EUROPEAN PARLIAMENT

Working Documents

1982-1983

5 July 1982

DOCUMENT 1-423/82

Report

drawn up on behalf of the Committee on the Environment, Public Health and Consumer Protection

on the proposal from the Commission of the European Communities to the Council (Doc. 1-633/81 COM(81) 517 fin.) for a decision adopting sectoral research and development programme of the European Economic Community in the field of medical and public health research concerted action - (1982 - 1986)

Rapporteur: Mrs Marie-Jane PRUVOT

Or NL

By letter of 15 October 1981 the President of the Council of the European Communities requested the European Parliament to deliver an opinion concerning the proposal for a Council decision adopting a sectoral research and development programme of the EEC in the field of medical and public health research - concerted action - (1982 - 1986).

On 3 November 1981 the President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Budgets and the Committee on Energy and Research for their opinions.

On 26 November 1981 the Committee on the Environment, Public Health and Consumer Protection appointed Mrs Pruvot rapporteur.

It considered the Commission proposal and the draft report at its meetings of 28 April, 18 May and 22 June 1982.

At the latter meeting the committee unanimously decided to recommend that Parliament should approve the Commission proposal subject to the following amendments.

The committee then unanimously approved the motion for a resolution as a whole.

The following took part in the vote: Mr Collins, chairman; Mr McCartin, Mr Johnson and Mrs Weber, vice-chairmen; Mrs Pruvot, rapporteur; Mr Alber, Mr Berkhouwer, Mr Bombard, Mr Ceravolo (deputizing for Mr Spinelli), Mr Del Duca, Mr Eisma (deputizing for Mrs Spaak), Mr Forth, Miss Hooper, Mrs Krouwel-Vlam, Mr Mertens (deputizing for Mr Ghergo), Mr Muntingh, Mrs Nielsen (deputizing for Mrs Scrivener), Mr Nordmann, Mr Pantazi, Mr Protopapadakis (deputizing for Mrs Lentz-Cornette), Mrs Schleicher, Mrs Seibel-Emmerling, Mr Sherlock, Mrs Squarcialupi and Mrs van Hemeldonck.

The opinion of the Committee on Energy and Research is attached. The opinion of the Committee on Budgets will be published separately.

CONTENTS

<u>Page</u>

Amendments	5
A. MOTION FOR A RESOLUTION	7
B. EXPLANATORY STATEMENT	10
Opinion of the Committee on Energy and Research	13

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The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following amendments and motion for a resolution together with explanatory statement:

Amendments proposed by the Committee on the Environment, Public Health and Consumer Protection Text proposed by the Commission of the European Communities

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)

(Doc. 1-633/81)

<u>No. 1</u>

Article 3

<u>Article 3</u>

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 appropriatior for each subprogramme envisaged.

In the light of experience gained during the implementation of the programme and after seeking the opinion of the committee referred to in Article 5(a), the Commission may transfer funds from one subprogramme to another, provided that such transfers do not result in an increase or a reduction of more than 10% in the original appropriation for each subprogramme.

<u>No. 2</u>

Article 4

The Commission shall draw up an interim report on the results of the programme at the beginning of the third year. The programme shall be thoroughly re-examined before the end of the third year. This reexamination shall be carried out by experts who are not members of the

<u>Article 4</u>

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The programme shall be re-examined at the end of the third year; this re-examination 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

- 5 -

PE 78.241/fin.

Amendments proposed by the Committee on the Environment, Public Health and Consumer Protection

committees referred to in Article 5 and who have not themselves received any funds from the research programme. It may lead to changes in the programme. A report on the re-examination and any changes shall be submitted to the European Parliament.

<u>No. 3</u>

<u>Article 6</u>

Second paragraph

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. (<u>remainder to</u> be deleted.) Text proposed by the Commission of the European Communities

shall be informed of the results of the re-examination.

<u>Article 6</u>

Second paragraph

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.

