



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 05.11.1998
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OPINION OF THE COMMISSION

pursuant to Article 189 b (2) (d) of the EC Treaty,
on the European Parliament's amendment
to the Council's common position regarding the

proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DECISION

**adopting a programme of Community action 1999-2003 on rare diseases in the
context of the framework for action in the field of public health,**

AMENDING THE PROPOSAL OF THE COMMISSION

pursuant to Article 189 a (2) of the EC Treaty

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EUROPEAN PARLIAMENT AND COUNCIL DECISION

**adopting a programme of Community action 1999-2003 on rare diseases in the
context of the framework for action in the field of public health,**

- (1) The initial proposal for a European Parliament and Council decision adopting a programme of Community action on rare diseases was adopted by the Commission on 26 May 1997¹.
- (2) The Economic and Social Committee² and the Committee of the Regions³ delivered favourable opinions on this initial Commission proposal.
- (3) In the light of the European Parliament's opinion after its first reading on 10-11 March 1998 the Commission, in accordance with article 189a (2) of the treaty, submitted an amended proposal for a decision⁴. This text incorporated amendments that clarified and broadened the actions covered by the programme.
- (4) The European Parliament (first reading) had adopted twenty-eight amendments of which sixteen could be accepted by the Commission: one in toto, two with slight rewording and thirteen partially (matched with a modified proposition).
- (5) The twelve amendments which were not acceptable by the Commission can be grouped as follows:
 - six concerned the recitals in the preamble;
 - five concerned the articles of the decision;
 - one concerned the annex;

The reasons for rejecting these twelve amendments were the following:

- four amendments were not acceptable for legal reasons (n° 6, 10, 20, 21) ;
 - one amendment fell outside the scope of the programme (n° 18)
 - three amendments were unacceptably limiting (n° 4, 15, 24)
 - two amendments were covered elsewhere (n° 11, 13)
 - two amendments were unacceptable due to budgetary limitations (n° 14, 19).
- (6) The Council of Ministers on 30 April 1998 unanimously reached a Common Position⁵. The Commission, in view of the second reading by the European Parliament, reserved its position, with particular reference to the following aspects: as regards the comitology procedure (article 5), the provision of a mixed management-advisory committee, as opposed to the advisory committee proposed by the Commission and supported by the Parliament, is likely to be excessive and inappropriate in the context of the programme, considering its limited budget allocation; furthermore the Commission reserved its position in respect to the Parliament's amendments (first reading) accepted (fully or partially) in its amended

(1) OJ N°C 203 of 03.07.97
(2) OJ N°C 19 of 21.1.98
(3) OJ N°C 64 of 27.2.98
(4) OJ N° C 160 of 27.5.98
(5) OJ N° C 227 of 20.7.98

proposal but not taken up by the Council. The Council accepted in its Common Position seven EP amendments: n° 2, 3 and 14 in toto; n° 7, 16, 22 and 23 partially; the Council did not accept twenty-one EP amendments: n° 1, 4, 5, 6, 8, 9, 10, 11, 12, 13, 15, 17, 18, 19, 20, 21, 24, 25, 26, 27 and 28.

- (7) On 8th October 1998, the European Parliament (second reading) adopted twenty amendments to the common position

Of these twenty amendments:

- nine concern the recitals in the preamble
- seven concern the articles of the decision (one concerns comitology and one concerns budget)
- four concern the annex (detail and content of the actions)

- (8) The opinion of the Commission concerning each of these amendments is given in the annex. Eleven amendments are acceptable, of which three in toto (n° 3, 12, 16) and eight partially (n° 1, 6, 7, 9, 11, 15, 17, 19).

Nine amendments are considered unacceptable:

- n° 4, 8, 13 for legal reasons;
- n° 5, 20 for internal consistency;
- n° 2, 10 because unacceptably limiting;
- n° 18 because covered elsewhere;
- n° 14 for budgetary reasons.

