COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 21.04.1995 COM(95) 131 final

94/0105 (COD)

Amended proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DECISION

adopting an action plan 1995–1999 to combat cancer within the framework for action in the field of public health

(presented by the Commission pursuant to Article 189 a (2) of the EC-Treaty)

Explanatory Memorandum

- 1. The original Commission Proposal for a European Parliament and Council Decision adopting an action plan 1995-1994 to combat Cancer was adopted by the Commission on 29 March 1994.
- 2. The original Commission Proposal received favourable opinions of the Economic and Social Committee¹ and the Committee of the Regions².
- 3. Following the opinion of the European Parliament delivered at first reading on 1 March 1995, the Commission is presenting an amended proposal for a Decision, pursuant to Article 189a of the Treaty. The text contains two main types of amendment:
- those adding useful details and clarifications to the initial proposal;
- a second group of amendments slightly strengthening the proposal in the sense of greater emphasis of Community action on the areas of prevention identified as having priority by the European Parliament.
- 4. The European Parliament adopted 36 amendments at its vote on 1 March 1995, 26 of which are fully or partly acceptable to the Commission (1, 2, 6, 7, 8, 10, 12, 13, 14, 15, 16, 18, 20, 21, 22, 23, 25, 26, 28, 30, 31, 32, 33, 34, 35 and 42).
- 5. The remaining ten amendments are not acceptable to the Commission.

Amendment 3 has not been accepted because the formulation put forward by the Commission is more faithful to the text of Article 3b of the Treaty.

Acceptance of amendment 4 on the distribution of budget resources within the programme would have distorted the management of the programme by allocating funds in advance to certain areas without knowing the quality of the projects to be financed.

Amendment 9 envisages the participation of non-governmental organisations in the Advisory Committee on the plan. This would be contrary to the current comitology rules.

Amendment 17 refers to a ban on advertising for tobacco products. The Commission completely shares the concerns expressed in the amendment, but has already proposed a Council Directive on this subject.

Amendment 19 envisages project arrangements which would not suit every case.

Plenary Session on 14.09.1994

² Plenary Session on 27/28.09.1994

Amended 27 proposes a pilot scheme to involve political leaders and others in antismoking activities. This type of action does not fall within the scope of the proposed action plan.

Amendment 29 limits the action proposed by the Commission to the risks associated with excessive exposure of the skin to the rays of the sun, rather than ultraviolet radiation. This limitation makes it unacceptable.

As far as amendments 36 and 43 are concerned, it should be noted that the role and existence of the Committee of Cancer Experts are not directly linked to the adoption of the proposal for a third action plan, as this Committee has existed since the creation of the programme in 1986. In addition, cooperation and research activities are regarded as satisfactory. These two amendments have been rejected.

Amendment 46 concerns the creation of no-smoking areas in the buildings of the European Parliament. Such action is outside the scope of the proposed plan, although the Commission supports the initiative.

Proposal for a European Parliament and Council Decision

adopting an Action Plan 1995-1999 to combat cancer

within the framework for action in the Field of Public Health

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The European Parliament and the Council of the European Union,

Having regard to the Treaty establishing the European Community, and in particular Article 129 thereof.

Having regard to the proposal by the Commission,

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

Having regard to the opinion of the Committee of the Regions,

- 1. Whereas, at its meetings in June 1985 in Milan and in December 1985 in Luxembourg, the European Council underlined the advantages of launching a European programme against cancer;
- 2. Whereas the Council and the representatives of the Governments of the Member States meeting within the Council adopted a resolution on 7 July 1986 on a first programme of action of the European Communities against cancer and on 17 May 1990 a decision establishing a second action plan under the "Europe against Cancer" programme for the period 1990-1994;
- 3. Whereas the European Parliament, in its resolution of 15 December 1993, asked that activities against cancer be intensified:

Modified proposal

1. Whereas measures to reduce the risk of cancer from exposure to carcinogens are included in a number of existing programmes in particular, in the programmes on the environment, worker protection, consumer protection, nutrition, agriculture and the internal market:

- 4. Whereas in the Resolution of 13 December 1993 the Council invited the Commission to submit in due course a draft third action plan, taking into account the Council resolution of 27 May 1993 on future action in the field of public health as well as the objectives and improvements set out in the Annex.
- 5. Whereas the prevention of cancer is a priority for Community action within the framework for action in the field of public health set out by the Commission while remaining compatible with other measures already undertaken by the Community in this field;
- 6. Whereas, in accordance with the principle of subsidiarity, actions on matters not under the exclusive competence of the Community, such as those on cancer prevention, must only be undertaken by the Community when, by reason of their scale or effects, they may be better carried out at Community level;
- 7. Whereas cooperation with the competent international organisations and with third countries should be strengthened;
- 8. Whereas cancer is a major disease associated with lifestyle, and the inherent risk factors need to be overcome, especially tobacco consumption, which also has an effect on combating other diseases, in particular cardiovascular diseases;

Modified proposal

4a (new) whereas cancer research is covered in the "Biomedicine and Health" (1994-1995) specific research and technological development programme.

- 9. Whereas by ensuring wider dissemination of knowledge of causes of cancer and of its prevention, ensuring improved comparability of actions especially in health education, the programme will contribute to achievement of the Community objectives set out in Article 129;
- 10. Whereas an important role is played in the implementation of the Programme by the Advisory Committee and the National Coordinating Committees;
- 11. Whereas, from the operational point of view, the investment made during the preceding action plans in terms of both the European pilot networks and of the mobilisation of all those involved in combating cancer should be safeguarded and developed;
- 12. Whereas, however, possible duplication of effort should be avoided by the promotion of exchanges of experience and by the joint development of basic information modules for the public, for health education and for training members of the health professions;

Modified proposal

9a.(new) whereas action must be taken to combat media advertising promoting habits conducive to cancer, including wrong dietary habits.

- 12. Whereas, nowever, possible duplication of effort should be avoided by the promotion of exchanges of experience and by the joint development of basic information modules for the public, for health education and for training members of the health professions, which may be targeted on specific groups.
- **12a.(new)** Whereas the principles of sound financial management must be observed if this action plan is to be fully effective.

Modified proposal

- 13. Whereas, in order to increase the value and impact of the action plan, a continuous assessment of the measures undertaken should be carried out, with particular regard to their effectiveness and the achievement of objectives both at national and Community level and, where appropriate, to make the necessary amendments;
- 14. Whereas this action plan should be of five-year duration in order to allow sufficient time for actions to be implemented to achieve the objectives set;

14a.(new) Whereas a systematic policy for combatting cancer includes all aspects of primary, secondary and tertiary prevention, including exchange of experience on quality control of diagnosis and treatment, and taking into account psycho-social aspects with particular emphasis on quality of life.

Article 1: A Community plan of action against cancer is adopted for the parameter 1995 to 31 December 1999.

Article 2: The Commission shall ensure implementation of the actions set out in Annex in accordance with article 5 of this decision and in close cooperation with the Member States and with institutions and organisations active in the prevention of cancer.

Article 3: The budgetary authority will determine the financial resources available for each exercise.

Modified proposal

Article 2: The Commission, in close cooperation with the Member States, the national coordination committees and with institutions and organisations active in the prevention of cancer, shall ensure implementation of the action plan in the following fields:

I. development and strengthening of a European network of Cancer registers and support to epidemiological studies focused on prevention.

II. public information and health education

III. training of health workers on cancer prevention.

IV. early detection and systematic screening.

V. exchanges of experience on quality control of diagnosis and treatment, including palliative care and supporting contributions for selecting priorities in cancer research and transfer of results of basic research into clinical trials

specific actions in these fields are set out in the annex.

Article 4: The Commission shall ensure that there is consistency and complementarity between the Community actions to be implemented under this action plan and the other relevant Community programmes and initiatives including the Biomedical and Health Research Programme under the Community's framework programmes for research.

Article 5: In implementing this action plan, the Commission shall be assisted by an advisory committee consisting of representatives of each Member State, and chaired by the Commission representative.

The Commission representative 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 the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition each Member State shall have the right to ask to have its opinion recorded in the minutes.

