FP4-BIOMED 2 - Specific research, technological development and demonstration programme in the field of biomedicine and health, 1994-1998

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To contribute to improving the effectiveness of research and development in medicine and health in the Member States, in particular through better coordination of their research and development activities, to applying their findings through Community cooperation and to using available resources in common.

Abstract

Part of the First activity of the Fourth Framework Programme, under the theme "Life sciences and technologies", this specific programme builds on the achievements of the 1990-1994 BIOMED I programme under the Third Framework Programme.

The programme's activities are geared towards the continued development of a strategy aimed at improving the health of citizens and the competitiveness of the Community's health industry.

Community research concentrates on complementing and adding value to the substantial investments already made by the Member States and European industry in the area of biomedicine and health, through integrated action, synergy of national efforts and interaction of all disciplines from basic to clinical research.

To this end, interdisciplinary research involving, for example, pharmacologists and cell, molecular and medical biologists will be pursued at the Community level. An emphasis will also be placed on larger, ambitious long-term projects which will contribute to keeping the social burden of health care tolerable, while laying the ground for a single European market for pharmaceuticals, medical devices and health care.

Particular attention is given to research related to prevention and public health, in support of the new Community policy on Public Health established by the Treaty on European Union (Article 129).

Demonstration activities are directed at facilitating comparative European multi-centre trials of new drugs, new therapeutic approaches, and ready-for-testing prototypes of new medical devices. A bottom-up approach is used, in cooperation with other life sciences programmes, to identify the best opportunities for pre-competitive demonstration, in order to test the technical and economic viability of new technologies.
Wherever possible, experimentation and testing on animals should be replaced by in vitro or other methods. In common with the other programmes under the "Life sciences and technologies" heading, no research modifying, or seeking to modify, the genetic constitution of human beings by alteration of germ cells or of any stage of embryo development which may make these alterations hereditary may be carried out. In addition, research into the process known as cloning is not permitted under the programme.

Research activities on biomedical ethics covered by the programme and the activities on the ethical, legal and social aspects carried out by the horizontal unit "Legal and Ethical Aspects" are performed jointly in order to benefit from interdisciplinary competencies. Horizontal actions in this area will also take into account the European Bioethics Convention and its draft Protocols.

The programme is implemented in synergy with the other specific programmes in the area of the life sciences, as well as those in such fields as telematics, measurement and testing and targeted socio-economic research.

Provisions are made for actions intended to encourage participation of SMEs, in particular technology stimulation measures and interaction between science parks and biomedical and health SMEs.

Subdivision

Seven areas:

- Pharmaceuticals research:
To develop the scientific and technical basis required for the evaluation of new drugs, notably for the treatment of neurological, mental, immunological and viral diseases. Research will mainly cover pharmacotoxicology, pharmacovigilance and clinical trials;

- Research on biomedical technology and engineering:
Health technology and assessment and prenormative research in the context of the European-wide market with its Directives concerning medical devices and accompanying standardization activities. R&D includes minimal intervention techniques and robotics, imaging techniques, biosensors, rehabilitation technologies and cellular engineering;

- Brain research:
To encourage developments in the area of neuroscience and in improvements in the prevention and treatment of neurodegenerative diseases;

- Research on diseases with major socio-economic impact: from basic research into clinical practice:
To integrate basic and clinical research to improve the prevention, diagnosis and treatment of illnesses with major socio-economic impact and the 5000 or so "orphan " illnesses which can best be tackled at an international level. Activities focus on cancer research; research on AIDS, tuberculosis and other infectious diseases; research on other cardiovascular diseases; research on chronic diseases, ageing and age-related problems; research on occupational and environmental health; research on "Orphan" illnesses;

- Human genome research:
To consolidate and, where appropriate, to modify, the activities and infrastructure achieved under preceding programmes in order to serve future needs. RTD includes gene mapping and genome analysis, analysis of gene function and regulation, diagnosis of genetic diseases, somatic gene therapy, and harmonization and sharing of genetic databanks;

- Public health research, including health services research:
To assist the Member States in strengthening their coverage of public health issues, assist in the formulation and implementation of objectives, policies and strategies, and contribute to the continuity of health protection provisions across the European Union;

- Research on biomedical ethics:
  Research addresses general standards for the respect for human dignity and the protection of the individual in the context of biomedical research and its clinical applications.