- (9) The Commission points out that in accordance with article 189b(3) of the Treaty if, within three months of receiving the Parliament amendments, the Council, acting by a qualified majority, approves all of the amendments, it shall amend its Common position accordingly and adopt the act in question; however, the Council shall act unanimously on the amendments on which the Commission has delivered a negative opinion. If the Council does not approve the act in question, the President of the Council, in agreement with the President of the European Parliament, shall forthwith convene a meeting of the Conciliation Committee.

ANNEX

Amendment 1: Commission opinion: partially acceptable.

The amendment is acceptable with the following formulation:

“whereas Community actions should be directed towards the prevention of diseases and whereas action by the Community can provide unique added value to tackling problems, the scale of which in individual countries is too small to allow the necessary analysis or proper action;”.

Amendment 2: Commission opinion: unacceptable.

This amendment is not appropriate, as it stresses the causation mechanism in the definition of rare diseases; the causation mechanism for many of them is unknown.. The amendment is unacceptably limiting.

Amendment 3: Commission opinion: acceptable.

Amendment 4: Commission opinion: unacceptable.

This amendment is not in line with the wording of article 129 of the EC Treaty; it is unacceptable for legal reasons.

Amendment 5: Commission opinion: unacceptable.

The provision of a Community databank contradicts amendment 17, which is acceptable on this point. For this reason, the amendment is unacceptable for internal consistency.

Amendment 6: Commission opinion: partially acceptable.

Patients and health professionals could be stressed with the following wording: “...of all involved, in particular health professionals, patients’ and support group associations”.

Amendment 7: Commission opinion: partially acceptable,

The amendment is acceptable with the following formulation: “whereas the Council resolution on equality of opportunity for people with disabilities of 20 December 1996 invites to promote the involvement of representatives of people with disabilities in the implementation and follow-up of relevant policies and actions in their favour.”

Amendment 8: Commission opinion: unacceptable.

This amendment is not in line with the wording of article 129 of the EC; it is unacceptable for legal reasons.

Amendment 9: Commission opinion: partially acceptable.

Research is not covered by this programme proposal. The first part of the amendment finishing at "under the programme" can be acceptable.

Amendment 10: Commission opinion: unacceptable,

See amendment 2. This amendment is not appropriate, as it stresses the causation mechanism in the definition of rare diseases; the causation mechanism for many of them is unknown.. The amendment is unacceptably limiting.

Amendment 11: Commission opinion: partially acceptable.

The amendment is acceptable with the following formulation: The wording "and strengthening national and international" should be replaced by "transnational": this would better implement the principles of Community added value and of subsidiarity; the wording "in particular patient self-help and relatives' groups" should be deleted, as it could refer to actions beyond the capacity of the programme.

Amendment 12: Commission opinion: acceptable.

Amendment 13: Commission opinion: unacceptable

This amendment is not in line with previous decisions for the European Parliament and the Council on other public health programmes. It is not acceptable for legal reasons.

Amendment 14: Commission opinion: unacceptable.

This amendment is not acceptable for budgetary reasons: current financial perspectives do not allow a financial envelope of ECU 14 million for the period 1999-2003.

Amendment 15: Commission opinion: partially acceptable.

The Commission agrees with Parliament as regards the preference for an advisory Committee rather than a mixed advisory-management Committee. The provision of two representatives, one to be drawn from voluntary organisations, is not in keeping with the wording of the "Comitology" decision (Council Decision of 13 July 1987). This part is unacceptable for legal reasons.

Amendment 16: Commission opinion: acceptable.

Amendment 17: Commission opinion: partially acceptable.

This amendment is acceptable with the following formulation: after "the condition.", the text to be accepted should stop with the phrase: "this information should be made as widely available as possible".

Amendment 18: Commission opinion: unacceptable

The provision for training is covered elsewhere: annex, action 7 of Commission proposals and 4 of Common Position.

