests which will aid in the prevention, early diagnosis and treatment of the disease.

- Evaluation and identification of specific needs as regards aids for disabled will be undertaken to define coordinated activities leading to technical developments.

- The pattern of care for the chronic or long term patient with several functional disabilities, and for the impaired elderly will be examined in a study on care delivery systems. Relevant epidemiological aspects will be taken into account.

Area 3 : Breakdown in adaptation

- The determination of measurable parameters which could indicate first a posteriori but also a priori the tendency or initiation of breakdown in adaptation or the form it may take if no counter-measure is introduced, forms this complex multidisciplinary programme. It is envisaged to developed it into parallel projects strictly coordinated between themselves. Particular attention will be given to high risk groups in the working population.

- Studies on quantification of parameters aim at the simultaneous evaluation of already measurable hormonal parameters as well as psychological and sociological ones. The improvement and standardization of methods for measuring possible biological markers of the adaptive process are part of these studies. The interaction of various disciplines closely associated with studies in the following projects form the basis of the whole area.

- Coordination of the ongoing uncorrelated efforts in several Member States to investigate the performance decrement of workers under various environmental conditions so as to avoid accident proneness is envisaged, using the multidisciplinary approach mentioned above.

- Application of the same multidisciplinary approach to the field of cardiovascular diseases with particular reference to hypertension and ischaemic heart diseases is here envisaged. Studies will be integrated with results from other projects and involve the evaluation of psychosocial and neuroendocrine factors in selected groups of subclinical and clinically established patients combined with appropriate monitoring of the relevant physiological variables.

- The model indicated above will be applied to correlate gastro-intestinal diseases with the results of psychobiological and psychosocial measurements. Subjects with borderline gastro-intestinal complaints and established cases will be studied.

- A further particular study of increasing importance for health and safety at work is envisaged in order to assess the relevant problems of drug abuse. Effects of alcohol abuse as well as the mechanisms involved in the proneness to it, of tobacco or products associated with its consumption, as well as of potential opiate intake on the central nervous system and the general metabolism, will be examined in biological and epidemiological studies.

## II. HEALTH RESOURCES

This subprogramme comprises 3 main areas of research : the 1st one aims at assessing health services research concerned with the development of health services particularly in relation to changes in social, demographic, environmental and occupational conditions. Correct and problem-oriented development of health technologies including the transfer of new knowledge and methods from basic hard and soft sciences into medical technologies, as well as the assessment and testing of medical equipment form the 2nd area in this subprogramme. Important impacts on the European biomedical industries can be foreseen.
The 3rd area deals with qualitative improvement of medical research scientists in fields in which knowledge and technology are progressing rapidly and where highly skilled researchers are critically needed.

### Area 1 : Health services research

Health services research has to develop generally acceptable scientific methods to investigate efficiency of different health systems, effectiveness of various medical procedures and technologies, and to analyse problems of planning, organization, management, evaluation and acceptability of health services in their relationship to social and environmental circumstances, in order to ensure optimal health of the working population in a cost-efficient way.

Variations in organization and structure of health services research in the Member States as well as special research requirements and difficulties entail a still poor development of research in this area.

The proposed research therefore aims, in a first phase, at the development on Community scale of a common methodology including strategies for comparative evaluation studies which involve evaluation of process (efficiency) and assessment of outcomes versus the originally stated objectives (effectiveness).

In a second phase, four interrelated topics are selected for elaboration :

- Coordination of health services research : following evaluation of the present state of the art of health services research in the Member States, of its problems and of its organisation and structure, this topic will aim at the coordination of ongoing national efforts in order to develop at Community level an efficient research in this area.

- Assessment of health status : the development of health indicators is a basic tool in occupational health, in determining the need for early care in specific population groups and in identifying risk factors.

- Research on prevention : the change in emphasis from medication to health promotion has increased the demand for further knowledge about 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; relevant national activities will be assessed in order to elaborate a concerted approach.

- Community versus hospital care : this research topic aims at assessing the feasibility and potential importance of community care to the population in its home and occupational environment, in comparison with hospitalization and by considering in particular technological progress in monitoring and drug delivery, as well as development of new drugs.