MOTION FOR A RESOLUTION

closing the procedure for consultation of the European Parliament on the proposal from the Commission of the European Communities to the Council for a decision adopting a sectoral research and develop ment programme of the European Economic Community in the field of medical and public health research - concerted action - (1982-1986)

The European Parliament,

- having regard to the proposal from the Commission (COM(81) 517 final)¹;
- having been consulted by the Council (Doc. 1-633/81);
- A. whereas the Treaties make no provision for a health policy;
- B. having regard to the disparities between national research policies;
- C. having regard to the report by the Committee on the Environment, Public Health and Consumer Protection and to the opinions of the Committee on Budgets and the Committee on Energy and Research (Doc. 1-423/82);
- D. having regard to the result of the vote on the proposal from the Commission
- Notes with satisfaction the fact that the Commission has followed up the first two research programmes designed to coordinate research in certain sectors at European level through concerted action, thus avoiding duplication;
- 2. Considers that the Community should make the fullest possible use of its powers with regard to research in the medical field so as to lay the foundations for a European health policy;

- 7 -

¹ OJ No. C 291 of 12.11.81, p. 13

- 3. Approves the provision in the Commission proposal for publicsector financing of the order of 20% for the coordination of research, which is twice as much as in the case of the previous programmes;
- 4. Welcomes the Commission's efforts to rationalize management structures, which should make for greater efficiency;
- 5. Regrets that the Commission has taken no account of the report assessing the concerted projects under the first programme, which contains some useful observations;
- 6. Calls on the Commission to define more closely its responsibilities in the field of coordination and the system of cooperation which it has established with the Committee on Medical Research and CREST;
- 7. Calls on the Commission to associate the Committee on Medical Research in the tasks assigned to the concerted action committees;
- 8. Stresses the need to keep the public informed of the progress and development of medical research work at European level and of the practical application of the results of such research;
- 9. Takes the view that, at the present stage of integration, increased cooperation on research must be geared to a Community strategy, which, while allowing for independent national initiatives, is directed at goals which can only be successfully achieved by means of coordinated measures;
- 10. Considers that the Commission, in cooperation with the Member States, should seek to ensure that more effective use is made of existing research potential so as to improve the quality and increase the diversity of medical research;
- 11. Wishes to see the Community play the role of promoter by setting up specialized research centres where European researchers could study a particular area and considers that this would constitute an important initial step towards conferring a greater and more improtant role on the Commission as regards Community research in the field of public health.

- 8 -

12. Instructs its President to forward to the Commission and the Council the proposal from the Commission as voted by Parliament and the corresponding resolution as Parliament's opinion.

EXPLANATORY STATEMENT

I. INTRODUCTION

1. The Commission proposes the implementation of a third medical research programme to consolidate and continue the activities of the first and second programmes under a new sectoral research programme comprising 33 projects grouped in eight research areas and three subprogrammes. The Community budget is to provide a total of 20m ECU for this purpose over a period of five years.

2. For the first medical research programme, which was approved on 13 February 1978¹, a total of 1.09m EUA was set aside for a period of four years. For the second programme, approved on 19 March 1980², a total of 2.7m FUA was earmarked, similarly for a period of four years. These Community resources are intended to cover direct coordination costs (staff, administration and contracts) rather than the actual cost of carrying out the research, which must be borne by the Member States.

3. The coordination costs for the first programme amounted to 1.09m EUA, or 12% of national expenditure totalling 8.95m EUA. In the case of the second programme, coordination cost 2.7m EUA, or 7.3% of 37m EUA in national expenditure. The coordination costs for the programme now proposed would amount to 20m ECU, or 6.66% of national expenditure of 300m ECU.

4. As is usual with research activities, third countries may also participate in these concerted actions under the COST agreements.

II. CONTENT OF THE PROGRAMME

5. The proposed sectoral research and development programme is directed at three critical areas of common interest. These subprogrammes cover various defined areas, for each of which a number of projects is proposed.

6. The first subprogramme comprises the continuation and extension of concerted action on the solution of health problems connected with the critical phases in human life, divided into three areas:

- pre-, peri- and post-natal care (5 projects)
- ageing, disabled and handicapped (5 projects)
- breakdown in adaptation (5 projects)
- ¹ OJ L 52 of 23.2.1979, p.20
- ² OJ L 78 of 25.3.1980, p.24

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It is estimated that 41 to 49% of the funds to be set aside for the programme will be spent on this area of research.

