II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 4 November 1988

on a Community action in the field of information technology and telecommunications applied to health care — Advanced informatics in medicine (AIM) — Exploratory action

(88/577/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 130Q (2) thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

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

Whereas the Community has as its task, by establishing a common market and progressively approximating the economic policies of Member States, *inter alia,* to promote throughout the Community a harmonious development of economic activity and closer relations between the States belonging to it;

Whereas the Heads of State and Government emphasized the importance of health care as a major factor for economic growth and social development;

Whereas the European Parliament, in its assessment of the situation and development, stressed the role of cooperation in health care and related areas for the future political, social and economic development of the Community;

Whereas the European Parliament, in its resolution on biotechnology in Europe and the need for an integrated policy (4), has stressed the importance of information technology and telecommunications applied to health care;

Whereas the Economic and Social Committee supports initiatives in this domain;

Whereas, with the emergence of advanced and mobile communication services and the progressive introduction of computing in health care and services, the conditions for major improvements for health care and possibilities for improved cost-effectiveness may be emerging;

Whereas it is important for increasing the quality, flexibility and accessibility of health care in the Community that there should be adequate consultation of organizations working in this field;

Whereas particular attention must be paid to questions of privacy, confidentiality and data protection and this can build on related work carried out in the framework of Esprit and RACE;

Whereas developments in health care will benefit the general public and the building of a competitive European industry for developing and sustaining advances in health services;

Whereas advances in health care will contribute to resolving pressing social needs associated with changing age structures

(1) OJ No C 355, 31. 12. 1987, p. 10.
(2) OJ No C 235, 12. 9. 1988, p. 66, and OJ No C 290, 14. 11. 1988.
(3) OJ No C 356 of 31. 12. 1987, p. 8.
(4) OJ No C 76, 23. 8. 1987, p. 25.

in the Community, and to the earliest possible recognition of new diseases and health care problems;

Whereas concerted efforts in this domain will contribute to the creation of the internal market and prevent the formation of new internal frontiers to health care;

Whereas the development of common functional specifications for equipment and services will permit the less developed regions to benefit fully from the efforts of Member States piloting the improvements of health care, management and infrastructure developments in the Community;

Whereas the development of common functional specifications for equipment and services will enable the better targeting of effort and use of scarce resources;

Whereas the development of a European health care infrastructure technology will encourage and draw upon the best work in the Community and will ensure the passage of such work into the process of health care;

Whereas the development of health care infrastructure technology and services offers a wide range of opportunities for small- and medium-sized undertakings in the manufacture of equipment and in the provision of specialized services for the provision of health care within the Community;

Whereas cooperation in prenormative and precompetitive R&D towards the development of standards can make a major contribution, notably by facilitating the evolution towards future more effective health care also at regional and local levels;

Whereas, by Council Decision 87/516/Euratom, EEC of 28 September 1987 concerning the framework programme for Community activities in the field of research and technological development (1987 to 1991) (1), as amended by Decision 88/193/EEC, Euratom (2), provision is made for research to be undertaken in the field of the application of information technology and telecommunications to meet common social needs; whereas the framework programme contains special provisions for a Community action in the field of information technology and telecommunications applied to health care;

Whereas under the terms of Article 130K of the Treaty the framework programme is to be implemented through specific programmes developed within each activity;

Whereas Decision 87/516/Euratom, EEC provides that a particular aim of Community research shall be to strengthen the scientific and technological basis of European industry, especially in strategic areas of high technology, and to encourage it to become more competitive at international level; whereas the same Decision further provides that Community action is justified where research contributes *inter alia* to the strengthening of the economic and social cohesion of the Community and the promotion of its overall harmonious development, while being consistent with the pursuit of scientific and technical quality; whereas it is intended that the exploratory action for advanced informatics in medicine (AIM) should contribute to the achievement of these objectives;

Whereas the need is recognized to construct a specific European infrastructure in which existing and advanced technologies can be developed and focussed on solving problems of health care; whereas the end beneficiary must be the individual patient;

Whereas the building of this infrastructure and achieving the human objectives is an urgent necessity; whereas the attainment of these objectives is best brought about by unifying the efforts of health care providers, research establishment, undertakings including small and medium-sized undertakings and other bodies in the Community;

Whereas exploratory investigations have confirmed the need and the advantages of setting up a programme of Community cooperation in this field;

Whereas it is in the Community's interest to consolidate the scientific and financial basis of European research by means of the involvement to a greater extent of participants from European third countries in certain Community programmes and particularly in programmes involving cooperation in information technology and telecommunications applied to health care;

