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Proposal for a

COUNCIL REGULATION

relating to a research and development coordination programme of the European Economic Community in the field of medical and health research (1987-1989)

(submitted to the Council by the Commission)

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PART I

PROGRAMME PROPOSAL

A. SUMMARY BACKGROUND

Each Member State, with its own experience and resources, is primarily responsible for promoting and preserving the health of its citizens.

The cost of health care is very high however, and is steadily increasing. Indeed, in the European Community, the yearly global expenditure for health care is presently estimated to be several hundred milliard ECU.

Medical and public health research aimed at improving both the quality and the economic efficiency of health care is one essential tool for the containment of these steadily mounting costs. Although the sum of national expenditure for medical and public health research can be estimated to exceed yearly 1.2 milliard ECU in the Community, relevant research efforts at national level alone prove to be inadequate. Therefore, European co-ordination of these national research activities is indispensable if the financial resources and capabilities available at national level are to be used as effectively as possible.

Furthermore, since most national programmes consist of a large number of relatively small projects carried out by relatively small and scattered research teams, co-operation and its co-ordination at both national and Community level is even more relevant.

It was not until 1978 that the Council adopted three "concerted actions", thus creating the first medical and public health research programme of the EEC and adding this research area to the Community's research and development activities.

This decision allowed the Commission to initiate the co-ordination of ongoing national research in limited and well-defined fields of common interest to all Member States, as well as to enlarge its efforts by further concerted actions in 1980, with the second programme. Since these pilot activities proved successful in creating a close European collaboration and thus improving remarkably the efficiency of national research efforts in the chosen fields, the Council adopted in 1982 the current large and coherent third sectoral programme encompassing more than 30 concerted actions.

The following table shows the growth of the scope of co-ordination of the Community programmes :

Programme	Duration	Nr of concerted actions	National teams participating
First	1978-1981	3	100
Second	1980-1983	7	230
Third	1982-1986	34	1.400

Non-Member States have taken the opportunity of participating in selected parts of the programme. Formal agreements of co-operation have been concluded with Sweden, Switzerland and Canada, and an informal exchange of expertise exists with Austria, Finland, Norway, Portugal (*), Spain (*) and Yugoslavia in the framework of COST (European Co-operation in the Field of Scientific and Technical Research), as well as with the National Institutes of Health, USA, and occasionally with Japan.

The **present proposal** is concerned with a fourth coordination programme of medical and health research for the period 1987 to 1989. It provides for :

(i) full development, reorientation or termination, respectively, of ongoing projects;
(ii) starting of new projects already prepared and being complementary to ongoing ones;
(iii) strengthening the joint use of health resources, encompassing medical technology development and health services research (research on health care delivery and organization);
(iv) substantial enlargement of co-ordinating efforts by including two new research targets of critical importance, namely :
  . cancer research, as a follow-up of the conclusions of several European Council since Milan in 1985,
  . research into AIDS, and
(v) exploratory activities for the preparation of new programmes.

The Community enlargement by Spain and Portugal, on the one hand, and the proposed programme extension with two new research targets, on the other, will **double** the size of present co-ordination: **more than 70 concerted actions are expected to become operational until 1989,** and these 70 concerted actions or "scientific networks" will embrace **between two to three thousand national teams.** Co-ordination of **about 25 %** of overal medical and health research in the Community would thus be achieved, creating a real European scientific community in the biomedical field.

A **programme duration of three years** is deemed opportune :

- to achieve in due time full conformity with the future Community Framework Programme 1987-1991, presently discussed at Council.
- to allow the new Member States both to adapt to the concerted action mechanism and to assert their particular national interests at an early stage of preparing new proposals;
- to allow for an adequate match between the new programme needs and the management structure.

(*) before joining the EC on 1st January 1986

B. MOTIVATION

1. Research co-ordination : Reasons, Objectives and Achievements

1.1. Co-ordination by concerted actions : reasons and characteristics

The main reasons for conducting the medical and health research co-ordination programme by means of the concerted action method arise from the following two facts :

- most national research programmes in the field of medicine and public health consist of a large number of relatively small projects, predominantly orientated to disease-related targets and carried out by many scattered and relatively small research teams, often working independently at universities, hospitals, etc.
- there is not yet a common health policy and, therefore, the existing national research policies/strategies differ widely between the national organizations competent in medical and public health research.
  Accordingly there are also differences in the structure of these organizations as well as variations in their ways of working, of categorizing research work at national level, and of defining priorities.

The principal characteristics of such a co-ordination programme are that the Member States themselves :

- select the research projects for co-ordination at Community level and hence participate wholly or partly in the programme according to their interests and available facilities;
- execute the actual R&D work in their participating institutes and totally finance it from national resources according to the rules and procedures applicable to their national programmes; and
- consequently determine the scale of the co-ordinating activities and ensure the overall programme management.

The Commission is responsible for the co-ordination at Community level of the national research contributions to the programme and the finances needed for that purpose which are modest (about 3 - 4 % of the global costs of the research contributions from the Member States) but of high return value due to their great catalytic effect.

1.2. Objectives of Community Medical and Health Research

The medical and health research co-ordination programme aims at promoting :

- Commmunity actions in jointly defined research areas considered critically relevant to the solution of major health problems, and
- Co-ordination of national research policies/strategies through programme implementation by, or in close association with, the competent research organizations of the Member States.