Area 2 : Health Technology

- A continuation and development of the ongoing concerted action on extracorporeal oxygenation will consider advanced technological developments for the replacement of body functions. Developments foresee further research on oxygenator design and performance as well as parallel studies into alternative methods of oxygenation including enzyme binding to membrane and research on biomaterials.

- The concerted action on common standards in electrocardiography will be continued in a broader context of quantitative functional assessment to include the standardization and improvement of diagnostic criteria. The same approach will be used for computerized analysis of other diagnostic functional parameters.

- The monitoring of developments in the field of imaging techniques, both in vivo and in vitro is of great interest and will be carried out in a specific project. Pilot studies to define common multipurpose packages for image elaboration may be initiated.

- Criteria for better exploitation of the possibility of ambulatory monitoring of physiological variables of great diagnostic importance will be defined. Its application to rehabilitation, therapeutic needs, drug use and occupational health will be examined.

- The development of clinical and technical evaluation of new medical devices and procedures, including cost/efficiency aspects is the scope of this action. It will include a comparative evaluation of medical equipment in technical and user trials undertaken by a panel of clinicians, scientists from the participating centers in liaison with health authorities.

Area 3 : Human Resources

This area shall deal with methodological research on ways and means for 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.

The projects aim first at the evaluation of present and future needs, confrontation of national measures taken, identification of suitable upgrading facilities, and subsequently at the development of coordinated procedures. Assessment of their efficiency through test cases in toxicology, advanced health technology and clinical investigation is envisaged.

## III. PERSONAL ENVIRONMENT (Diet and Drugs)

A nutritional research programme will aim at ascertaining the diet component involved in the occurrence of diseases such as arterial hypertension and digestive tract diseases. It incorporates development and implementation of specific methodologies for the study of food and the detection of individual predisposition to the relevant diseases. Research based on multicenter studies will aim at assessing by post-marketing clinical trials of adequate scale the efficacy of specific drugs as well as at developing a drug surveillance project.

Area 1 : Nutrition

- The importance of dietary factors in the promotion of hypertension will be investigated to identify adequate measures of preventing their effects. This project includes biological and epidemiological aspects so as to define the prevalence in each Member State and the environmental causes of the disease. These studies will have a relevant impact on the European food industry at production and marketing level.

Area 2 : Pharmaceuticals

Adequate post-marketing drug surveillance and multicenter controlled clinical trials require studies on very large populations for the short- and long-time evaluation of both new and old pharmaceuticals. Ongoing activities in the Member States are scattered, unrelated to each other and therefore of minor effectiveness. By regrouping and coordination, thus by making better and more

effective use of existing and potential resources, joint medical research conducted at Community level would give a greater and more consistent support to the pharmaceutical industry, contribute to drug development, and ensure a quicker warning system.

- It is proposed to stimulate and coordinate post-marketing clinical trials to test the efficacy or some specific effects of pharmaceuticals. Such controlled trials of adequate scale aim at appropriate collection, storage and dissemination of information on new developments and on the efficacy of old and new drugs.

- In order to improve existing mechanisms for identifying adverse effects of drugs which because of low incidence or late occurrence have escaped premarketing testing, it is proposed to develop a post-marketing drug surveillance project. It would promote exchange and early dissemination of information and would attempt to supplement existing methods by different approaches i.e. case control surveillance and record linkage drug surveillance.

## E. PROGRAMME IMPLEMENTATION

The basis for optimal implementation of the proposed R & D programme is the sharing of its inherent responsibilities between the Member States and the Commission :

- The Member States endeavour to carry out, according to the rules and procedures applicable to their national programmes, the execution of the research as described in the foregoing chapter D, and are prepared to integrate such research into a process of coordination at Community level over the programme period.

- The Commission is responsible for such coordination of the national contributions to the programme as well as for the management of the Community budget allocated to it (see chapter G).

Implementation is carried out as a concerted action programme relating to well defined research fields chosen for European collaboration, and including the actions of the 1st and 2nd medical programme.

The national contributions to this programme and their coordination at national level, as well as the selection of national experts for their scientific management, will be part of the responsibilities of the concerned authorities in the Member States. These authorities are indicated in Appendix 3 of the proposed Council Decision.

An active participation of all Member States in each single project is not mandatory e.g. in the case of absence of a national programme in a particular research line.