Whereas the AIM exploratory action will benefit from the results of Esprit and RACE as well as the on-going efforts in standardization;

Whereas the Community's programme in biotechnology (1985 to 1989) will include the application of information technology and telecommunications to this field and draw on the results of the work to be undertaken under AIM;

Whereas there exists a need for close coordination with actions on the national level and periodic reviews; whereas it is therefore necessary for the execution of the exploratory action that the Commission is assisted by a committee;

Whereas the implementation of concerted actions on the COST framework is an essential element to complement industrially-oriented R&D projects;

Whereas the Scientific and Technical Research Committee (Crest) has expressed its opinion,

(1) OJ No L 302, 24. 10. 1987, p. 1.
(2) OJ No L 89, 6. 4. 1988, p. 35.

HAS ADOPTED THIS DECISION:

Article 1

1. An exploratory Community action in the field of information technology and telecommunications applied to health care, advanced informatics in medicine (AIM), hereinafter called the 'action', shall be adopted for a maximum period of 24 months starting on 1 June 1988.

2. The action is designed to make available to citizens and health services, at minimum cost and minimum delay, improvements in health care, thereby contributing to social and economic objectives.

3. The action is designed to promote development of a European infrastructure and framework within existing developments and new advances can be brought to health care by cooperation between public and private activities at national and international levels.

Article 2

1. The action shall consist of the development of a common conceptual framework for cooperation, prenormative work and technology exploration and the investigation of the non-technological factors as required for the objective of concerting European efforts in improving health care by means of the application of information technology and telecommunications to this field.

2. The action is intended to provide cost-effective advances in the care of the individual citizen and in the development, planning and management of health care services. In work relating to patient information, the action will place priority on the development of safe and reliable methods for the protection of medical records, in particular against loss, data corruption or unauthorized disclosure.

3. The field of application includes:

1. development of a common conceptual framework for cooperation;
2. medical informatics environment;
3. data structures and medical records;
4. communication and functional integration;
5. integration of knowledge-based systems into health care;
6. advanced instrumentation, equipment and services for health care and medical research environment;
7. non-technological factors.

The summary and objectives of AIM are set out in more detail in Annex II.

Article 3

1. Projects relating to the action shall be executed by means of shared-cost contracts. Contractors shall be expected to bear a substantial proportion of the costs, which should normally be at least 50 % of the total expenditure.

Alternatively, in respect of universities and research institutes carrying out projects or actions, the Community may bear up to 100 % of the additional expenditure involved.

2. The proposals for projects shall, as a rule, be submitted in reply to an open invitation to tender and involve the participation of at least two independant partners not all established in the same Member State. At least one of the partners shall be an industrial undertaking. Within each project, at least one partner should be concerned with health care. The invitation to tender shall be published in the *Official Journal of the European Communities*.

3. In exceptional cases concerning projects indispensable for implementing key requirements of the workplan:

— where a proposal would involve:
  (i) an unreasonable burden on the participants, particularly small- and medium-sized enterprises and research establishments;
  (ii) only one independent partner;
  (iii) only independent partners established in the same Member State, or

— where an open tendering procedure would be unjustified on grounds of cost or efficiency, or

— where the amount of the Community's contribution to the cost does not exceed 0,25 million ECU,

it may be decided, in accordance with the procedures laid down in Article 8, to depart from the general provisions set out in paragraphs 1 and 2 of this Article.

4. The contracts for all parts of the action shall be concluded with undertakings, including small and medium-sized undertakings, service providers, universities, research establishments and other bodies established in the Community.

Article 4

Where framework agreements for scientific and technical cooperation between non-Community European countries and the European Community have been concluded, organizations and undertakings established in these countries may, in accordance with the procedures laid down in Articles 3 and 8, become partners to a project undertaken within this action.

Article 5

1. The funds estimated as necessary for the Community contribution to the execution of the action amount to 20 million ECU over a maximum period of 24 months, including expenditure on a staff of 12.

2. The indicative allocation of these funds is set out in Annex I.

Article 6

1. The Commission shall ensure that the action is properly performed and establish the appropriate implementation measures.

2. The Commission shall establish a draft work plan defining the detailed objectives, the type of projects and actions to be undertaken and the corresponding financial plan.