The main objectives of this European collaboration are to :
- optimize the capacity and economic efficiency of health care efforts, and thus to combat their steadily mounting costs, by initiating or implementing concerted projects in defined areas considered as critically relevant to the solution of major health problems and their effects on occupational health;
- increase the efficiency of relevant R&D efforts in the Member States through the mobilization of the available research potential of national programmes and through their gradual co-ordination at Community level;
- improve scientific and technical knowledge in the R&D areas selected for their importance by all the Member States, and to promote its efficient transfer into practical application, taking particular account of potential industrial and economic development in the areas concerned.

1.3. Achievements of the Research Co-ordination Programme

The achievements of the current medical and health research co-ordination programme must mainly be measured in terms of the attainment of its aims and objectives.

Concerning promotion of Community actions, the measures laid down in the Council Decision for meeting the relevant objectives were successfully taken, as already shown on page 3 by the table illustrating the growth of co-ordination :

- As to "initiating and implementing concerted actions", their number gradually quintupled over the programme period (from 7 in 1982 to 34 in 1986).
- As to "mobilizing the available research potential", the number of participating national teams sextupled correspondingly (from 230 in 1982 to 1400 in 1986). If a national team is composed of an average of 3 scientists, then co-ordination of about 4000 scientists has gradually been achieved at Community level.

Concerning improvement of scientific and technical knowledge, it is widely recognized that various concerted actions have contributed significantly to present knowledge in biomedical science, and to the development of advanced medical techniques and devices, and thus to improved health care. Unfortunately this is not sufficiently acknowledged as being a result of transnational cooperation made possible by Community co-ordination, because the whole of the research work is totally carried out and financed at national level and, therefore, all inventions, licences and patents as well as publication rights are in individual hands.
However, there are each year several hundred "joint" publications, reports from numerous international symposia, progress reports, etc. which are widely distributed, as well as thousands of individual articles published by the participants in scientific journals.

Concerning co-ordination of national research policies/strategies, the realization of this rather delicate aim has also steadily advanced mainly due to:

- the implementation of the programme by or in close association with the research organizations of the Member States;
- the close collaboration which has developed particularly over recent years between the former CRM (today's CGC) representing the competent national research and health authorities, and the Commission itself;
- the steadily increasing amount of co-ordination of the relevant national activities both at national and Community level, which required a national adaptation to it.

A further important achievement is the steadily increasing wishes of non-Member States to participate in the programme : mainly attracted by both the quality and the efficiency of this transnationally conducted research, more than 80 teams from these countries (as already described on page 4) are now actively participating on a formal or informal basis.

The Evaluation Report Nr.5, EUR 7730, and a recent one, Nr.15, EUR 10,606, as well as the Report from the Commission to the Council and the European Parliament on "Assessment of RD & D Programme Achievements", Doc. COM(86)15 of 7 March 1986, support the value of medical and health research co-ordination programmes, on the one hand, and describe some typical achievements on the other.Three examples are chosen here for illustration :

- The project "Registration of congenital abnormalities" succeeded through an enormous amount of spadework on elaboration of guidelines, continued co-ordination of recording, monitoring, validation and collaborative research among the participating national registers, in forming the basis for a European network involving 20 regional registers in Europe. This now makes it possible to register babies with congenital abnormalities under agreed protocols, to set up similar registers within each country, and to monitor incidence and prevalence of congenital abnormalities including those potentially arising from environmental factors, with statistical significance which was and is far beyond the possibilities of a single Member State.
- The project "Common standard for quantitative electrocardiography" established at Leuven (Belgium) a measurement data bank for the standardization of computer-derived ECG measurements which has become an internationally recognized yardstick for the evaluation and improvement of European, American and Japanese ECG programmes, and is unique in the world. It represents a step towards developing common diagnostic criteria in order to build the next generation of intelligent software tools for automated interpretation.
  Considering that in the EC 70-80 million ECGs are taken yearly, (of which the costs are close to one milliard ECU), improved computerized reading (presently still under 10 %) can have a considerable impact on costs of health care.
- The project "Hearing impairment - Artificial auditory stimulation" created both a European collaboration between independent and often competitive teams specialized in making deaf people hear and communicate with the help of external electrical impulses (= cochlear implants), and also developed close contacts with American teams. This led to major advances in the development of implants and to the establishment of an EC-standard for assessing the clinical results after implantation. Today there are about 750 patients in Europe and about 2,000 patients world-wide who have received such a cochlear implant.

2. Relationships to the Framework Programmes

2.1. The first Framework Programme (1984-1987)

The conduction of the medical and public health research programme (1982-1986) found its justification within the seventh goal relating to "Improving living and working conditions" and its particular objective : "Improving safety and protecting health".

Since health refers to the state of well-being of the individual and safety to his protection from environmental risks, both were deemed interdependent and, therefore, considered jointly.

Hence, the following Community programmes were grouped together :
1. Radiation protection, based on the EURATOM-Treaty,
2. Medical and public health research, based on the EEC-Treaty,
3. Seven programmes dealing with health (in terms of occupational medicine and hygiene) and safety at the working place, based on the ECSC-Treaty.

Overall programme management was and is ensured by separate committees, for institutional and/or practical reasons, mainly because the responsibilities for the fields covered by these programmes lie within the competence of different national authorities.

The quantitative and qualitative contributions of the programmes to the implementation of the Framework Programme were reported by the Commission in the documents COM(85)140 and COM(86)15.

2.2. The second Framework Programme (1987-1991)

The proposal for a Council Regulation concerning the second Framework Programme describes the "Health" line of activities as composed of the following sectors :
- Medical and public health research
- Development of predictive medicine and novel therapy
- Radiation protection research.