Following the Council Decision, third countries involved in European cooperation in the field of Scientific and Technical Research (COST) will be invited to participate to all or parts of this programme.

A reexamination of the programme is foreseen at the end of the third year which may lead to a revision in the course of the fourth year as well as in the preparation of a proposal for a possible new programme intended to constitute a follow-up to the present one.

## F. OPERATIONAL AND MANAGEMENT STRUCTURE

An adequate operational and management structure is indispensable in order to :

- ensure maximum efficacy in both programme implementation and coordination,
- meet the requests stressed by the Council in its Resolution of 1974 and its Conclusions of 1979,
- achieve the objectives of this programme (given in chapter C.1.),
- maximize economy and profits of the allocated budget while ensuring all the specific requests to achieve the research goals of the programme (see page 6).

The rationalization of structures and the simplification of procedures aimed at in the present attempt of grouping R & D actions in the sector of medical and public health research, should also allow a greater flexibility in programme implementation and management.

### 1. Operational structure

Three subprogrammes are forming the overall R & D programme; their operational structure is shown in the following Tables I - III.

Each subprogramme is divided into 3 research areas which group scientifically related projects.

Some projects will of course have to go through an organizational preparatory phase before active coordination can start.

The following steps will have to be taken for each project :

- the setting up of its own operational structure including a technical steering committee,
- the identification of the contributing national institutes,
- the appointment of a project leader, and
- the conclusions of contracts making available the funds needed for coordination purposes.

TABLE I

## SUBPROGRAMME I : HEALTH PROBLEMS

### Research Areas and Projects

Area I.1. Pre-, peri-, and postnatal care

Project I.1.1. Perinatal Monitoring
I.1.2. Chromosome Analysis
I.1.3. Inborn Metabolic Errors
I.1.4. Congenital Anomalies
I.1.5. Care Delivery Systems

Area I.2. Ageing, Disabled and Handicapped

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. Drug Abuse

TABLE II

## SUBPROGRAMME II : HEALTH RESOURCES

### Research Areas and Projects

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 vs. 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. | " " Health Service Management |
| | II.3.3. | " " Occupational Health |
| | II.3.4. | " " Advanced Technology |
| | II.3.5. | " " Epidemiology |
| | II.3.6. | " " Clinical Investigation |

TABLE III

## SUBPROGRAMME III : PERSONAL ENVIRONMENT

(Diet and Drugs)

### Research Areas and Projects

Area III.1. Nutrition

Project III.1.1. Diet, Hypertension and Digestive Tract Diseases

Area III.2. Pharmaceuticals

Project III.2.1. Clinical Trials

Project III.2.2. Drug Surveillance

## 2. Management structure

On the basis of the experience gained from the ongoing concerted actions and following a critical examination of the most rational management structure for the optimal implementation of this multidisciplinary R & D programme, the Commission, in agreement with CRM, proposes the setting up of the following Committees :

a) One "General Concerted Action Committee", hereinafter referred to as the "General Committee", ensures the best possible implementation of the overall programme. For this purpose it is composed of representatives of the Member States responsible for science and technology in the field of medical and public health research.

At national level, its representatives take care of the integration of those parts of their research activities, which correspond with this programme, into a process of coordination at Community level, while the Commission ensures the coordination of the national contributions to the programme.

The General Committee :

- advices the Commission on the allocation of Community funds needed for : coordinating purposes, supporting centralized facilities, meeting urgent needs in critical areas, and undertaking exploratory activities in view of the preparation of future programmes;
- coordinates within the programme the activation, duration and possibly early termination of the projects forming the research areas of this programme, on advise of the respective COMAC's (see under b) assisting it in its scientific-technical management tasks, and according to emerging needs or results of periodical evaluations;
- indicates guidelines to the COMAC's.

b) Four "Concerted Action Committees", hereinafter referred to as "COMAC's", ensure the scientific-technical management of those projects entrusted to each COMAC, in conformity with its respective competence, by the General Committee.

For this function, each COMAC is oriented towards one of the following research domains :

1. Epidemiology, statistics and clinical trials.
2. Bioengineering, technology evaluation, transfer and standardization.
3. Applied biology, physiology and biochemistry.
4. Health services research.

