(6) According to the World Health Organisation (WHO) European Health report 2005, in terms of Disability Adjusted Life-Years (DALYs), the most important causes of the burden of disease in the WHO European Region are non-communicable diseases (NCDs — 77 % of the total), external causes of injury and poisoning (14 %) and communicable diseases (9 %). Seven leading conditions — ischaemic heart disease, unipolar depressive disorders, cerebrovascular disease, alcohol use disorders, chronic pulmonary disease, lung cancer and road traffic injuries — account for 34 % of the DALYs in the region. Seven leading risk factors — tobacco, alcohol, high blood pressure, high cholesterol, overweight, low fruit and vegetable intake and physical inactivity — account for 60 % of DALYs. In addition, communicable diseases such as HIV/AIDS, influenza, tuberculosis and malaria are also becoming a threat to the health of all people in Europe. An important task of the Programme, in cooperation, where appropriate, with the Community Statistical Programme, should be to identify better the main health burdens in the Community.

(7) Eight leading causes of mortality and morbidity from NCDs in the WHO European Region are cardiovascular diseases, neuropsychiatric disorders, cancer, digestive diseases, respiratory diseases, sense organ disorders, musculoskeletal diseases and diabetes mellitus. The Programme, in synergy with other Community initiatives and funding, should contribute to better knowledge of and information on the prevention, diagnosis and control of major diseases. Accordingly, the Commission may submit, during the course of the Programme, proposals for pertinent Council Recommendations. The Programme should also foster appropriate coordination and synergies among Community initiatives regarding the collection of comparable data on major diseases, including cancer.

(8) Microbial resistance to antibiotics and nosocomial infections are becoming a threat to health in Europe. The lack of new effective antibiotics as well as the means to ensure the proper use of existing antibiotics are major concerns. Therefore it is important to collect and analyse relevant data.

(9) Strengthening the role of the European Centre for Disease Prevention and Control established by Regulation (EC) No 851/2004 of the European Parliament and of the Council [1] is important in the fight against communicable diseases.

(10) The Programme should build on the achievements of the previous Programme for Community action in the field of public health (2003-08). It should contribute towards the attainment of a high level of physical and mental health and greater equality in health matters throughout the Community by directing actions towards improving public health, preventing human diseases and disorders, and obviating sources of danger to health with a view to combating morbidity and premature mortality. It should further contribute to providing citizens with better access to information and thereby increase their ability to make decisions which best cater for their interests.

(11) The Programme should place emphasis on improving the health condition of children and young people and promoting a healthy lifestyle and a culture of prevention among them.

(12) The Programme should support the mainstreaming of health objectives in all Community policies and activities, without duplicating work carried out under other Community policies. Coordination with other Community policies and programmes is a key part of the objective of mainstreaming health in other policies. In order to promote synergies and avoid duplication, joint actions may be undertaken with related Community programmes and actions and appropriate use should be made of other Community funds and programmes, including the current and future Community framework programmes for research and their outcomes, the Structural Funds, the European Solidarity Fund, the European strategy for health at work, the programme of Community action in the field of consumer policy (2007-13) [2], the programme 'Drugs prevention and information', the programme 'Fight against violence (Daphne)' and the Community Statistical Programme within their respective activities.

(13) Special efforts should be undertaken to ensure coherence and synergies between the Programme and the Community's external actions, particularly in the areas of avian influenza, HIV/AIDS, tuberculosis and other cross-border health threats. In addition, there should be international cooperation in order to promote general health reform and general health institutional issues in third countries.

(14) Increasing Healthy Life Years (HLY) by preventing disease and promoting policies that lead to a healthier way of life is important for the well-being of EU citizens and helps to meet the challenges of the Lisbon process as regards the knowledge society and the sustainability of public finances, which are under pressure from rising health care and social security costs.

[1] OJ L 142, 30.4.2004, p. 1.

[2] Decision No 1926/2006/EC of the European Parliament and of the Council (OJ L 404, 30.12.2006, p. 39).

(15) The enlargement of the European Union has brought additional concerns in terms of health inequalities within the EU and this is likely to be accentuated by further enlargements. This issue should, therefore, be one of the priorities of the Programme.

