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*(Acts whose publication is obligatory)*

**DECISION No 1295/1999/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of 29 April 1999**

**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,

recognised as less than 5 per 10 000 in the  
Community;

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

(4) 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;

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the Economic and Social  
Committee <sup>(2)</sup>,

(5) 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;

Having regard to the opinion of the Committee of the  
Regions <sup>(3)</sup>,

Acting in accordance with the procedure laid down in  
Article 189b of the Treaty <sup>(4)</sup>, in the light of the joint text  
approved by the Conciliation Committee on 4 February  
1999,

(1) Whereas Community measures must relate to the  
prevention of diseases and Community action may  
contribute unique added value to the treatment of  
problems the scale of which in individual countries  
is too small to allow the necessary analysis or effective  
intervention;

(6) 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;

(2) Whereas, for the purposes of this programme, rare  
diseases, including those of genetic origin, 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 morbidity or perinatal or  
early mortality or a considerable reduction in an  
individual's quality of life or socio-economic  
potential;

(7) Whereas understanding of rare diseases needs to be  
improved, since they may constitute danger signs  
from a public health perspective;

(3) Whereas, as a guide, low prevalence can be under-  
stood as meaning prevalence which is generally

(8) 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;

(9) Whereas Article 129 of the Treaty expressly  
provides for Community competence in this field  
insofar as the Community contributes by encour-  
aging 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 organ-  
izations 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;

<sup>(1)</sup> OJ C 203, 3.7.1997, p. 6, and  
OJ C 160, 27.5.1998, p. 8.

<sup>(2)</sup> OJ C 19, 21.1.1998, p. 4.

<sup>(3)</sup> OJ C 64, 27.2.1998, p. 96.

<sup>(4)</sup> Opinion of the European Parliament of 11 March 1998 (OJ C 104, 6.4.1998, p. 133), Council Common Position of 30 April 1998 (OJ C 227, 20.7.1998, p. 1) and Decision of the European Parliament of 8.10.1998 (OJ C 328, 26.10.1998, p. 148). Decision of the Council of 22 April 1999 and Decision of the European Parliament of 14 April 1999.

- (10) Whereas Community action should aim to improve the quality of life of all citizens of the Union;
- (11) 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;
- (12) 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;
- (13) 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;
- (14) Whereas, in its Resolution of 16 January 1996 on the medium-term social action programme 1995-1997<sup>(1)</sup>, the European Parliament asked the Commission to present, under the proper procedures, the action programme for rare diseases provided for in that communication;
- (15) 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;
- (16) 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 mobilisation of all involved, in particular health professionals, researchers and persons directly or indirectly affected by such diseases;
- (17) Whereas the creation of a coherent and complementary European information network on rare diseases and access to it should be promoted as soon as possible from the start of this programme onwards, using the existing data bases, among other things;
- (18) Whereas cooperation with international organisations competent in the sphere of public health, in particular the World Health Organisation (WHO), and with third countries, should be fostered, as well as transnational collaboration between voluntary support groups for those directly or indirectly affected by rare diseases;
- (19) 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; whereas this technology should be used to enhance the achievement of the objectives and actions envisaged under the programme; 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, the commercial profitability of which could be insufficient, and medical research;
- (20) 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<sup>(2)</sup>; whereas a regular exchange of information and data must therefore be ensured between this programme and that programme of Community action on health monitoring;
- (21) Whereas this programme should last five years in order to allow sufficient time to implement measures to achieve the objectives set;
- (22) 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;
- (23) 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;

<sup>(1)</sup> OJ C 32, 5.2.1996, p. 24.

<sup>(2)</sup> OJ L 193, 22.7.1997, p. 1.

- (24) 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;
- (25) 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;
- (26) Whereas it is important that the Commission should ensure implementation of this programme in close cooperation with the Member States;
- (27) Whereas a *modus vivendi*<sup>(1)</sup> 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;
- (28) 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<sup>(2)</sup>, for the budgetary authority during the annual budgetary procedure,

HAVE DECIDED AS FOLLOWS:

#### *Article 1*

##### **Duration and aim of the programme**

1. A programme of Community action on rare diseases, including genetic 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.
2. The aim of this programme is to contribute, in coordination with other Community measures, towards ensuring a high level of health protection in relation to rare diseases by improving knowledge, for example by promoting the setting-up of a coherent and complementary European information network on rare diseases, and facilitating access to information about these diseases, in particular for health professionals, researchers and those affected directly or indirectly by these diseases, by encouraging and strengthening transnational cooperation between voluntary and professional support groups for those concerned, and by ensuring optimum handling of clusters and by promoting the surveillance of rare diseases.

<sup>(1)</sup> OJ C 102, 4.4.1996, p. 1.

<sup>(2)</sup> OJ C 102, 4.4.1996, p. 4.

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

#### *Article 2*

##### **Implementation**

1. 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.
2. The Commission shall cooperate with institutions and organisations 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**

1. The financial framework for the implementation of this programme for the period referred to in Article 1 is hereby set at EUR 6,5 million.
2. The annual appropriations shall be authorized by the budgetary authority within the limits of the financial perspective.

#### *Article 5*

##### **Committee**

1. The Commission shall be assisted by a committee consisting of two representatives of each Member State and chaired by a representative of the Commission.
2. The representative of the Commission shall submit to the committee a draft of the measures to be taken concerning:
  - (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 organisations 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:

- 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.

3. 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.

4. 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**

1. Subject to Article 228 of the Treaty, 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 in accordance with the procedure laid down in Article 5.

2. 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**

1. 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.

2. 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.

3. 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, 29 April 1999.

*For the European Parliament*

*The President*

J. M. GIL-ROBLES

*For the Council*

*The President*

W. MÜLLER

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ANNEX

**ACTIONS**

1. Promote the development of, and access to, a coherent and complementary 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. The availability of this information must be made as widely known as possible, including via the Internet.
  2. Contribute to training and refresher courses for professionals in order to improve early detection, recognition, intervention and prevention in the field of rare diseases.
  3. Promote transnational 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.
  4. Support at Community level the monitoring of rare diseases in the Member States and early warning systems for clusters, and promote the networking and training of experts concerned with the handling of rare diseases and with rapid response to the phenomenon of clusters.
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