Its members will be chosen among national experts in such a way that all appropriate competences needed are made available by complementing one another; they will be appointed by their responsible national authorities.

Each COMAC, in particular :

- evaluates the results of the projects entrusted to it, draws conclusions as regards their application and reports its opinions and recommendations to the General Committee;
- keeps abreast of ongoing relevant research and technical development likely to affect the execution of the projects;
- suggests guidelines to the project leaders.

## G. WAYS AND MEANS

### 1. Research funding

The financial volume of the national research contributions to this research and development programme is estimated at 300 million ECU over the programme period, which corresponds to about 12 % of the aggregate funding of medical and public health research in the Member States (*).

### 2. Coordination costs

The cost of coordination, charged to the Community budget, is estimated at 20 million ECU for the duration of the programme.
These costs include administrative and technical expenditures, and expenditure for staff subdivided as follows :

| | | | |
|---|---|---|---|
| a) | Administration | 1.40 | million ECU |
| b) | Technical (contracts) | 15.30 | " " |
| c) | Staff | 3.30 | " " |
| | | 20.00 | " " |

a) Administrative expenditures are used mainly for organizing the meetings of the 5 Concerted Action Committees, as well as for convocation of experts, publication, missions, etc.

b) Technical expenditures are spent :

- for contracts with project leaders in order to ensure scientific coordination (organization of meetings of technical steering committee and of workshops, exchange of personnel, dissemination of information, administrative help, etc.).

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(*) Doc. CREST No 1245/79

- for support needed by centralized facilities, whenever its proper functioning requires substantial and/or additional funding, such as : need of computer including programming, production and exchange of costly material, breeding or maintenance of certain animals, data evaluation of clinical trials, preparation of reference software, etc.

- for support of national experts in order to perform exploratory activities by means of studies, workshops or seminars needed either to complement ongoing actions or to prepare new ones.

- for support of national or private institutes in order to make possible a rapid intervention in the case of an unexpected but urgent need of recognized importance.

Their distributions among the subprogrammes are as follows :

| | | | |
|---|---|---|---|
| Subprogramme | I | : | 41 - 49 % |
| " | II | : | 36 - 44 % |
| " | III | : | 13 - 17 % |

c) Staff expenditures

Staff requested for executing the coordination of the programme at Community level is 10 officials, i.e. 6 additional staff.

At present, 4 officials (2 A and 2 C) are allocated to the 2nd Medical research programme.

The 6 additional staff (3 A, 1 B and 2 C) are requested in view of the competence necessary to cope with the new research areas proposed, to ensure the secretariats of the General Committee and its four COMAC's, and to carry out the coordination tasks.

ANNEX I

Proposal for a Council Decision

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

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,

Having regard to the opinion of the Economic and Social Committee,

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 Decision 78/167/EEC,[1] as amended by Decision 81/21/EEC [2], and Decisions 78/168/EEC[3] and 78/169/EEC[4], the Council has adopted three concerted projects as a first research programme in the field of medical and public health research;

Whereas by Decision 80/344/EEC [5] the Council has adopted a second research programme in the field of medical and public health research, consisting of four multiannual concerted projects;

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(1) OJ No L 52, 23.2.1978, p. 20.
(2) OJ No L 43, 13.2.1981, p. 12.
(3) OJ No L 52, 23.2.1978, p. 24.
(4) OJ No L 52, 23.2.1978, p. 28.
(5) OJ No L 78, 25.3.1980, p. 24.

Whereas in its resolution of 14 January 1974 on an initial outline programme of the European Communities in the field of science and technology (6) 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 (7) 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 R & D 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;

Whereas the Treaty does not provided 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 the research indicated in Annex 1, and are prepared to integrate such research into a process of coordination at Community level until 31 December 1986;

Whereas the cost of such research, as indicated in the aforesaid Annex 1, performed in the Member States is evaluated at about 300 million ECU;

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(6) OJ No C 7, 29.1.1974, p. 6

(7) OJ No C 7, 29.1.1974, p. 2

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 of concerted actions 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 Agreement between the EEC and the Swiss Confederation on a concerted project (8) ;

Whereas the Scientific and Technical Research Committee (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.

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(8) OJ No L 113, 25.4.1981, p. 44.