(16) The Programme should help to identify the causes of health inequalities and encourage, among other things, the exchange of best practices to tackle them.

(17) It is essential to systematically collect, process and analyse comparable data, within national constraints, for an effective monitoring of the state of health in the European Union. This would enable the Commission and the Member States to improve information to the public and formulate appropriate strategies, policies and actions to achieve a high level of human health protection. Compatibility and interoperability of the systems and networks for exchanging information and data for the development of public health should be pursued in the actions and support measures. Gender, socioeconomic status and age are important health considerations. Data collection should wherever possible build on existing work, and proposals for new collections should be costed and based on a clear need. The collection of data should be in compliance with the relevant legal provisions on the protection of personal data.

(18) Best practice is important because health promotion and prevention should be measured on the basis of efficiency and effectiveness, and not purely in economic terms. Best practice and latest treatment methods for diseases and injuries should be promoted in order to prevent further deterioration of health, and European reference networks for specific conditions should be developed.

(19) Action should be taken in order to prevent injuries by collecting data, analysing injury determinants and disseminating relevant information.

(20) Health services are primarily the responsibility of Member States but cooperation at Community level can benefit both patients and health systems. Activities funded by the Programme as well as new proposals developed as a result of these should have due regard to the Council Conclusions on common values and principles in European Union Health Systems [1] adopted in June 2006 that endorse a statement on the common values and principles of EU Health Systems and invite the institutions of the European Union to respect them in their work. The Programme should take due account of future developments as regards Community action on health services as well as the work of the High Level Group on Health Services and Medical Care, which provides an important forum for collaboration and exchange of best practice between Member States' health systems.

(21) The Programme should contribute to the collection of data, the promotion and development of methods and tools, the establishment of networks and various kinds of cooperation and the promotion of relevant policies on patient mobility as well as on the mobility of health professionals. It should facilitate the further development of the European e-Health Area, through joint European initiatives with other EU policy areas, including regional policy, while contributing towards work on quality criteria for health-related websites and towards a European health insurance card. Telemedicine should be taken into account as telemedicine applications may contribute to cross-border care while ensuring medical care at home.

(22) Environmental pollution is a serious risk to health and a major source of concern for European citizens. Special action should focus on children and other groups which are particularly vulnerable to hazardous environmental conditions. The Programme should complement the actions taken within the European Environment and Health Action Plan 2004-10.

(23) The Programme should address genderrelated and ageing-related health issues.

(24) The Programme should recognise the importance of a holistic approach to public health and take into account, where appropriate and where there is scientific or clinical evidence about its efficacy, complementary and alternative medicine in its actions.

(25) The precautionary principle and risk assessment are key factors for the protection of human health and should therefore be part of further integration into other Community policies and activities.

(26) This Decision establishes, for the entire duration of the Programme, a financial envelope which constitutes the prime reference within the meaning of point 37 of the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management [2], for the budgetary authority during the annual budgetary procedure.

[1] OJ C 146, 22.6.2006, p. 1.

[2] OJ C 139, 14.6.2006, p. 1.

(27) In order to ensure a high level of coordination between actions and initiatives taken by the Community and Member States in the implementation of the Programme, it is necessary to promote cooperation between Member States and to enhance the effectiveness of existing and future networks in the field of public health. The participation of national, regional and local authorities at the appropriate level in accordance with the national systems should be taken into account in regard to the implementation of the Programme.

(28) It is necessary to increase EU investment in health and health-related projects. In this regard, Member States are encouraged to identify health improvements as a priority in their national programmes. Better awareness about the possibilities of EU funding for health is needed. Exchange of experience between the Member States on funding health through the Structural Funds should be encouraged.

(29) Non-governmental bodies and specialised networks can also play an important role in meeting the objectives of the Programme. In pursuing one or more objectives of the Programme, they may require Community contributions to enable them to function. Hence, detailed eligibility criteria, provisions regarding financial transparency and the duration of Community contributions for non-governmental bodies and specialised networks qualifying for Community support should be set out in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1]. Such criteria should include the obligations of such bodies and networks in establishing clear objectives, action plans and measurable results representing a strong European dimension and a real added value for the objectives of the Programme. Given the particular nature of the organisations concerned and in cases of exceptional utility, it should be possible for the renewal of Community support to the functioning of such bodies and specialised networks to be exempted from the principle of gradual decrease of the extent of Community support.