- 7. A second subprogramme concerns the improvement and appropriate use of the health resources needed to ensure the best possible cost/benefit ratio in health care. This subprogramme is again divided into three areas:
 - health services research (4 projects)
 - health technology (5 projects)
 - human resources (6 projects)

This subprogramme will consume 36 to 44% of estimated funds.

8. The third subprogramme stems from the need for a better understanding of the effects diet and drugs have on the health of the individual. Two research areas are proposed in this case, nutrition (1 project) and pharmaceuticals (2 projects). Thirteen to 17% of the funds will be earmarked for this subprogramme.

9. The management structure proposed by the Commission for the implementation of this multidisciplinary research and development programme consists of a 'General Concerted Action Committee' and four 'Concerted Action Committees' (COMACs) to assist the General Committee in its scientific and technical management tasks (see Article 5).

10. The adoption of this research and development programme will entail the repeal of the second programme (1979–1983) (see Article 9).

III. GENERAL COMMENTS

11. During the deliberations on the first two concerted actions in the field of medicine, Parliament emphasized that it was essential to be able to indicate the need for cooperation and the coordination of national activities as a means of avoiding superfluous activities and raising the level of research. In addition, they must be of interest for the Community as a whole, principally concern prevention, diagnosis and rehabilitation, be of practical interest from a socio-economic point of view and produce practical results within a reasonable period.

12. Although this proposal breaks new ground at Community level, which accounts for its being based on Article 235, it is difficult to escape the impression that a great deal has already been done for a number of projects.

13. The list of activities compiled by the Committee on the Environment, Public Health and Consumer Protection and included in the report assessing the first medical research and development programme clearly reveals that Community resources are already being used to finance a considerable number of studies and seminars on ways of curing diseases and the organization of biomedical research.

14. In order to increase the effectiveness of medical research efforts, it would seem advisable for national activities to be subject to greater coordination and concertation. In this connection, stress should, however, be laid on the need for planned research to be completed on schedule and for the future administrative structures to remain flexible and transparent.

15. In addition, steps will have to be taken to ensure that the latest discoveries are put to practical use and that information concerning them is disseminated at Community level.

16. In this respect, the committee willingly takes over the amendments proposed by the Committee on Energy and Research (see paragraphs 15 and 16 of attached opinion).

IV. CONCLUSION

17. Having regard to the above comments and the amendments which have been tabled, the Committee on the Environment, Public Health and Consumer Protection takes the view that the extension and transposition of current specific medical research activities into a sectoral programme answers in both scale and content the European Parliament's frequent calls for coordination in the public health field by applying the provisions of Article 235 of the EEC Treaty.

OPINION OF THE COMMITTEE ON ENERGY AND RESEARCH

Draftsman: Mr A. GHERGO

On 25 November 1981 the Committee on Energy and Research appointed Mr A. GHERGO draftsman.

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At its meetings of 11 November 1981 and 27 January 1982 the committee considered the opinion which it adopted unanimously with one abstention at the last mentioned meeting.

The following took part in the vote: Mrs WALZ, chairman; Mr GALLAGHER, vice-chairman; Mr NORMANTON, vice-chairman; Mr GHERGO, draftsman; Mr BOMBARD (deputizing for Mr PERCHERON), Mr CALVEZ (deputizing for Mr PINTAT), Mr K. FUCHS, Mr GALLAND, Mr LINKOHR, Mrs LIZIN, Mr MARKOPOULOS, Mr MORELAND, Mr MULLER-HERMANN, Mr PETERSEN, Mr PETRONIO, Mr PROTOPAPADAKIS, Mr ROGALLA, Mr SASSANO, Mr SCHMID, Mr SELIGMAN and Mr VERONESI.