The programme shall consist in coordination at Community level, within the research areas described in Annex 1, 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 appropriations necessary to finance the Community contribution to the coordination, the amount of which is estimated at 20 million ECU, including the expenditure relating to a staff of ten officials, shall be entered in the budget of the European Communities. These figures are given merely by way of indication.

The indicative internal distribution of funds is shown in Annex 2.

In the light of experience gained during the implementation of the programme, and provided the opinion of the Scientific and Technical Research Committee (CREST) and of the committee referred to in Article 5 a) is secured beforehand, the Commission is authorized to transfer funds from one to another subprogramme, provided that such transfers do not result in an increase or a reduction of more than 10 % in the original appropriation for each subprogramme envisaged.

Article 4

The programme shall be reexamined at the end of the third year; this reexamination may lead to a revision of the programme in the course of the fourth year following the appropriate procedures, and after the Committee referred to in Article 5 a) has been consulted. The European Parliament shall be informed of the results of the reexamination.

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 3.

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 rules of internal procedure. Its secretariat shall be provided by the Commission.

Implementation and coordination of the national contribution to the programme shall be carried out by the bodies listed in Annex A.

Article 6

In accordance with a procedure to be laid down by the Commission after having consulted the General Committee referred to in Article 5 a), the participating Member States and the Commission shall regularly exchange all useful information concerning the execution of the research covered by such activities. 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.

At the 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 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 the latter has been sent to the Member States, unless a Member State objects. In the latter case, the report shall be distributed only to those institutions and enterprises that request it and whose research or production activities justify access to the results of research arising from the programme. The Commission shall make the necessary arrangements for the report to remain confidential and not to be divulged to third parties.

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 on 1 January 1982.

Done at

For the Council

The President

Annex 1

SCIENTIFIC AND TECHNICAL CONTENT

(Concerted Action Programme)

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

- to increase the efficiency of relevant R & D efforts in the Member States through the mobilization of the available research potential of parts of national programmes and its gradual coordination at Community level;
- to improve the scientific and technical knowledge in the R & D areas, selected for their importance to all Member States taking a particular account of potential economic and industrial development within the projects forming them, and
- to provide for the continuation of the 3 concerted projects of the first medical research programme (1978-1981), the integration of the 4 ones of the second programme (1980-1984) 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 ongoing project relating to perinatal monitoring (1), with emphasis on technological development and assessment of devices and procedures for non-invasive monitoring, and extension to prevention of mother's distress and risk as well as of foetal loss.
- Improvement of techniques needed for (partially) automated chromosome analysis as well as biochemical and genetical studies to increase possibilities of its 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 intrauterine diagnosis and studies on early foetal loss, death in early childhood and foetal growth disturbances.

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(1) for programme description see : O.J. No L 78, 25.3.80, p. 24.

(2) " " " " : O.J. No L 52, 23.2.78, p. 20.

- 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, Disabled and Handicapped

- Continuation of the project relating to cellular ageing [2] with extension of its immunological subproject to the understanding of arthritic diseases and of its subproject concerning organs to studies of the brain and senile dementia.
- Continuation of the project relating to hearing impairment [1] and of the subproject on ageing of the crystalline lens of the foregoing project [2]; development of adequate aids for visual and auditory sensorial impairment including biomaterial compatibility studies.
- Continuation of the ongoing 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, identification of specific needs and their technological development.
- Examination of care pattern for the chronic patient with several functional disabilities and for the impaired elderly including epidemiological aspects.

Research area 3 : Breakdown in adaptation

- Evaluation, improvement, 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 above mentioned 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.

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(1) for programme description see : O.J. No L 78, 25.3.80, p. 24.
(2) " " " " : O.J. No L 52, 23.2.78, p. 24.

- 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 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 health services research 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 potential importance of community care to the population in its home and occupational environment, in comparison with hospitalization.

### Research area 2 : Health Technology

- Continuation of the project relating to extracorporeal oxygenation[2] with extension to advanced technological developments for the replacement of further body functions including research on biomaterials.
- Continuation of the ongoing project relating to common standards in quantitative electrocardiography[1] with extension to standardization and improvement of diagnostic criteria; the same approach will be used for computerized analysis of other diagnostic functional parameters.
- In vivo et in vitro 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 great diagnostic importance to rehabilitation, therapeutic needs, drug use and occupational health.