Amendment 19: Commission opinion: partially acceptable.

This amendment is acceptable with the following formulation: "promote collaboration and networking between groups of persons directly or indirectly affected by the same rare conditions or volunteers and professionals involved and coordination at Community level in order to encourage continuity of work and trans-national cooperation;"

Amendment 20: Commission opinion: unacceptable

The wording "rapid response systems" is not consistent with the provision of article 1, and disproportionate in the context of the programme. The amendment is unacceptable for internal consistency.

AMENDED PROPOSAL

**FOR A EUROPEAN PARLIAMENT AND COUNCIL DECISION
ADOPTING A PROGRAMME OF COMMUNITY ACTION 1999-2003 ON RARE
DISEASES IN THE CONTEXT OF THE FRAMEWORK FOR ACTION IN THE FIELD
OF PUBLIC HEALTH,**

COUNCIL COMMON POSITION

AMENDED PROPOSAL

DECISION No /98/EC OF THE
EUROPEAN PARLIAMENT AND OF
THE COUNCIL
Of

Adopting a programme of Community action
On rare diseases within the framework for
action
in the field of public health
(1999 to 2003)

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 from the
Commission ⁽¹⁾,

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

Having regard to the Opinion of the Committee
of the Regions ⁽³⁾,

Acting in accordance with the procedure laid
down in Article 189b of the Treaty ⁽⁴⁾,

(0) Whereas Community actions should be directed towards the prevention of diseases and whereas action by the Community can provide unique added value to tackling problems, the scale of which in individual countries is too small to allow the necessary analysis or proper action;

⁽¹⁾ OJ C 203, 3.7.1997, p. 6.

⁽²⁾ OJ C 19, 21.1.1998, p. 4.

⁽³⁾ OJ C 64, 27.2.1998, p. 96

⁽⁴⁾ Opinion of the European Parliament of 11 March 1998 (not yet published in the Official Journal), Council Common Position of (not yet published in the Official Journal) and Decision of the European Parliament of (not yet published in the Official Journal).

<p>(1) Whereas, for the purposes of this programme, rare diseases are life-threatening or chronically debilitating diseases which are of such low prevalence that special combined efforts are needed to address them so as to prevent significant perinatal and early morbidity or mortality or a considerable reduction in an individual's quality of life or socio-economic potential;</p> <p>(2) Whereas, as a guide, low prevalence can be understood as meaning prevalence which is generally recognized as less than 5 per 10 000 in the Community;</p> <p>(3) Whereas the very fact of the rarity of low-prevalence diseases and conditions and the lack of information about them may mean that people affected by such diseases and conditions do not benefit from the health resources and services which they need;</p> <p>(4) Whereas the number of people affected by individual rare diseases is, by definition, relatively small in comparison with more commonplace disorders; whereas, however, these diseases taken together are quite prevalent and affect a significant percentage of the general population;</p> <p>(5) Whereas rare diseases are considered to have little impact on society as a whole owing to their low prevalence individually; whereas, however, they pose serious difficulties for sufferers and their families;</p> <p>(6) Whereas, in accordance with Article 3(o) of the Treaty, Community activities are to include a contribution to the attainment of a high level of health protection;</p>	<p><u>(5a) Whereas understanding of rare diseases needs to be improved, since they constitute warning signs from a public health perspective to the extent that problems shown to affect a small section of the population could, as time passed, spread to the community as a whole if the incidence of the causes were to become more frequent;</u></p>
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- (7) Whereas Article 129 of the Treaty expressly provides for Community competence in this field insofar as the Community contributes by encouraging cooperation between the Member States and, if necessary, lending support to their action, promoting coordination of their policies and programmes, and fostering cooperation with third countries and the competent international organizations in the sphere of public health; whereas Community action should be directed towards the prevention of diseases and the promotion of health education and information;
- (8) Whereas, by helping to improve knowledge and understanding of rare diseases and foster a wider dissemination of information about them and by developing actions complementary to other Community programmes and actions and to initiatives which are of direct relevance to achievement of the objective of this programme, while avoiding unnecessary duplication, the programme will contribute to the achievement of the Community objectives set out in Article 129 of the Treaty;
- (9) Whereas an action programme on rare diseases should be undertaken as part of a coherent overall approach which includes initiatives in the sphere of orphan drugs and medical research;
- (10) Whereas rare diseases have been identified as a priority area for Community action in the Commission's communication of 24 November 1993 on the framework for action in the field of public health;
- (11) Whereas, in its Resolution of 16 January 1996 on the Medium-Term Social Action Programme 1995-1997 ⁽¹⁾, the European Parliament asked the Commission to present, under the proper procedures, the action programme for rare diseases provided for in that communication;