"Predictive medicine" is a projet still being prepared. A proposal will be made to Council as soon as possible. "Radiation protection research" carried out in a 1985-89 programme already decided upon by Council. The present proposal deals with the first sector of the envisaged "Health" activities and, in accordance with the 2nd Framework Programme proposal, focuses on major health problems common to all Member States. It includes Cancer and AIDS research as new targets, and proposes to continue actions on age-related, environment and life-style related health problems, as well as on medical technology development and health services research.

3. Community added value

The S/T content of the present proposal has been defined taking into account the added value of actions carried out at Community level.

Consequently, the proposed actions

- respond to collective needs. In particular, health problems common to all Member States demand common solutions whether in order to avoid unnecessary duplication and to promote harmonization of methods, or to reduce the costs and to increase the benefits to all European citizens through a sharing of tasks,

- contribute to the strenthening of the Community's economic and social cohesion, with a gradual reinforcement of the S/T potential of less favoured countries and regions, an improvement of the quality level of the Community's R&D potential through liaisons and cooperations in priority areas, and the opening and stimulation of the Community-wide internal market of S/T knowledge deriving from the results of the programme.

Cooperation with non-Member States and with organizations has successfully developped in the past and will be continued, in particular

- co-operation with COST-countries or with other non-member States such as USA, Canada and Japan (see p. 4), .collaboration with international organizations such as the WHO-European Office, the Council of Europe (Ministers of Health) and the ESF (European Medical Research Councils).

4. Member States interest

The particular interest of all Member States in the co-ordination of medical and health research at Community level is not only expressed by their active and steadily increasing participation in the programme but is also documented by

- the national positions on the proposed Community actions of the new Framework Programme, given by the titular members of CREST in May 1986, where the line "Health" received a favourable and practically uniform ranking from all Member States;

- the "Statement" of the Ministers of Health, meeting within the Council on 29 May 1986

C. CONCEPTUAL PROGRAMME STRUCTURE

The proposed programme, forming a coherent scheme of Community actions and making use of Europe's multidisciplinary research potential, is subdivided into two sub-programmes :

Sub-programme I : Major health problems
Sub-programme II : Health resources.

Each is divided into research targets grouping three to five detailed research areas, subdivided into individual research projects, as indicated in the subsequent tables.

The first sub-programme deals with those major health problems which confront the citizens of all Member States and of which the solutions are of the utmost medico-social and economic importance.

As new targets, CANCER research, as a follow-up of the European Councils since Milan in 1985, and research into AIDS are included. It will also provide for the continuation of those ones referring either to age-related (including disabilities) or to environment and life-style related health problems, respectively. It would thus promote the identification of ways and means likely to maximize the results of scientific progress, and to minimize the negative economic and social consequences related to inappropriate intervention.

The second sub-programme is orientated to the improvement and joint use of those health resources required to ensure optimization of the cost/effectiveness ratio in the health care field. Particular attention will be given to

- strengthening medical technology development, as endorsed by the European Council in Milan, by pooling in advanced fields the more or less scarce national expertise and by jointly exploring new R&D avenues which will create a real innovation potential and hence contribute to the industrial development;

- further developing health services research, e.g. research on health care delivery and organization, which is deemed essential to curb effectively the steadily increasing health care expenditures.

Concerning its preparation :

- Target I.1. relating to **CANCER** was recently elaborated, in line with the conclusions of the 12 high-level oncology experts (COM(86)150), by an invited group of oncologists and of national experts, appointed by the CGC, and of COMAC representatives who defined the target's scientific-technical content.

- Target I.2. relating to **AIDS** was prepared by the CGC's Working Party on AIDS, composed of the national co-ordinators accompanied by selected experts; they met periodically for more than two years, monitoring both the health problems and the scientific progress, ensuring the co-ordination between about 90 national teams and defining the actual R&D needs.

- All further targets (I.3 - II.2) were prepared in a closely co-ordinated way by the four COMACs.

- The final selection of the individual projects of the programme proposal (1987-1989) was made with the CGC over several occasions; particular attention was given, when selecting a project, to

  (i) its medico-social and economic importance;
  (ii) its scientific-technical content, complementary character and stage of development;
  (iii) Member States'interest and available facilities;
  (iv) the conclusions of the Evaluation Report N° 15.

- The effect which that evaluation has had on this preparation was principally a thorough examination by the responsible COMACs of those seven projects (out of 13 evaluated ones) which attracted criticism. This review resulted in

  - the termination of three projects, considered as having reached their original objectives,
  - the reorientation of one project, and
  - the continuation of three projects.

  As regards relations with other Community programmes or projects : in order to avoid undue overlapping and maximise synergies, adequate relations and coordination will be developed with other programmes, e.g. ESPRIT, RACE and BRITE in relation with medical technology development, and with the BICEPS exercise in relation with health services research.