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(1) for programme description see : O.J. No L 78, 25.3.80, p. 24

(2) for programme description see : O.J. No L 52, 23.2.78, p. 28.

- 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.

Research area 3 : Human Resources

- Methodological research on ways and means for 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, confrontation 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, advanced health technology and clinical investigation.

## SUB-PROGRAMME III : PERSONAL ENVIRONMENT (Diet and Drugs)

Research area 1 : Nutrition

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

Research area 2 : Pharmaceuticals

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

- Development of a post-marketing drug surveillance project of 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 occurrence, including case control surveillance and record linkage drug surveillance.

Annex 2

INDICATIVE INTERNAL DISTRIBUTION OF FUNDS

(1982 - 1986)

| | | | |
|---|---|---|---|
| Subprogramme | I | : | 45 % |
| Subprogramme | II | : | 40 % |
| Subprogramme | III | : | 15 % |

Annex 3

Implementation and coordination of the national contributions to the programme

The following authorities of the participating Member States will endeavour to ensure the implementation of the national contributions to the research areas of the three subprogrammes indicated in Annex 1, as well as their coordination at national level :

| | | |
|---|---|---|
| Belgium | : | FRSM - Fonds de la recherche scientifique médicale, Bruxelles<br>FGWO - Fonds voor Geneeskundig Wetenschappelijk Onderzoek, Brussel |
| Denmark | : | Statens Laegevidenskabelige Forskningsråd, København |
| France | : | INSERM - Institut national de la santé et de la recherche médicale, Paris |
| Germany | : | Bundesminister für Forschung und Technologie, Bonn<br>Bundesminister für Jugend, Familie und Gesundheit, Bonn<br>Bundesminister für Arbeit und Sozialordnung, Bonn |
| Greece | : | Ipiresia Epistimonikis Erevnis ke Technologhias, Athens<br>Simvoulion Iatrikon Erevnon, Athens |
| Ireland | : | Medical Research Council of Ireland, Dublin<br>Medico-Social Research Board, Dublin |
| Italy | : | CNR - Consiglio nazionale della ricerca, Roma and<br>Istituto superiore di sanità, Roma |
| Luxembourg | : | Ministère de la santé, Luxembourg |
| Netherlands | : | Hoofdgroep Gezondheidsonderzoek TNO, Den Haag |
| United Kingdom | : | MRC - Medical Research Council, London and<br>DHSS - Department of Health and Social Security, London |

Annex 4

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 to 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 1 of the present Decision, coordinate the activation, 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 the allocation of funds for coordination purposes, supporting centralized facilities, meeting urgent needs in critical areas, and undertaking eploratory 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 paragraph of article 6;
- keep abreast of national research being done in the field of the projects, and more especially of scientific and technical development 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 and the project leaders.

ANNEX II

# FINANCIAL RECORD

1. RELEVANT BUDGET HEADING

2. TITLE OF THE BUDGETARY HEADING: Sectoral R&D programme in the field of Medical and Public Health Research - Concerted Action

3. LEGAL BASIS:

- Implementation of Article 235 of the Treaty establishing the EEC

- Decision of the Council of .....

4. DESCRIPTION, OBJECTIVE AND JUSTIFICATION OF THE PROGRAMME:

4.1. Description

The present proposal deals with a new sectoral research and development programme of the EEC in the field of medical and public health research, to be carried out by means of the concerted action method.
It is subdivided into three subprogrammes:

- Subprogramme 1: Health problems

- Subprogramme 2: Health resources

- Subprogramme 3: Personal environment (diet and drugs).

Each subprogramme is further detailed in research areas grouping several projects.

4.2. Objective

It aims at increasing the efficiency of the relevant R&D efforts in the Member States through the mobilization of the available research potential of parts of national programmes and its gradual coordination at Community level.

4.3. Justification

This proposal constitutes a step towards the sectoral grouping of Community research actions in medical and public health research and towards the rationalization of structures and procedures for the implementation of Community R&D programmes.

The programme proposal, by presenting a coherent scheme of Community concerted research, provides for the continuation of the first medical research programme (1978 - 1981) and the integration of the second one (1980 - 1984) as well as for new activities in critical areas of common interest.