Modified proposal

Article 4: The Commission shall ensure that there is consistency and complementarity between the Community actions to be implemented under this action plan and the other relevant Community programmes and initiatives including the Biomedical and Health Research Programme under the Community's framework programmes for research and the programmes establishing an integrated information network (information technology in areas of general interest).

5b The Commission shall make every effort to simplify and improve the Programme's basic administrative procedures; these procedures shall be properly publicised.

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The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

Article 6:

- 1. In the course of implementing this action plan, cooperation with third countries and with international organisations competent in the field of public health, including the World Health Organisation and the International Agency for Research on Cancer, will be encouraged.
- 2. The EFTA countries and the countries of Central and Eastern Europe may be associated with the activities described in the Annex under the conditions set out in the agreements concluded with the European Community.

Article 7:

1. The Commission will regularly publish information on the progress of the action plan and on potential Community financing in the various fields of action; this shall be forwarded to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions in the form of an annual report, with account being taken of reports to be drawn up by each of the Member States.

Article 7/1: The Commission will regularly publish information on the progress of the action plan and on potential Community financing in the various fields of action. The report shall pay particular attention to the complementary between this action and those mentioned in Article 4. It shall be forwarded to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions in the form of an annual report, with account being taken of reports to be drawn up by each of the Member States.

Modified proposal

2. On the basis of an interim report to be submitted by the Commission before the end of 1997, the Council and the European Parliament will evaluate the actions undertaken. An overall report will be submitted at the end of the action plan.

Annex

Measures to be implemented in the period 1995-1999

- I. Cancer registers and epidemiological studies
- 1. Support for exchanges of information and experience relating to the collection and dissemination of reliable and comparable data for cancer registers (incidence, mortality and survival rate). Development and strengthening of a European network in cooperation with the International Agency for Research on Cancer (IARC).
- 1. Support for exchanges of information and experience relating to the collection and dissemination of reliable and comparable data for cancer registers (prevalence, incidence, mortality and survival rate and age groups). Development and stre. Julie and of a European network in cooperation with the International Agency for Research on Cancer (IARC).

Support for the carrying out of epidemiological studies at European level and for the dissemination of their conclusions with regard identification of carcinogens (physical, chemical and biological), the risks arising from exposure to them, methods of prevention and for estimating survival rates and sources of disparities in those rates. On the basis of these conclusions, support for the drawing up and dissemination of recommendations. Cohort studies on cancer, diet and health (EPIC network), support for epidemiological studies based on research into nutrition as a potential preventive factor (identification protective agents, modification specific dietary factors) and, where appropriate, preventive chemical agents.

II. Prevention A. Public information

3. Establishment of an annual "Europe against Cancer" week.

Modified proposal

Support for the carrying out of epidemiological studies at European level and for the dissemination of their conclusions with regard identification of carcinogens (physical, chemical and biological), the risks arising from exposure to them (types of exposure and the population subgroups affected), methods of prevention and the introduction of programmes for the objective estimation of survival rates on the basis of certain criteria (age. sex. location of the tumour, evolutionary stage, histological type, etc.), and for estimating sources of disparities in those rates. On the basis of these conclusions, support for the drawing up and dissemination of recommendations. Cohort studies on cancer, diet and health (EPIC network), support for epidemiological studies based on research into nutrition as a potential preventive factor (identification of protective agents, modification specific diatan' factors) and, where appropriate. preventive chemical agents.

- 4. Improving the effectiveness of cancer prevention messages, in particular the recommendations of the European Code against Cancer, by supporting targeted measures (for teachers, general practitioners, etc.) and pilot projects, studies and analyses of health promotion techniques and assessments of action in this field.
- 5. Supporting pilot action networks for providing information and exchanges with regard to cancer prevention, taking into account the recommendations of the European Code against cancer and those of the committees of experts meeting for this purpose in order to contribute to the highlighting and dissemination of best practice.
- 6. Promoting information and awareness-raising campaigns for specific population groups on health promotion and cancer prevention, particularly in public places and at work.