(30) Implementation of the Programme should be carried out in close cooperation with relevant organisations and agencies, in particular with the European Centre for Disease Prevention and Control.

(31) The measures necessary for the implementation of this Decision should be adopted in accordance with Decision 1999/468/EC, respecting the need for transparency as well as a reasonable balance between the different objectives of the Programme.

(32) The Agreement on the European Economic Area (hereinafter referred to as 'the EEA Agreement') provides for cooperation in the field of health between the European Community and its Member States, on the one hand, and the countries of the European Free Trade Association participating in the European Economic Area (hereinafter referred to as 'the EFTA/EEA countries'), on the other. Provision should also be made to open the Programme to participation by other countries, in particular the neighbouring countries of the Community and countries that are applying for, are candidates for, or are acceding to, membership of the European Union, taking particular account of the potential for health threats arising in other countries to have an impact within the Community.

(33) Appropriate relations with third countries not participating in the Programme should be facilitated in order to help achieve the objectives of the Programme, taking account of any relevant agreements between those countries and the Community. This may involve third countries taking forward complementary activities to those financed through the Programme on areas of mutual interest, but should not involve a financial contribution under the Programme.

(34) It is appropriate to develop cooperation with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, as well as with the Council of Europe and the Organisation for Economic Cooperation and Development, with a view to implementing the Programme through maximising the effectiveness and efficiency of actions relating to health at Community and international level, taking into account the particular capacities and roles of the different organisations.

(35) The successful implementation of the objectives under the Programme should be based on good coverage of the issues included in the annual work plans, on selection of appropriate actions and funding of projects, which all have an in-built appropriate monitoring and evaluation process in place, and on regular monitoring and evaluation, including independent external evaluations, which should measure the impact of actions and demonstrate their contribution to the overall objectives of the Programme. Programme evaluation should take into account the fact that the achievement of the Programme objectives may require a longer time period than the duration of the Programme.

(36) The annual work plans should cover the main foreseeable activities to be funded from the Programme through all the different funding mechanisms, including calls for tender.

[1] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

(37) Since the objectives of this Decision cannot be sufficiently achieved by the Member States due to the transnational nature of the issues involved, and can therefore, by reason of the potential for Community action to be more efficient and effective than national action alone in protecting the health and safety of citizens, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Decision does not go beyond what is necessary in order to achieve those objectives.

(38) In accordance with Article 2 of the Treaty, which provides that equality between men and women is a principle of the Community, and in accordance with Article 3(2) thereof, which provides that the Community shall aim to eliminate inequalities, and to promote equality between men and women in all Community activities including the attainment of a high level of health protection, all objectives and actions covered by the Programme contribute to promoting a better understanding and recognition of men's and women's respective needs and approaches to health.

(39) It is appropriate to ensure a transition between the Programme and the previous programme it replaces, in particular regarding the continuation of multi-annual arrangements for its management, such as the financing of technical and administrative assistance. As of 1 January 2014, the technical and administrative assistance appropriations should cover, if necessary, the expenditure related to the management of actions not yet completed by the end of 2013.

(40) This Decision replaces Decision No 1786/2002/EC. That Decision should therefore be repealed,

HAVE DECIDED AS FOLLOWS:

Article 1

Establishment of the Programme

The second programme of 'Community action in the field of health (2008-13)' covering the period from 1 January 2008 to 31 December 2013 (hereinafter referred to as 'the Programme') is hereby established.

Article 2

Aim and objectives

1. The Programme shall complement, support and add value to the policies of the Member States and contribute to increased solidarity and prosperity in the European Union by protecting and promoting human health and safety and improving public health.

2. The objectives to be pursued through the actions set out in the Annex shall be:

— to improve citizens' health security,

— to promote health, including the reduction of health inequalities,

— to generate and disseminate health information and knowledge.