PROGRAMME SCHEME

SUB-PROGRAMME I : MAJOR HEALTH PROBLEMS

Target I.1. : CANCER

Area I.1.1. : Cancer research training scheme
I.1.2. : Clinical treatment research
I.1.3. : Epidemiological research
I.1.4. : Early detection and diagnosis
I.1.5. : Drug development
I.1.6. : Experimental (fundamental) research

Target I.2. : A I D S

Area I.2.1. : Disease control and prevention
I.2.2. : Viro-immunological research
I.2.3. : Clinical research

Target I.3. : AGE-RELATED HEALTH PROBLEMS

Area I.3.1. : Reproduction
I.3.2. : Ageing and diseases
I.3.3. : Disabilities

Target I.4. : ENVIRONMENT AND LIFE-STYLE RELATED HEALTH PROBLEMS

Area I.4.1. : Breakdown in human adaptation
I.4.2. : Nutrition
I.4.3. : Consumption of illicit drugs
I.4.4. : Infections

SUB-PROGRAMME II : HEALTH RESOURCES

Target II.1. : MEDICAL TECHNOLOGY DEVELOPMENT

Area II.1.1. : Diagnostic methods and monitoring
II.1.2. : Treatment and rehabilitation
II.1.3. : Technical and clinical evaluation

Target II.2. : HEALTH SERVICES RESEARCH

Area II.2.1. : Research on prevention
II.2.2. : Research on care delivery systems
II.2.3. : Research on health care organization
II.2.4. : Health technology assessment

The sequence of targets and research areas does not constitute a priority ranking.

TARGET I.1. CANCER RESEARCH

Area I.1.1. : Cancer Research Training Scheme

Fellowships of about 50 men/year
(2/3 fundamental and 1/3 clinical research)
subdivided into long-term and short-term.

Area I.1.2. : Clinical Treatment Research

Projects

1. Improvement of the quality control of multicentre clinical trials for common cancers, including establishment of international guidelines.
2. Co-ordination of multicentre clinical trials for uncommon cancers.
3. Creation of a European network of data centres co-ordinating clinical trials.

Area I.1.3. : Epidemiological Research

Projects

1. Dietary factors and cancer
2. Occupational cancer
3. Cancer and reproduction
4. Passive smoking and cancer.

Particular emphasis should be given to the establishment of basic methodologies for surveys and for population based registries.

Area I.1.4. : Early Detection and Diagnosis

Projects

1. Development and clinical-technical evaluation of automated devices for cytology, histology, chromosome analysis and molecular analysis
2. Evaluation of screening programmes for breast, cervix and colon cancer
3. Comparative appraisal of routine screening for early diagnosis

Area I.1.5. : Drug Development

Project

1. Methodological research, applicable to the development of new cytotoxic drugs, with emphasis on in vitro methods for screening the biological activity of molecules.

Area I.1.6. : Experimental (fundamental) Research

Exploratory activities for the preparation of new programmes.

P.S. : Advantage should be taken of the concurrent development of the Cancer Prevention Action Programme in order to develop methodologies for an evaluation of its achievements.

TARGET I.2. AIDS

Area I.2.1. : Disease Control and Prevention

Projects
1. Prospective epidemiological surveillance studies.
2. Comparaison of macro modelling for public health research.

Area I.2.2. : Viro-immunological Research

Projects
1. Serological testing (antibodies and antigens)
2. Quantitation of HIV infection
3. Pathogenesis and experimental therapies in animal studies and in vitro
4. Promotion of vaccine development and antiviral protection.
5. AIDS virus-host interaction : immunocompetence, immunopathology and immunogenetics.

Area I.2.3. : Clinical Research

Projects
1. Therapeutic surveys and clinical trials of opportunistic infections and tumours
2. Development of multicentre clinical trials in AIDS.

TARGET I.3. AGE-RELATED HEALTH PROBLEMS

Area I.3.1. : Reproduction

Projects
1. Congenital abnormalities
2. Mortality, pre-term births and growth anomalies
3. Inborn metabolic diseases.

Area I.3.2. : Ageing and Diseases

Projects
1. Ageing of crystalline lens
2. Changes in immune response
3. Drug metabolism in the elderly
4. Brain ageing, dementia
5. Epidemiology and prevention of dementia.

Area I.3.3. : Disabilities

Projects
1. Thrombosis
2. Multiple sclerosis
3. Epidemiology and prevention of diabetes.

TARGET I.4. ENVIRONMENT AND LIFE-STYLE RELATED HEALTH PROBLEMS

Area I.4.1. : Breakdown in Human Adaptation

Projects
1. Quantification of parameters
2. Decrement of performance
3. Cardiovascular disfunctions
4. Gastrointestinal disfunctions.

Area I.4.2. : Nutrition

Project
1. Re-assessment and development of epidemiological methodologies in nutrition research.

Area I.4.3. : Consumption of Illicit Drugs

Project
1. Harmonization of epidemiological surveillance.

Area I.4.4. : Infections

Project
1. Epidemiological assessment and prevention of hospital infections and of epidemics.

TARGET II.1. MEDICAL TECHNOLOGY DEVELOPMENT

Area II.1.1. : Diagnostic Methods and Monitoring

- Monitoring Systems :

Projects

1. Detection and measurement of visual impairment in pre-verbal children
2. Diagnostic performance of ECG computer programmes
3. Objective medical decision making
4. System engineering in medicine
5. Ambulatory monitoring
6. Microsensors for medical application
7. New methods for perinatal surveillance
8. Medical telemetry
9. Evoked potentials.

- Imaging Techniques :

10. Positron emission tomography
11. Applied potential tomography
12. Automated cytology
13. Chromosome analysis.

Area II.1.2. : Treatment and Rehabilitation

Projects

1. Advanced technologies for communication in the hearing impaired
2. Replacement of body parts and functions
   - biomaterial research
3. Therapeutic use of collagen
4. Electrical stimulation
5. Laser - application to medicine
6. Rehabilitation of the visually impaired

Area II.1.3. : Technical and Clinical Evaluation

Projects

1. Comparative evaluation of medical equipment
2. Blood flow measurement by ultrasound
3. Ultrasonic tissue characterization
4. Identification and characterization of biological tissues by NMR
5. Assistive devices for paralysed persons
6. Monitoring of fracture healing

TARGET II.2. HEALTH SERVICES RESEARCH

(Health Care Delivery and Health Care Organization)

Area II.2.1. : Research on Prevention

Projects

1. Health status assessment : assessment of the measurement of chronic conditions
2. Health services and avoidable deaths
3. Evaluation of cancer screening programmes
4. Evaluation of integrated non-communicable diseases prevention and control programmes
5. Evaluation of sense-organ function screening at pre-school age.