Modified proposal

- 4. Improving the frequency and the effectiveness of cancer prevention particular messages, in recommendations of the European Code Against Cancer, by supporting targeted measures (for educators. oncologists. general practitioners. pharmacists, journalists and other media persons) and pilot projects, studies and analyses of health promotion techniques and assessments of action in this field.
- 5. Supporting and expanding pilot action networks for providing information and exchanges with regard to cancer prevention, taking into account the recommendations of the European Code against cancer and those of the committees of experts meeting for this purpose in order to contribute to the highlighting and dissemination of best practice.

- Encouraging projects 7. with European dimension relating to the prevention of tobacco consumption; assessment of the implementation of recommendations on the use of tobacco in public places, particularly on public transport and in education establishments. Promotion of a policy aimed at protecting the most vulnerable groups from the risk of passive smoking, in particular pregnant women and children. Assessment of the effect of measures taken in the Member States to reduce tobacco consumption. for example by the banning and control direct or indirect advertising. exclusion of tobacco from the price index and dissemination of knowledge acquired from such assessments. Support and assessment of pilot measures for preventing tobacco consumption as part of the exchange networks between Member States, for example networks of no-smoking towns, no-smoking hospitals and youth of a cooperation with health-care workers and teachers.
- 8. Selection, dissemination and evaluation of the impact of the best methods of reducing tobacco consumption in the Member States as part of pilot measures to implement these methods in liaison with health-care workers. Continuing classification of dangerous substances and preparations with the aim of improving packaging and labelling.

B. Health education

- Contributing to the formulation and implementation of integrated health education programmes in different contexts, with cancer prevention given a particularly important role. Definition and implementation of supplementary cancer prevention projects for specific groups in different contexts. Evaluation of health education initiatives with priority beina aiven to making individuals more aware their responsibility for their own health. tobacco consumption. preventing promoting a healthy diet and making people aware of the risks associated with excessive exposure of the skin to ultraviolet radiation, targeted at young people.
- 10. Support for exchanges of experience under the integrated health education programmes with the aim of improving initial and continuing training for teachers and project supervisors in the field of cancer prevention, taking account in this context of the experience gained in the framework of programmes such as Erasmus and the supporting actions of the Commission in the education field.

Modified proposal

Contributing to the formulation and implementation of integrated health education programmes in different contexts, with cancer prevention given a particularly important role. Definition and implementation of supplementary cancer prevention projects for specific groups (town planners, environmental specialists, architects, radiologists) in different contexts. Evaluation of health education initiatives with priority being given to making individuals more aware of their responsibility for their own preventing tobacco consumption, promoting a healthy diet including an increased consumption of fruit and vegetables and appropriate media campaigns on healthy diets and making people aware of the risks associated with excessive exposure of the skin to ultraviolet radiation, targeted at young people.

- 11. Support for the production, dissemination and evaluation of the impact of Community teaching materials relating to cancer prevention, particularly those tested in the pilot networks.
- 12. Implementation of studies and dissemination of their conclusions, making it possible to improve the level of knowledge on the perceptions of young people with regard to cancer, tobacco, diet and the risks associated with excessive exposure of the skin to ultraviolet radiation. Carry out analyses with the aim of increasing the effectiveness of preventive programmes among children and young people.

C. Training for health-care workers

13. Pursuing the implementation of the Commission recommendation of 8 November 1989 concerning the training of health personnel in the matter of cancer; assistance with the introduction and periodic assessment of the impact of the European pilot networks on initial and continuing training in cancer for the medical, nursing and dentistry professions

13. Pursuing the implementation of the Commission recommendation of 8 November 1989 concerning the training of health personnel in the matter of cancer; assistance with the introduction and periodic assessment of the impact of the European pilot networks on initial and continuing training in cancer for the medical, nursing and dentistry professions with particular attention to personnel working in paediatric oncology.

- 14. Support the mobility of the health professions (particularly trainers) in order to improve theoretical and practical knowledge of cancer (primary prevention, mass screening, particularly for cervical and breast cancer, early diagnosis and quality of care) between those centres of excellence in Member States offering training of a high quality, where such mobility is not ensured under existing Community programmes such as COMETT II or FORCE.
- 15. Support exchanges of experience and the drawing up and dissemination of conference recommendations for a consensus on good medical practice and of recommendations by groups of experts in order to speed up the dissemination and implementation of the results of controlled studies. Preparation of teaching materials of European interest aimed at improving training in cancer for health-care workers, particularly through the use of interactive computer programmes; assessment of the impact of these materials in the pilot networks. In particular, support for the development, implementation and evaluation of prevention modules intended for the health professions and of models to assist in diagnosis and in making decisions with regard to treatment.