The actions referred to in the first subparagraph shall, where appropriate, support the prevention of major diseases and contribute to reducing their incidence as well as the morbidity and mortality caused by them.

Article 3

Funding

1. The financial envelope for the implementation of the Programme for the period specified in Article 1 is hereby set at EUR 321 500 000.

2. Annual appropriations shall be authorised by the budgetary authority within the limits of the financial framework.

Article 4

Financial contributions

1. Financial contributions by the Community shall not exceed the following levels:

(a) 60 % of costs for an action intended to help achieve an objective forming part of the Programme, except in cases of exceptional utility, where the Community contribution shall not exceed 80 %; and

(b) 60 % of costs for the functioning of a non-governmental body or a specialised network, which is non-profit-making and independent of industry, commercial and business or other conflicting interests, has members in at least half of the Member States, with a balanced geographical coverage, and pursues as its primary goal one or more objectives of the Programme, where such support is necessary to pursue those objectives. In cases of exceptional utility, the Community contribution shall not exceed 80 %.

2. The renewal of financial contributions set out in paragraph 1(b) to non-governmental bodies and specialised networks may be exempted from the principle of gradual decrease.

3. Financial contributions by the Community may, where appropriate given the nature of the objective to be achieved, include joint financing by the Community and one or more Member States or by the Community and the competent authorities of other participating countries. In this case, the Community contribution shall not exceed 50 %, except in cases of exceptional utility, where the Community contribution shall not exceed 70 %. These Community contributions may be awarded to a public body or a non-governmental body, which is non-profit-making and independent of industry, commercial and business or other conflicting interests, and pursues as its primary goal one or more objectives of the Programme, designated through a transparent procedure by the Member State or the competent authority concerned and agreed by the Commission.

4. Financial contributions by the Community may also be given in the form of a lump sum and flat-rate financing where this is suited to the nature of the actions concerned. For such financial contributions, the percentage limits stipulated in paragraphs 1 and 3 shall not apply, although co-financing is still required.

Article 5

Administrative and technical assistance

1. The financial allocation of the Programme may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities required directly for the management of the Programme and the realisation of its objectives, in particular studies, meetings, information and publication actions, expenses linked to informatics networks focusing on information exchange, as well as all other technical and administrative assistance expense that the Commission may have recourse to for the management of the Programme.

2. The financial allocation may also cover the technical and administrative assistance expenses necessary to ensure the transition between the Programme and the measures adopted under Decision No 1786/2002/EC. If necessary, appropriations could be entered in the budget beyond 2013 to cover similar expenses, in order to enable the management of actions not yet completed by 31 December 2013.

Article 6

Methods of implementation

Actions in pursuit of the aim and objectives set out in Article 2 shall make full use of appropriate available methods of implementation, including in particular:

(a) direct or indirect implementation by the Commission on a centralised basis; and

(b) joint management with international organisations, where appropriate.

Article 7

Implementation of the Programme

1. The Commission shall ensure the implementation, in close cooperation with the Member States, of the actions and measures set out in the Programme in accordance with Articles 3 and 8.

2. The Commission and the Member States shall take appropriate action, within their respective areas of competence, to ensure the efficient running of the Programme and to develop mechanisms at Community and Member State level to achieve the objectives of the Programme. They shall ensure that appropriate information is provided about actions supported by the Programme and that appropriate participation is obtained.

3. For the attainment of the objectives of the Programme, the Commission shall, in close cooperation with the Member States:

(a) pursue the comparability of data and information, and the compatibility and interoperability of the systems and networks for exchange of data and information on health; and

(b) ensure the necessary cooperation and communication with the European Centre for Disease Prevention and Control and other relevant EU agencies in order to optimise the use of Community funds.

4. In implementing the Programme, the Commission, together with the Member States, shall ensure compliance with all relevant legal provisions regarding personal data protection and, where appropriate, the introduction of mechanisms to ensure the confidentiality and safety of such data.