Area II.2.2. : Research on Care Delivery Systems

Projects

1. Perinatal care delivery systems
2. Care delivery systems for the elderly
3. Primary health care systems and interfaces
4. Comprehensive community care of the mentally ill.

Area II.2.3. : Research on Health Care Organization

Projects

1. Health care planning and management
2. Cost containment in health care
3. Health information systems
4. Evaluation of clinical practice in hospitals.

Area II.2.4. : Health Technology Assessment

Projects

1. Economic appraisal of health technologies
2. Analysis of regional variations in the use of health technologies
3. Collaborative research in mechanisms to promote national diffusion and use of health technologies
4. Effectiveness in terms of health improvement.

MEDICAL AND HEALTH RESEARCH CO-ORDINATION

Re : Number of participating teams : December 1985

TARGET	B	DK	D	E	F	GR	IRL	I	L	NL	P	UK	COST	TOTAL
I. 1 CANCER														
I. 2 AIDS	11	9	14	2	13	7	2	10	2	12	1	9	2	94
I. 3 Age-related Health Problems	19	12	26	-	31	2	8	32	1	29	-	42	17	219
I. 4 Environment and Life-style related Problems	15	10	43	1	26	14	7	18	2	26	1	36	15	214
II. 1 Medical Technology Development	56	52	114	2	111	29	28	85	4	75	2	132	46	736
II. 2 Health Services Research	23	19	19	-	17	22	17	25	1	22	-	29	3	197
TOTAL	124	102	216	5	198	74	62	170	10	164	4	248	83	1.460

D. OPERATIONAL PROGRAMME STRUCTURE

1. Implementation

The basis for optimal implementation of the proposed co-ordination programme is the close co-operation between the Member States and the Commission, as well as the readiness of the competent national authorities to assume the inherent responsibilities and to share the managerial tasks with the Commission.

Since this programme will be mainly executed by means of the concerted action method, Member States should endeavour, in accordance with the rules and procedures applicable to their national programmes, to carry out all or part of the research indicated in the preceding Chapter C, and should be prepared to integrate such research into a process of co-ordination at Community level over the programme period.

The Commission ensures the implementation of the co-ordination programme and the management of the Community budget allocated to it.

The choice of the national contributions to this programme and their co-ordination at national level will be the responsibility of the competent research and halth authorities of the Member States listed for guidance in Annex III of the Council Regulation.

Following programme adoption by the Council, third countries involved in European co-operation in the field of Scientific and Technical Research (COST) will be invited to participate wholly or partly in it, according to the procedures in force.

2. Management structure

2.1. The CGC and the COMACs

By Council Decision 82/616/EEC, adopting the ongoing programme (1982-1986), five management committees have been established, namely one General Concerted Action Committee (GCAC) and four Concerted Action Committees (COMACs).

In order to facilitate programme execution, the Council and the Commission agreed that the terms of reference of the GCAC should be assumed by the Committee on Medical and Public Health Research (CRM/CREST) which was dissolved at the end of 1984.

However, the Council Decision 84/338/Euratom, ECSC, EEC, dealing with structures and procedures for the management and co-ordination of Community research, development and demonstration activities, intentionally did not dissolve the GCAC (and its four COMACs). Its terms of reference were transferred to the newly established Management and Coordination Advisory Committee, the **CGC - Medical and Health Research**, which for its part now acts simultaneously as the GCAC in addition to its function as advisory committee to the Commission.

2.2. On the basis of the past experience, the Commission proposes to create an Advisory Committee for Research in Medicine and Health, which will assist it in its tasks. The Committee shall be composed of representatives of Member States responsible for science and technology in the area of medical and health research, and for the coordination of national contributions to the programme. The Committee may be assisted by concerted action committees (COMAC) composed of scientific experts and by working parties entrusted with specific tasks (such as helping to steer the Cancer and AIDS targets).

2.3. Project Leaders

The project leaders will assist the Commission in its co-ordination tasks. They are appointed by the Commission, after having consulted the committee.

Each project leader is hence responsible for the organization and administration of the activities of his project. His tasks include :

- organization of meetings, seminars, workshops and plenary sessions of all participants;
- dissemination of information,
- short-term exchange of personnel,
- preparation and distribution of materials and reference products,
- centralized data handling, etc.

He is assisted in his tasks by a small PMG - Project Management Group - of which the members are selected from among the participating national teams.

E. FUNDING AND STAFF

1. General remark

The concerted action method aims at the coordination on Community level of relevant parts of ongoing national activities. No additional national research funding is needed for programme implementation.

Sharing of work among competent European research teams, selected for their participation in defined joint actions, allows national savings in the respective research areas by increasing the efficiency of the overall R&D effort.