**Implementation**

The Commission is responsible for execution of the programme, assisted by a committee of a consultative nature composed by representatives of the Member States and chaired by a representative of the Commission. The Commission is responsible for drawing up an initial work programme, detailing the scientific and technological objectives of the action, the stages in the programme’s implementation and the corresponding financial arrangements. This work programme may provide for participation in certain activities originating from the EUREKA framework.

Calls for proposals for RTD projects are issued by the Commission on the basis of the work programme. Only those proposals with a sound scientific concept, a high likelihood of success, and a clear Community added value will be selected.

Participation in the programme is open to all legal entities regularly carrying out RTD activities in the Community or in countries with whom the Community has concluded specific agreements. To this end, the Commission is authorized to negotiate bilateral agreements with European third countries not covered by the EEA, with a view to involving them in all or part of the programme. Provisions are also made to facilitate cooperation with international organizations. The Joint Research Centre (JRC) may participate in the indirect activities covered by the programme.

The programme is mainly implemented through shared-cost activities, concerted actions, specific measures and various preparatory, accompanying and support measures.

Community support for shared-cost activities such as industrial RTD projects, technology stimulation measures, research projects within thematic networks to be created around genetic technologies, support for the infrastructures or facilities necessary to reinforce coordination, and demonstration activities aimed at encouraging the utilization of technologies and bridging the gap between producers and users will not normally exceed 50% of total costs. Other shared-cost activities, (e.g. networks, training, feasibility awards and accompanying measures) may receive financial support of up to 100% of either the additional costs or the total costs of the action.

Concerted actions, which will coordinate RTD and demonstration projects already financed by public or private bodies, may qualify for a contribution of up to 100% of the concertation costs. Specific measures, such as those encouraging standardization, and those measures intended to set up general service tools for research organizations, may also be eligible for funding of up to 100% of total costs.

The programme budget is divided between the seven areas as follows: Pharmaceuticals research ECU 37 million; Research on biomedical technology and engineering ECU 37 million; Brain research ECU 40.5 million; Research on diseases with a major socio-economic impact ECU 141 million (this is divided between the 6 activities as follows: cancer research ECU 33.5 million; research on AIDS, tuberculosis and other infectious diseases ECU 27 million; research on cardiovascular diseases ECU 27 million; research on chronic diseases, ageing and age-related problems ECU 33.5 million; research on occupational and environmental health ECU 13.5 million; research on "Orphan" illnesses ECU 6.5 million); Human genome research ECU 40.5 million; Public health research, including health services research ECU 33.5 million; Research on biomedical ethics ECU 6.5 million.
These figures include an allocation of a maximum of 8.5% for staff and administrative expenditure. Up to 5% of the funds are to be allocated to horizontal demonstration activities, 1% to horizontal activities on ethical, social and legal aspects and 5% to horizontal training activities. A further sum of ECU 3 million is included for the dissemination and exploitation of the programme’s results. This will be closely coordinated with the specific programme under the Third Activity of the Fourth Framework Programme concerning the dissemination and utilization of RTD results.

The budget allocated to the programme may increase before the end of June 1996, in accordance with the Decision establishing the Fourth Framework Programme.

The Commission will continuously review the implementation of the programme to ensure that its objectives, priorities and financial resources remain appropriate. On the basis of this review process it shall, where appropriate, submit proposals to adapt or supplement the programme.

In addition, regular assessments of the activities covered by the specific programme will be conducted by independent experts who, upon completion of the programme, will carry out a final evaluation of the results achieved compared to initial objectives. A report of this final evaluation will be communicated to the Council, the European Parliament and the Economic and Social Committee.

Remarks

The budget allocated to this specific programme was increased from ECU 336 to ECU 358 million by Council Decision 616/96/EC (new Member States). It was further increased to ECU 374 million by Decision 2535/97/EC on 1/12/1997.

Subjects
Biotechnology - Medicine and Health

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