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- 13 -

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

2. On this basis, the Commission prepared the present proposal for a 'sectoral' research and development programme designed to coordinate several existing and new research projects. In particular, the proposal provides for the continuation of the projects of the first programme (three concerted projects for the period 1978 - 1981) and the integration of the second programme (four concerted projects for the period 1980 - 1984), as well as for new activities in critical areas of common interest.

3. It should be stressed, by the way, that this Commission initiative corresponds to the **position** of the European Parliament which when delivering its opinion on earlier programmes, maintained that '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, intregrated with similar research being carried out in other parts of the world'.

4. Because of its competence in the area of remearch, our committee has to express its opinion as it did when the previously mentioned programmes were approved.

5. The Community's commitment to research in general, and to medical research in particular, has never really been commensurate with the importance of the results which might derive from it. One reason for this is that until now, more emphasis has been given to national projects, even in the granting of Community financial aid. This has led to a fragmentation of specific projects and fundamental differences in the various countries' research policies and strategies, which are often split up into many relatively small research groups, lacking overall coordination: at the present time, there are 500 research workers and 235 national institutes which carry on their own activities in the context of EEC programmes regarding the two current research sectors.

6. Therefore, it is obviously desirable to coordinate these efforts more fully.

¹OJ No. L 78, 25.3.1980, p. 24

- 14 -

7. Current national programmes are oriented above all to pure research or its applications in the field of pathology, while less attention is generally paid to problems of public health and, in particular, to health service organization and health protection.

8. We therefore share the opinion of the Commission, which does not consider that further efforts at coordinating these objectives on the Community level are appropriate or necessary, but plans to orient its own sectoral R & D programme towards wider objectives divided into three subprogrammes.

9. The first subprogramme is essentially oriented to the solution of those health programmes involving the critical phases of human life, namely birth and old age, to the effect 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.

10. The second subprogramme is oriented to the improvement and appropriate use of those health resources required to ensure optimization of the costeffectiveness ratio in the health care field.

11. The third subprogramme focuses on the need for a better understanding of the effects on the individual's health resulting from his diet and intake of pharmaceuticals, with particular regard to dietary factors leading to hypertension, and to methods of controlling the side effects of commercially available drugs.

12. The need for increased research cooperation should aim, as far as possible, for a Community strategy which, while respecting independent national initiatives, pursues objectives which can be profitably realized only through concerted action.

13. On this basis, your rapporteur believes that our committee can take a favourable view of the Commission's proposal, though with the recommendation that the actual structures set up should be sufficiently streamlined, practical and 'transparent'.

14. In practical terms, it is suggested that:

- (a) liaison between the various research projects should not be burdened with excessive formality, such as a multiplicity of committees and various bodies which are not strictly necessary;
- (b) the results of the coordinated research should be made public, either by periodic reports or as they occur;

PE 78.241/fin.

(c) the coordination should aim at ensuring that the results of the research are put to practical use.

15. Support can be given particularly to the proposals regarding the drugs sector; it would be advisable, however, if emphasis were given in the programmes to new fields of research, and if everything connected with normal surveillance activity were considered as of secondary importance, useful though it may be.

16. For the purpose of ensuring that the programme is sufficiently transparent and can be monitored by the European Parliament as suggested in paragraphs 13 and 14, the Committee on Energy and Research recommends that the committee responsible include in its report the following amendments to the text of the Commission proposal:

1. Third paragraph of Article 3 to read:

In the light of experience gained during the implementation of the programme and after seeking the opinion of the committee referred to in Article 5(a), the Commission may transfer funds from one subprogramme to another, provided that such transfers do not result in an increase or a reduction of more than 10% in the original appropriation for each sub-programme.

2. Article 4 to read:

The Commission shall draw up an interim report on the results of the programme at the beginning of the third year. The programme shall be thoroughly re-examined before the end of the third year. This reexamination shall be carried out by experts who are not members of the committees referred to in Article 5 and who have not themselves received any funds from the research programme. It may lead to changes in the programme. A report on the re-examination and any changes shall be submitted to the European Parliament.

- 16 -

3. Second paragraph of Article 6 to end with the words ' ... at the social level.' Delete the rest of the paragraph.

PE 78.241/fin.