2. Total budget requirement and repartition

2.1. For the period of three years (1987 - 1989) financial allocations of a total of 37 million ECU are requested from the Community budget, distributed as follows :

Target	Title	million ECU	%	
I.1.	Cancer	11.05	30	Newly added
I.2.	AIDS	5.45	15	45%
I.3.	Age-related health problems	5.65	15	
I.4.	Life-style related " "	3.35	9	Continuation
II.1.	Medical Techn. Development	6.95	19	55%
II.2.	Health Services Research	4.55	12	
		37.00	100	

The allocations take account of

(i) level of funding of ongoing activites;
(ii) the enlargement of the programme by 45% (Cancer and AIDS);
(iii) the enlargement of the Community on 1.1.1986;
(iv) administrative costs for management and staff, inherent to each target;
(v) the financing of so-called "centralized facilities".

2.2. The allocation of 37 MioECU is included in the amount of 150 MioECU deemed necessary for the "Health" activities in the 2nd Framework Programme proposal.

3. Particular points

3.1. Level of funding

It should be noted that the ongoing co-ordination programme (1982-1986) by its very nature did not reach a uniform level of funding. There was and still is a gradual increase in yearly funding requirements, due to the yearly growth of co-ordination as measured by the absolute number both of operational projects and of participating national teams, which is in the order of 10% ; the level presently (1986) reached in terms of appropriations for "commitment" is in the order of five million ECU.

The budget forecast (1987-1989) of the four "old" targets (I.3 to II.2) can thus be estimated at

1987 :	5.5	million ECU
1988 :	6.1	" "
1989 :	6.6	" "
	18.2	million ECU
+ increase for Spain and Portugal :	2.3	" "
	20.5	million ECU,

and will represent 55% of the total request.

3.2. Centralized facilities

A "centralized facility" is a selected institution providing a costly or unique service to other institutions participating in a defined project; this undertaking, indispensable for coordination, generally requires substantial additional funding of the selected institution which cannot be charged to a national budget.

Such centralized services were and are needed for various ongoing projects; they consist for example of : centralized computing, programming, data evaluation, etc.; breeding and maintenance of animals, tissue cultures, etc.; preparation of standards and reference products, etc.

3.3. Staff

The minimum staff requested for ensuring programme co-ordination at Community level are 12 officials, composed as follows :

- 7 category A officials, i.e. one A for each programme target and for the secretariat of the Advisory Committee;
- 2 category B official, taking care of administrative aspects, and
- 3 category C officials.

Taking account of the staff allocated for 1982-1986, namely 5 A + 2 B + 2 C = 9, it would represent an increase by two category A + one category C officials.

PART II

Proposal for a

COUNCIL REGULATION

relating to a research and development coordination programme of the European Economic Community in the field of medical and health research (1987-1989)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

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

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

Whereas Article 2 of the Treaty assigns to the Community the task inter alia 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 (3), as amended by Decision 81/21/EEC (4), and Decisions 78/168/EEC (5) and 78/169/EEC (6), 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 (7) the Council adopted a **second** research programme in the field of medical and public health research;

Whereas by Decision 82/616/EEC (8) the Council adopted a **third** and sectoral research programme in the field of medical and public health research;

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(1) OJ No C
(2) OJ No C
(3) OJ No L 52, 23.2.1978, p. 20
(4) OJ No L 43, 13.2.1981, p. 12
(5) OJ No L 52, 23.2.1978, p. 4
(6) OJ No L 52, 23.2.1978, p. 20
(7) OJ No L 78, 25.3.1980, p. 24
(8) OJ No L 248, 24.8.1982, p. 12

Whereas the **fourth** research and development programme, dealt with by this Regulation, 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 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 1989;

Whereas the cost of the research indicated in Annex I, performed in the Member States, is estimated at more than 1 thousand million ECU;

Whereas in its Resolution of 25 July 1983 the Council adopted a First Framework Programme for Community Research, Development and Demonstration activities (9); whereas Community research in the field of medical and health research has contributed effectively to the aim of improving safety and protecting health within the objective of improving living and working conditions;

Whereas the European Council in Milan on 28-29 June 1985 emphasized the value of launching a European action programme against cancer; whereas, pursuant to the conclusions of further European Councils , the respective research part dealt with by this Regulation would constitute the contribution of medical research and development towards such programme of action;

Whereas AIDS (Acquired Immune Deficiency Syndrome) is a rapidly increasing transmissible disease of the greatest concern to the public health authorities of the Member States; whereas the European Parliament in its Resolution of 13 March 1986 (10) called on the Commission to give priority to research into AIDS in the new medical research programme for the period 1987-1989; whereas the representatives of the Governments of the Member States, meeting within the Council, stated in their Resolution of 29 May 1986 on AIDS that research efforts in the Community and co-ordination of such efforts are therefore of special importance (11); whereas the respective research part dealt with by this Regulation would meet either demand;

Whereas the Community is empowered to conclude agreements with non-member States in the fields covered by this Regulation; whereas it may prove advisable to associate the non-member States participating in European Cooperation in the field of Scientific and Technical Research (COST),

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(9) OJ N° C 208, 4.8.1983, p. 1
(10) OJ N° C 88, 14.4.1986, p. 83
(11) OJ N° C 148, 23.7.1986, p. 21

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wholly or partly with the programme covered by this Regulation; whereas by Decisions 82/178/EEC(12), 83/224/EEC(13), 83/225/EEC(14), 85/150/EEC(15), 86/71/EEC(16) and 86/233/EEC(17) the Council has concluded or amended such agreements on concerted projects in the field of medical and public health research;

Whereas the Treaty has not provided the necessary powers;

Whereas the Scientific and Technical Research Committee (CREST) has delivered its opinion,

HAS ADOPTED THIS REGULATION :

Article 1

A research and development co-ordination programme of the European Economic Community in the field of medical and health research is hereby adopted for a period of three years commencing on 1 January 1987.