⁽¹⁾ OJ C 32, 5.2.1996, p. 24.

(12) Whereas, in accordance with the principle of subsidiarity, action on matters which do not fall within the exclusive competence of the Community, such as action on rare diseases, should be undertaken by the Community only if and insofar as, by reason of its scale or effects, its objectives can be better achieved by the Community;

(13) Whereas the Community is in a position to provide added value to the actions of Member States concerning rare diseases through the coordination of national measures, the dissemination of information and experience, the joint establishment of priorities, the development of networking as appropriate, selection of Community-wide projects and the motivation and mobilization of all involved;

(14) Whereas cooperation with international organizations competent in the sphere of public health, in particular the World Health Organization (WHO), and with third countries, should be fostered;

(13) Whereas the Community is in a position to provide added value to the actions of Member States concerning rare diseases through the coordination of national measures, the dissemination of information and experience, the joint establishment of priorities, the development of networking as appropriate, the selection of Community-wide projects and the motivation and mobilization of all involved, in particular health professionals and patients' and support group associations";

(13a) Whereas the Council resolution on equality of opportunity for people with disabilities of 20 December 1996 invites to promote the involvement of representatives of people with disabilities in the implementation and follow-up of relevant policies and actions in their favour;

(14a) Whereas the high level of technology currently available can contribute significantly to the acquisition of better knowledge and understanding of, and the wider dissemination of information about rare diseases, as stated above, and whereas this technology should be used to enhance the achievement of the objectives and actions envisaged under the programme;

- (15) Whereas the systematic collection of health data is carried out within the framework of the programme of Community action on health monitoring (1997 to 2001) adopted by Decision No 1400/97/EC of the European Parliament and of the Council ⁽¹⁾; whereas a regular exchange of information and data must therefore be ensured between this programme and that programme of Community action on health monitoring;
- (16) Whereas this programme should last five years in order to allow sufficient time to implement measures to achieve the objectives set;
- (17) Whereas, in order to increase the value and impact of the programme, there should be continuous assessment of the measures taken, with particular regard to their effectiveness and the achievement of the objectives set;
- (18) Whereas it should be possible to adjust or modify this programme in the light of its evaluation and of any developments that may take place in the general context of the Community framework for action in the field of public health;
- (19) Whereas the introduction of specific Community arrangements should help to ensure that Member States are swiftly informed in the event of an emergency situation, so that the protection of the population can be ensured;
- (20) Whereas these Community arrangements for the rapid exchange of information will not affect the Member States' rights and obligations under treaties or bilateral and multilateral conventions;
- (21) Whereas it is important that the Commission should ensure implementation of this programme in close cooperation with the Member States;

⁽¹⁾ OJ L 193, 22.7.1997, p. 1.

(22) Whereas a modus vivendi⁽¹⁾ between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the Treaty was reached on 20 December 1994;

(23) Whereas this Decision lays down, for the entire duration of the programme, a financial framework constituting the principal point of reference, within the meaning of point 1 of the Declaration of the European Parliament, the Council and the Commission of 6 March 1995⁽²⁾, for the budgetary authority during the annual budgetary procedure,

HAVE DECIDED AS FOLLOWS:

Article 1

Duration and aim of the programme

A programme of Community action on rare diseases, hereinafter referred to as "this programme", is hereby adopted for the period from 1 January 1999 to 31 December 2003 within the framework for action in the field of public health.