3. The procedure laid down in Article 8 shall apply to:

— the establishment of the work plan referred to in paragraph 2 of this Article,

— any departure from the general conditions laid down in Article 3 (1) and (2),

— the measures to be undertaken to evaluate each part of the action carried out by appropriate organizations, groups and other bodies,

— the assessment of the proposed projects and the estimated amount of the Community's financial contribution to them when this contribution is in excess of 0,4 million ECU,

— the participation in any project by European organizations and undertakings as provided for in Article 4.

4. The Commission may consult the committee referred to in Article 7 on any matter falling within the scope of this Decision.

Article 7

The Commission shall be assisted in the performance of its tasks by a committee, hereinafter referred to as 'the committee'. The committee, consisting of two representatives of each Member State, shall be set up by the Commission on the basis of nominations by the Member States.

Members of the committee may be assisted by experts or advisers depending on the nature of the issues under consideration.

The committee shall be chaired by a Commission representative.

The proceedings of the committee shall be confidential. The committee shall adopt its own rules of procedure. The secretarial services shall be provided by the Commission.

Article 8

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the committee, either on his own initiative or at the request of one of its members.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which shall normally be one month and shall in no case exceed two months. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period which may in no case exceed two months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission for matters falling under Article 6 (3).

Article 9

1. The result of the action shall be reviewed by the Commission after 12 months. The Commission shall report to the European Parliament and the Council on the results of this review.

2. After completion of the action, the Commission shall send to the European Parliament and the Council a report on the performance and results of the action.

3. The abovementioned report will be carried out in relation to the precise objectives set out in Annex II to this Decision and in accordance with Article 2 (2) of Decision 87/516/Euratom, EEC.

Article 10

1. With regard to the cooperation between the activities provided for in Article 1, the Member States and the Commission shall exchange all appropriate information to which they have access and which they are free to disclose

concerning activities in the areas covered by this Decision, whether or not planned or carried out under their authority.

2. Information shall be exchanged according to a procedure to be defined by the Commission after consulting the committee, and shall be treated as confidential at the supplier's request.

Article 11

This Decision shall apply with effect from 1 June 1988.

Article 12

This Decision is addressed to the Member States.

Done at Brussels, 4 November 1988.

For the Council

The President

A. TSOCHATZOPOULOS

ANNEX I

INDICATIVE ALLOCATION OF FUNDS FOR THE AIM EXPLORATORY ACTION

Summary of Areas	Estimated Community contribution in million ECU
ACTION LINE I	
Improvement of the effectiveness of public and private actions	4,80
1. Development of a common conceptual framework for cooperation	
ACTION LINE II	
Strengthening Europe's position in the application of information technology and telecommunications to health care	10,70
2. Medical informatics environment	
3. Data structures and medical records	
4. Communication and functional integration	
5. Integration of knowledge based systems into health care	
6. Advanced instrumentation, equipment and services for health care and medical research environment	
ACTION LINE III	
Creation of an environment favourable to the rapid introduction and appropriate application of medical and bio-informatics (MBI) in health care	2,25
7. Non-technological factors	
Personnel costs	1,69
Administrative costs	0,56
TOTAL	20,00

ANNEX II

SUMMARY AND OBJECTIVES OF THE AIM ACTION

1. RATIONALE

The accurate understanding of the nature, role and use of information in the medical domain is fundamental to the success of any system designed to be an effective aid to satisfy society's health needs because health care is in a process of continuous evolution and so is the technology supporting it. Information-related activities are growing rapidly and the cost of such activities in many health care organizations has become very significant.

The impetus behind a progressive implementation of an integrated health environment (IHE) at the national and international level stems from various factors.

Firstly, there is the rising cost of medical care, the major element of which comes from hospital services. In the context of a more efficient use of resources devoted to health care, there is a strong need:

— to obtain adequate indicators of performance and of quality of care,

— to make these indicators available and comparable on computerized systems in order to better understand variations in costs as well as in practices and outcomes of care,

— to provide the primary care physician with the advanced IT tools needed to allow him to perform his 'gate-keeping function' by referring patients only when appropriate for hospital investigation or specialist opinion,

— to define the requirements for allowing a breakthrough in the provision of hospital information services which today are not optimized because clinical and administrative processes and procedures are generating numerous records for each patient, complicating storage, retrieval, and analysis of information required to support hospital functions,

— to shorten the delays related to health care process by increasing the level of interaction between the health care providers through the facilitation of the flow and utilization of the existing skills and structures in the system (specialist availability, clinical data, health and pharmaceutical information, administrative mailing, professional documentation).