The programme shall be carried out by means of the concerted action method.

The programme shall consist in co-ordination 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 ensure the implementation of the co-ordination programme.

Article 3

The funds estimated as necessary for the Community contribution to the co-ordination amount to 37.0 million ECU, which includes expenditure on a staff of twelve.

The internal and indicative allocation of these funds is set out in Annex II.

Article 4

1. In the execution of its tasks, the Commission shall be assisted by an Advisory Committee for Research in Medicine and Health, hereinafter designated "the Committee", which replaces the Advisory Committee for Management and Coordination "Research in Medicine and Health" instituted by Council Decision 84/338/Euratom, ECSC, EEC (18).

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(12) OJ N° L 83, 29.3.1982, p. 1
(13) OJ N° L 126, 13.5.1983, p. 1
(14) OJ N° L 126, 13.5.1983, p. 7
(15) OJ N° L 58, 26.2.1985, p. 26
(16) OJ N° L 75, 20.3.1986, p. 31
(17) OJ N° L 158, 13.6.1986, p. 58
(18) OJ N° L 177, 4.7.1984, p. 25

The Committee shall be composed of Member State representatives responsible for science and technology in the area of medical and health research, and in particular for the coordination of national contributions to the programme, with a maximum of two per Member State.

The members of the Committee may be assisted by experts or advisers according to the nature of the problems to be dealt with.

The Committee shall establish its rules of procedure.

The Committee may be assisted by "concerted action committees" (COMAC) composed of experts designated by the competent authorities of the Member States. It may also be assisted by working parties entrusted with specific tasks.

The Commission shall ensure the secretariat of the Committee.

2. The Committee shall debate on opinion requests formulated by the Commission. The latter, when asking for the opinion of the Committee, may set a dead-line for the opinion to be given. The discussions of the Committee shall not be concluded by a vote. However, each member of the Committee may require his opinion to be registered in the minutes.

Article 5

Implementation and co-ordination of the national contributions to the programme shall be carried out by the national bodies in the list given for guidance in Annex III.

Article 6

In accordance with a procedure to be laid down by the Commission, after having consulted the Committee, the participating Member States and the Commission shall regularly exchange all useful information concerning the execution of the research covered by this Regulation. The participating Member States shall provide the Commission with all information relevant for co-ordination 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 required by the Member State which provides it.

On completion of the programme, the Commision, in agreement with the 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

In accordance with Article 228 of the Treaty, the Community may conclude agreements with the non-member States participating in European Co-operation in the field of Scientific and Technical Research (COST) with a view to associating them wholly or partly with this programme.

Article 8

The amounts which have been authorized in the corresponding items of the 1982, 1983, 1984, 1985 and 1986 budgets and which, on 1 January 1987, have been committed but not yet settled, shall be used in implementing this Regulation.

Article 9

This Regulation shall enter into force on 1 January 1987.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done in Brussels,

For the Council

The President

ANNEX I

SCIENTIFIC AND TECHNICAL CONTENT
(Co-ordination programme 1987 - 1989)

The co-ordination programme, for which the expenditure commitments are estimated at 37 million ECU, comprises the following two sub-programmes :

SUB-PROGRAMME I : MAJOR HEALTH PROBLEMS

Target I.1. : CANCER

Area I.1.1. : Cancer research training scheme
I.1.2. : Clinical treatment research
I.1.3. : Epidemiological research
I.1.4. : Early detection and diagnosis
I.1.5. : Drug development
I.1.6. : Experimental (fundamental) research

Target I.2. : A I D S

Area I.2.1. : Disease control and prevention
I.2.2. : Viro-immunological research
I.2.3. : Clinical research

Target I.3. : AGE-RELATED HEALTH PROBLEMS

Area I.3.1. : Reproduction
I.3.2. : Ageing and diseases
I.3.3. : Disabilities

Target I.4. : ENVIRONMENT AND LIFE-STYLE RELATED HEALTH PROBLEMS

Area I.4.1. : Breakdown in human adaptation
I.4.2. : Nutrition
I.4.3. : Consumption of illicit drugs
I.4.4. : Infections

SUB-PROGRAMME II : HEALTH RESOURCES

Target II.1. : MEDICAL TECHNOLOGY DEVELOPMENT

Area II.1.1. : Diagnostic methods and monitoring
II.1.2. : Treatment and rehabilitation
II.1.3. : Technical and clinical evaluation

Target II.2. : HEALTH SERVICES RESEARCH

Area II.2.1. : Research on prevention
II.2.2. : Research on care delivery systems
II.2.3. : Research on health care organization
II.2.4. : Health technology assessment

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ANNEX II

INDICATIVE INTERNAL DISTRIBUTION OF FUNDS
(1987 - 1989)

SUB-PROGRAMME I - MAJOR HEALTH PROBLEMS

		million ECU	%
Target I.1.	CANCER	11.05	30
Target I.2.	AIDS	5.45	15
Target I.3.	AGE-RELATED HEALTH PROBLEMS	5.65	15
Target I.4.	ENVIRONMENT AND LIFE-STYLE RELATED HEALTH PROBLEMS	3.35	9

SUB-PROGRAMME II - HEALTH RESOURCES

		million ECU	%
Target II.1.	MEDICAL TECHNOLOGY DEVELOPMENT	6.95	19
Target II.2.	HEALTH SERVICES RESEARCH	4.55	12
	T O T A L :	37.00	100%