The aim of this programme is to contribute, in coordination with other Community measures, towards insuring a high level of health protection in relation to rare diseases by facilitating access to information about these diseases, in particular for health professionals, researchers and for those affected directly or indirectly by these diseases, by encouraging cross-border cooperation of voluntary support groups for the last mentioned and by ensuring optimum handling of clusters.

The actions to be implemented under this programme are set out in the Annex.

Article 1

Duration and aim of the programme

The aim of this programme is to contribute, in coordination with other Community measures, towards insuring a high level of health protection in relation to rare diseases by improving knowledge about and facilitating access to information about rare diseases, in particular for health professionals, researchers, and for those affected directly or indirectly by these diseases, by encouraging and strengthening transnational cooperation of voluntary support groups for the last mentioned and by ensuring optimum handling of clusters and by fostering the setting up of a system of surveillance for rare diseases so that a rapid and effective response can be made;

⁽¹⁾ OJ C 102, 4.4.1996, p. 1.

⁽²⁾ OJ C 102, 4.4.1996, p. 4.

Article 2

Implementation

The Commission shall ensure implementation of the actions set out in the Annex in close cooperation with the Member States, in accordance with Article 5.

The Commission shall cooperate with institutions and organizations active in the field of rare diseases.

Article 3

Consistency and complementarity

The Commission shall ensure that there is consistency and complementarity between the actions to be implemented under this programme and with those implemented under other Community programmes and actions, in particular in the sphere of public health, on the one hand, and initiatives in the sphere of orphan drugs and medical research, on the other.

Article 4

Budget

The financial framework for the implementation of this programme for the period referred to in Article 1 is hereby set at ECU 6,5 million.

The annual appropriations shall be authorized by the budgetary authority within the limits of the financial perspective.

Article 5

Committee

The Commission shall be assisted by a Committee consisting of two representatives of each Member State and chaired by a representative of the Commission.

The representative of the Commission shall submit to the Committee a draft of the measures to be taken concerning:

Article 2

Implementation

The Commission shall ensure implementation of the actions set out in the Annex in close cooperation with the Member States.

Article 5

Committee

In implementing this Action Plan, the Commission shall be assisted by an advisory committee, hereinafter referred to as "the Committee" consisting of representatives from each Member State, and chaired by the representative of the Commission.

The representative of the Commission shall submit to the Committee a draft of the measures to be taken concerning, in particular

- (a) the Committee's rules of procedure;
- (b) an annual work programme indicating the priorities for action;
- (c) the arrangements, criteria and procedures for selecting and financing projects under this programme, including those involving cooperation with international organizations competent in the sphere of public health and participation of the countries referred to in Article 6(2);
- (d) the evaluation procedure;
- (e) the arrangements for dissemination and transfer of results;
- (f) the procedures for coordination with programmes and initiatives which are of direct relevance to achievement of the aim of this programme;
- (g) the arrangements for cooperating with the institutions and organisations referred to in Article 2(2).

The Committee shall deliver its opinion on the draft measures referred to above within a time limit which the Chairman may lay down according to the urgency of the matter. 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.

The Commission shall adopt measures which shall apply immediately. However, if these measures are not in accordance with the opinion of the Committee, they shall be communicated by the Commission to the Council forthwith. In that event:

- a) the criteria, and procedures for selecting and financing projects under this programme;

- b) the evaluation procedure

The Committee shall deliver its opinion on the draft, within a time limit which the chairperson 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 position recorded in the minutes.

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.

The representative of the Commission shall keep the Committee regularly informed of programmes in other policy areas which are relevant to the achievement of the objectives of this programme.