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14. Support the mobility of the health professions (particularly trainers) in order to improve theoretical and practical knowledge of cancer (primary prevention, early diagnosis, mass screening, particularly for cervical and breast cancer, therapeutic principles, health-care conventions, individualized treatment) between those centres of excellence in Member States offering training of a high quality, where such mobility is not ensured under existing Community programmes such as COMETT II or FORCE.

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- III. Prevention by means of early detection and systematic screening
- 16. Support the introduction and evaluation of European pilot project networks in the field of mass screening for breast and cervical cancer, on the basis of recommendations established at European level with regard to ensuring the quality of screening, and support for the organisation of meetings to examine the feasibility of extending pilot projects to national and regional levels.
- 17. Support the preparation at European level and dissemination of a common terminology and classification in order to improve the quality of anatomical and cytopathological interpretation, particularly of suspect growths in the breast and uterus, in particular for anatomists and cytopathologists in the European Community.
- 18. Support European feasibility studies for early mass screening for other cancers (of the ovary, prostate, skin, colon/rectum and mouth), taking particular account of the medical, psychological, social and economic aspects.

18a. In order to improve early detection techniques and systematic screening, promotion of pilot action involving the collaboration of interdisciplinary teams specialized in a broad spectrum of fields such as immunology, genetics, anatomy, cytopathology and molecular biology, with a view to increasing biomedical and clinical cooperation.

Modified proposal

- IV. Studies and measures relating to the quality of care for cancer patients
- 19. Support European studies and dissemination of their conclusions, particularly in the context of Europeanlevel meetings and exchanges of experience, in order to gain a better understanding and improve the effectiveness of quality control methods both in diagnosis (radiological and anatomo-cytopathological examination) and in treatment (radiation therapy and chemotherapy), including palliative care. taking into account the psychological and social aspects, with particular regard to the quality of life of patients. Dissemination and evaluation of best practice in quality assurance in the pilot project networks.
- 19. Promote initiatives and support European studies and dissemination of their conclusions, particularly in the context of European-level meetings and exchanges of experience, in order to identify shortcomings and to gain a better understanding and improve the effectiveness of quality control methods both in diagnosis (radiological and anatomo-cytopathological examination) and in treatment (radiation therapy and chemotherapy), including palliative care, correctly administrated at a sufficiently early stage. taking into account the psychological and social aspects, with particular regard to the quality of life of patients. Dissemination and evaluation of best practice in quality assurance in the pilot project networks, including that related to checks on radiotherapy installations and to the training of healthcare personnel.
- Support for European studies on the introduction of a common terminology for the classification and evaluation of complications arising from the treatment of patients affected by various forms of cancers.

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V. Research

20. Make a supporting contribution to selecting priorities for cancer research be carried out under to Community's framework programmes research and specifically the Biomedical and Health Research Programme which includes basic and clinical cancer research. Support for the establishment of an inventory of European basic and clinical cancer research measures; help with the transfer to clinical trials of the results of basic research: information exchange networks for clinical trials in progress, and help with the launching of multiplecentre and multinational clinical trials in order to speed up the assessment of new methods of care.

20. Make a supporting contribution to selecting priorities for cancer research carried out under be the Community's framework programmes for research and specifically the Biomedical and Health Research Programme which includes basic and clinical cancer research, and promote lines of investigation aimed at establishing accurate and reliable early diagnosis through laboratory diagnostic techniques based in particular on immunology and genetics. Support for the establishment of an inventory of European basic and clinical cancer research measures; help with the transfer of the results of basic research to clinical trials and from there to standard therapeutic practice. Help with the setting up and establishment of information exchange networks for clinical trials in progress and access systems for involvement in such trials and help with the launching of multiplecentre and multinational clinical trials in order to speed up the assessment of new methods of care.

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