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ANNEX III

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 respective research areas indicated in Annex I, as well as their coordination at national level :

Belgium :	Ministère de la Santé Publique et de la Famille, Bruxelles Service de Programmation de la Politique scientifique, Bruxelles
Denmark :	Statens laegevidenskabelige Forskningsrad, Kobenhavn
France :	INSERM - Institut national de la santé et de la recherche médicale, Paris Ministère des Affaires sociales et de la Solidarité nationale, 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 :	Ministry of Energy, Research and Technology, Athens Ministry of Health, Welfare and Social Security, Athens
Ireland :	Medical Research Council of Ireland, Dublin Department of Health, Dublin
Italy :	CNR - Consiglio nazionale della ricerca, Roma Istituto superiore di sanità, Roma
Luxembourg :	Ministère de la santé, Luxembourg
Netherlands :	Ministry of Welfare, Health and Culture, Leidschendam TNO MEDIGON : Stichting voor Medisch Onderzoek en Gezondheidsonderzoek
Portugal :	National Institute of Health, Lisboa
Spain :	Ministerio de Sanidad y Consumo, Madrid CSIC - Consejo Superior de Investigaciones Cientificas Madrid
United Kingdom :	MRC - Medical Research Council, London DHSS - Department of Health and Social Security, London

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FINANCIAL RECORD

MEDICAL RESEARCH PROGRAMME

1. RELEVANT BUDGET HEADING

- Item : 7325.1
- Title : Medical Research - Concerted action

2. LEGAL BASIS

- Application of Article 235 of the Treaty establishing the EEC
- Council Regulation of

3. DESCRIPTION OF THE PROJECT AND OBJECTIVE

3.1. Description

Co-ordination at Community level of the most important research activities, which are part of research programmes of the Member States, within the following research targets :

SUB-PROGRAMME I : MAJOR HEALTH PROBLEMS

Target I.1. Cancer
I.2. AIDS
I.3. Age-related health problems
I.4. Environment and life-style related health problems

SUB-PROGRAMME II : HEALTH RESOURCES

Target II.1. Medical technology development
II.2. Health services research

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

3.2. Objective

The aim of this research programme is, by means of co-ordination at European level, to increase both the effectiveness and the quality of the results obtained from research activities carried out and funded by the Member States.

4. JUSTIFICATION OF THE PROJECT

Co-ordination of national research activities in the medical sector is indispensable if the financial resources and abilities available nationally are to be used as effectively as possible.

The proposed programme provides for the continuation of the third medical research programme and for the extension of co-ordination to critical areas of greatest concern : Cancer (as follow-up of the European Councils) and AIDS (at request of the European Parliament).

5. **FINANCIAL IMPLICATION OF THE PROJECT IN RESPECT OF EXPENDITURE** (including staff expenditure and administrative and technical operating expenditure)

5.1. Overall cost for the whole of its expected duration : more than 1 milliard ECU

5.2. Chargeable to the Community budget : 37,000,000 ECU

Chargeable to national budgets :

Chargeable to other sectors at national level :

5.3. Multiannual time-table

5.3.1.1. Appropriation for commitment in million ECU

Type of expenditure	1987*	1988**	1989	1990	1991	TOTAL
Staff	0.712	0.870	0.905	-	-	2.487
Administration	1.200	1.200	1.200	-	-	3.600
Contracts	10.088	20.030	0.795	-	-	30.913
Total	12.000	22.100	2.900	-	-	37.000

5.3.1.2. Appropriation for payment in million ECU

Type of expenditure	1987*	1988**	1989	1990	1991	TOTAL
Staff	0.712	0.870	0.905	-	-	2.487
Administration	1.200	1.200	1.200	-	-	3.600
Contracts	0.288	9.930	14.895	4.800	1.000	30.913
Total	2.200	12.000	17.000	4.800	1.000	37.000

* 1987 : 7A, 2B, 2C (of who 2A for 6 months)

** 1988 : 7A, 2B, 3C

5.3.2. Method of calculation

a) Staff expenditure

Staffing needs have been calculated on the basis of a staff of 12 for the programme :

7 Category A staff
2 Category B staff
3 Category C staff.

In estimating expenditure for the years 1988-1989, a rate of increase of 6.0% has been assumed.

b) Administrative and/or technical operating expenditure

This heading covers in particular expenditure connected with the coordination and cooperation within the programme(more than 70 concerted projects are foreseen), the organization of meetings and the dissemination of information,missions,and the technical operating expenditure.

c) Contract expenditure

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 committees, seminars, workshops, exchanges of personnel, dissemination of information, scientific and administrative help, etc.), with institutes ensuring costly centralized services to all Member States (for computing including programming, production and exchange of materials, 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.), as well as the financing of the cancer research training scheme.

6. **FINANCIAL IMPLICATIONS ON THE STAFF AND NORMAL OPERATING APPROPRIATIONS**
(See under paragraph 5 above)

7. **FINANCING**

Appropriations to be entered under future budgets.

8. **FINANCIAL IMPLICATIONS OF THE PROJECT IN RESPECT OF REVENUE**

- Community tax on officials' salaries
- Officials' contributions to the pension scheme
- Possible contributions from non-member states.

9. TYPE OF CONTROL TO BE APPLIED

- Scientific control by the responsible officials in DG XII assisted by the Advisory Committee.

- Administrative control by the Directorate-General for Financial Control (DG XX) with regard to the implementation of the Budget and to check that the expenditure is in order and conforms to the relevant provisions; and by the Contracts Division of DG XII.