Secondly, the rapid development of information technology and telecommunications provides a great opportunity to improve quality, accessibility, efficiency and economy of health care services. But this can be achieved only if a progressive standardization matches the growth of computerized information in health care which is now leading to a proliferation of independent systems in Europe. International, or at least European standardization does not mean a strict uniformity of measurement systems, but rather an increase in consistency of approaches through a better transparency of results and a more systematic exchange of comparable information. Early agreement by sector actors on open standards and requirements supporting IHE implementation will simultaneously provide transparency in practices, outcomes and costs of health care, a larger potential market in Europe, economies of scale to producers and a minimization of investment risks.

2. GLOBAL OBJECTIVES AND DELIVERABLES

The development and application of information and telecommunications to health care will allow a breakthrough in the performance of health care systems, a major increase of the productivity of medical and bio(techno)logical research and development, and a significant reduction in the growth rate of health expenditures.

AIM will set a framework for possible government support to speed implementation of potentially beneficial developments in both the provision and management of health care in Europe.

AIM will be a very significant contribution to the creation of IHE. This means that it will be concerned with all forms of care, from preventive medicine through primary care to secondary care.

This Community programme will initially focus on common users requirements and technological and functional options concerning the development and application of information technology and telecommunications to health care. It will concentrate on complementing the cooperative efforts in which research institutions, hospitals and industry are already engaged, taking into account the requirements of public administrations, and on harmonizing industrial and medical priorities to advance the prenormative work needed for the introduction of IHE throughout Europe.

Both industry and health care professionals need, and have asked for, the cooperation of public authorities because the new systems which could be introduced require:

— common standards at the European level, and if possible at the international level;

— design, development and management,

— certification of those systems which are concerned with public health, data protection and ethical aspects in general,

— public and political acceptance as reflected in regulatory provisions.

The theme of AIM is the sustained improvement of health care in the Community within economically acceptable limits by exploiting the potential of information technology and telecommunications being applied to it.

Given this general objective, AIM will be concerned with realization of the following goals, namely to:

1. improve the quality, accessibility and flexibility of health care;

2. increase the effectiveness of patient care, bringing about a reduction of unit costs;

3. contribute to the establishment of minimum standards and common functional specifications;

4. contribute to agreed codes of good practice, protection of privacy and reliability;

5. stimulate collaboration and concertation in the analysis of the requirements and opportunities of medical and bio-informatics and its application;

6. contribute to the common adaptation of the regulatory framework to advances in the nature of health care.

These goals are best served by a phased approach in which this action covers the exploratory phase concentrating on the identification of user requirements, R&D systems elucidating cost-benefits as well as the choice of technological options, and the development of the appropriate evaluation tools.

The deliverables and precise objectives of the AIM exploratory action include:

— development of a practical approach to interdisciplinary working on a European scale in this domain mobilizing the different actors involved in health care and setting up the required fora for the identification of common needs, definition of the best approaches and consensus building,

— development of a conceptual model for health care information systems, by identifying its functions, components, requirements and interrelations. This model should cover the different levels of care (primary, secondary and tertiary care) and should be the basis for a common understanding of health care, leading to the further development of compatible procedures, services and systems,

— definition of data requirements and information flows at the different levels of the health care system, taking into consideration the specific needs and constraints at the patient, clinical, scientific and administrative level. This should lead to the study of the medical record architecture and be followed by the evaluation of the different codification systems, their state of advance in the different countries and the agreement on common codification systems,

— identification and definition of the minimum standards, recommendations and common agreed practices required to facilitate harmonious development of hospital information systems. This work should be done in close coordination with other international organizations in this field,

— tailoring of existing or developing technologies for their introduction and acceptance in the health care environment. The work will be focused on specific requirements, such as the human factor, the integration

of systems and the acceptability and practical use in daily work. The different applications of knowledge-based systems and the advanced instrumentation will be considered,

— the implementation of pilot projects aimed at testing the application and integration of developing technologies and methodologies in health care,

— detailed evaluation of the potential of information technology and telecommunications to meet ethical, social and economic needs arising in the field of health care. This evaluation will pay special attention to the protection of privacy of information, authorized access to systems, data security, the impact on the doctor-patient relationship, the human factor in systems engineering in order to facilitate the acceptability of new systems, and legal aspects concerning issues of liability and the practical use of advanced systems in health care.

These deliverables, as detailed in the draft work plan, will represent useful results in their own right. In addition, the scope and orientation of the work has been chosen to prepare and facilitate future European collaboration in this domain independent of the framework in which this may be undertaken.