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5. FINANCIAL IMPLICATIONS IN RESPECT OF INTERVENTION APPROPRIATIONS
(including expenditure on staff and administrative and technical expenditure)

5.1. Total cost for the expected duration: 320 Mio ECU

5.2. Proportion financed from:

- the Community budget 20 Mio ECU*
- national budgets 300 Mio ECU

5.3. Multi-annual timetable

5.3.1. Appropriations for commitment (in Mio ECU)

| Type of expenditure | 1982 | 1983 | 1984 | 1985 | 1986 | TOTAL |
|---|---|---|---|---|---|---|
| Staff | 0.54 | 0.61 | 0.66 | 0.72 | 0.77 | 3.3 |
| Administration | 0.26 | 0.32 | 0.26 | 0.29 | 0.27 | 1.4 |
| Contracts | 2.0 | 4.0 | 5.0 | 3.3 | 1.0 | 15.3 |
| TOTAL | 2.8 | 4.93 | 5.92 | 4.31 | 2.04 | 20.0* |

5.3.2. Appropriations for payment (in Mio ECU)

| Type of expenditure | 1982 | 1983 | 1984 | 1985 | 1986 | 1987 | TOTAL |
|---|---|---|---|---|---|---|---|
| Staff | 0.54 | 0.61 | 0.66 | 0.72 | 0.77 | - | 3.3 |
| Administration | 0.26 | 0.32 | 0.26 | 0.29 | 0.27 | - | 1.4 |
| Contracts | 1.0 | 3.0 | 4.5 | 4.2 | 2.1 | 0.5 | 15.3 |
| TOTAL | 1.8 | 3.93 | 5.42 | 5.21 | 3.14 | 0.5 | 20.0* |

5.4. Method of calculation

5.4.1 Staff expenditure

Requirements have been calculated on the basis of a staff complement of 10** persons (including the staff complement of 2 category A and 2 category C officials allocated to the 2nd medical research programme), i.e. :

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* Since Decision 80/344/EEC will be repealed with effect from 1 January 1982, the amounts which are authorized under the relevant heading in the 1980 and 1981 budget and which, as at 1 January 1982, have not yet been committed or have been committed but not yet paid may be used for the execution of the present programme.

** For 1982, the staff complement requested in the budget is as follows: 4 category A, 1 category B, 3 category C.

- 5 category A officials
- 1 category B official
- 4 category C officials.

Apart from the actual staff complement, the calculations also take account of the rates of salary increases of Commission staff used to estimate the appropriations entered in the 1982 budget; the estimated overall increases for subsequent years are based on the rate of change in the general Community price index used in drawing up the triennial estimates, i.e. 8,6 % per annum.

5.4.2. Administrative and/or technical expenditure

This expenditure specifically covers the cost of the organization of meetings (5 committees of 30 - 40 members meeting 4 times 2 days), convocation of experts and that of missions. It has been estimated on the basis of average requirements.

5.4.3. Expenditure on contracts

This expenditure covers the financial contribution of the Community to the coordination essentially carried out under contracts to be concluded with the project leaders (for organization of: meetings of technical steering committee, seminars, workshops, exchange of personnel, disseminations of information, scientific and administrative help, etc.), with institutes ensuring costly centralized services to all Member States (for computer including programming, production of exchange of material, breeding and maintainance of certain animals, data evaluation of clinical trials, preparation of reference software, etc.), with national experts (for exploratory activities in form of studies, etc.) and with national or private institutes (for rapid intervention in the case of an unexpected but urgent need etc.).

6. FINANCIAL IMPLICATIONS IN RESPECT OF APPROPRIATIONS FOR STAFF AND CURRENT ADMINISTRATIVE EXPENDITURE:

(see point 5 above)

7. FINANCING OF EXPENDITURE

Appropriations to be entered under future budgets

8. IMPLICATIONS IN RESPECT OF REVENUE

- Community taxes on officials' salaries
- Officials' contribution to the pension scheme.

9. TYPE OF MONITORING TO BE APPLIED

- Administrative checks by the DG for Financial Control with regard to the implementation of the budget and to ensure that the expenditure has been incurred in a regular and proper manner plus checks carried out by the Contracts Service of DG XII.
- Scientific checks: General Concerted Action Committee assisted by 4 Concerted Action Committees.