- the Commission shall defer application of the measures which it has decided upon for a period of two months from the date of such communication;

- the Council, acting by a qualified majority, may take a different decision within the time limit laid down in the preceding indent.

In addition, the Commission may consult the Committee on any other matter concerning the implementation of this programme.

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 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 position recorded in the minutes.

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.

The representative of the Commission shall keep the Committee regularly informed of:

- financial assistance granted under this programme (amount, duration, breakdown and beneficiaries);

- Commission proposals or Community initiatives and the implementation of programmes in other fields which are of direct relevance to achievement of the objective of this programme, so as to ensure consistency and complementarity as referred to in Article 3.

Article 6

International cooperation

Subject to Article 228 of the Treaty, in the course of implementing this programme, cooperation with third countries and with international organizations competent in the sphere of public health, in particular the World Health Organization (WHO), shall be encouraged and implemented as regards the actions covered by this programme in accordance with the procedure laid down in Article 5.

This programme shall be open to participation by the associated countries of central Europe, in accordance with the conditions laid down in the Association Agreements or Additional Protocols relating thereto concerning participation in Community programmes.

This programme shall be open to participation by Cyprus and Malta on the basis of additional appropriations in accordance with the same rules as those applied to the countries of the European Free Trade Association (EFTA), in accordance with procedures to be agreed with those two countries.

Article 7

Monitoring and evaluation

In the implementation of this Decision, the Commission shall take the necessary measures to ensure the monitoring and continuous evaluation of this programme, taking account of the aim set out in Article 1.

The Commission shall submit an interim report to the European Parliament and to the Council during the third year of this programme and a final report upon completion of this programme. It shall incorporate into these two reports information on Community financing in the various fields of action and on consistency and complementarity with the other actions referred to in Article 3, as well as the results of the evaluation referred to in paragraph 1 of this Article. The reports shall also be submitted to the Economic and Social Committee and the Committee of the Regions. The interim report should also take account of developments occurring within the framework for Community action in the field of public health.

Article 6

International cooperation

1. In the course of implementing this programme, cooperation with third countries and with international organisations competent in the sphere of public health, in particular the World Health Organisation (WHO), shall be encouraged and implemented as regards the actions covered by this programme.

On the basis of the interim report referred to in paragraph 2, the Commission may, if necessary, make appropriate proposals for modifications or adjustments to this programme.

Done at Luxembourg,

For the European Parliament For the Council
The President
The President

ANNEX

Actions

1. Promote the development of, and access to, a European information network on rare diseases, using the existing databases whenever possible. The information is to comprise entries listing the disease name, synonyms, a general description of the disorder, symptoms, causes, epidemiological data, preventive measures, standard treatments, clinical trials, diagnostic laboratories and specialized consultations, research programmes and a list of sources that can be contacted for further information about the condition. The availability of this information should be made as widely known as possible.
2. Encourage and support the drawing up of recommendations by professionals in order to improve early detection, recognition, intervention and prevention in the field of rare diseases.
3. Promote cross-border collaboration and networking between groups of persons directly or indirectly affected by the same rare conditions or volunteers and professionals involved and coordination at Community level in order to encourage continuity of work and transnational cooperation.
4. Support at Community level the monitoring of rare diseases in the Member States and early warning systems for clusters, and stimulate the networking and training of experts concerned with the handling of rare diseases and their clusters.

1. Promote the development of, and access to, a European information network on rare diseases, using the existing databases among other things. The information is to comprise entries listing the disease name, synonyms, a general description of the disorder, symptoms, causes, epidemiological data, preventive measures, standard treatments, clinical trials, diagnostic laboratories and specialised consultations, research programmes and a list of sources that can be contacted for further information about the condition. This information should be made as widely available as possible.

3. Promote collaboration and networking between groups of persons directly or indirectly affected by the same rare conditions or volunteers and professionals involved and coordination at Community level in order to encourage continuity of work and transnational cooperation

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