Article 8

Implementation measures

1. The measures necessary for the implementation of this Decision relating to the following shall be adopted in accordance with the procedure referred to in Article 10(2):

(a) the annual work plan for the implementation of the Programme, setting out:

(i) priorities and actions to be undertaken, including the allocation of financial resources;

(ii) criteria for the percentage of Community financial contribution, including criteria for assessing whether or not exceptional utility applies;

(iii) the arrangements for implementing the joint strategies and actions referred to in Article 9;

(b) selection, award and other criteria for financial contributions to the actions of the Programme in accordance with Article 4.

2. Any other measures necessary for the implementation of this Decision shall be adopted in accordance with the procedure referred to in Article 10(3).

Article 9

Joint strategies and actions

1. To ensure a high level of human health protection in the definition and implementation of all Community policies and activities and to promote the mainstreaming of health, the objectives of the Programme may be implemented as joint strategies and joint actions by creating links with relevant Community programmes, actions and funds.

2. The Commission shall ensure the optimal synergy of the Programme with other Community programmes, actions and funds.

Article 10

Committee

1. The Commission shall be assisted by a committee (hereinafter referred to as 'the Committee').

2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at two months.

3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 11

Participation of third countries

The Programme shall be open to the participation of:

(a) the EFTA/EEA countries in accordance with the conditions established in the EEA Agreement; and

(b) third countries, in particular countries to which the European Neighbourhood Policy applies, countries that are applying for, are candidates for, or are acceding to, membership of the European Union, and the western Balkan countries included in the stabilisation and association process, in accordance with the conditions laid down in the respective bilateral or multilateral agreements establishing the general principles for their participation in Community programmes.

Article 12

International cooperation

In the course of implementing the Programme, relations and cooperation with third countries that are not participating in the Programme and relevant international organisations, in particular the WHO, shall be encouraged.

Article 13

Monitoring, evaluation and dissemination of results

1. The Commission, in close cooperation with the Member States, shall monitor the implementation of the actions of the Programme in the light of its objectives. It shall report yearly to the Committee on all actions and projects funded through the Programme, and shall keep the European Parliament and the Council informed.

2. At the request of the Commission, which shall avoid a disproportionate increase in the administrative burden of the Member States, Member States shall submit any available information on the implementation and impact of the Programme.

3. The Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions:

(a) not later than 31 December 2010, an external and independent interim evaluation report on the results obtained in relation to the objectives of the Programme and the qualitative and quantitative aspects of its implementation as well as its consistency and complementarity with other relevant Community programmes, actions and funds. The report shall in particular make it possible to assess the impact of measures on all countries. The report shall contain a summary of the main conclusions, and it shall be accompanied by remarks by the Commission;

(b) not later than 31 December 2011, a communication on the continuation of the Programme;

(c) not later than 31 December 2015, an external and independent *ex-post* evaluation report covering the implementation and results of the Programme.

4. The Commission shall make the results of actions undertaken pursuant to this Decision publicly available and shall ensure their dissemination.

Article 14

Repeal

Decision No 1786/2002/EC shall be repealed with effect from 1 January 2008.

The Commission shall adopt any administrative arrangement necessary to ensure the transition between the measures adopted under Decision No 1786/2002/EC and those implemented under the Programme.

Article 15

Entry into force

This Decision shall enter into force on the day following its publication in the *Official Journal of the European Union*.

Done at Strasbourg, 23 October 2007.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	M. LOBO ANTUNES

ANNEX

Actions referred to in Article 2(2)

1. Improve citizens' health security.

1.1. Protect citizens against health threats.

1.1.1. Develop strategies and mechanisms for preventing, exchanging information on and responding to health threats from communicable and non-communicable diseases and health threats from physical, chemical or biological sources, including deliberate release acts; take action to ensure high-quality diagnostic cooperation between Member States' laboratories; support the work of existing laboratories carrying out work with relevance to the Community; work on the setting up of a network of Community reference laboratories.

1.1.2. Support the development of prevention, vaccination and immunisation policies; improve partnerships, networks, tools and reporting systems for immunisation status and adverse events monitoring.

1.1.3. Develop risk management capacity and procedures; improve preparedness and planning for health emergencies, including preparing for coordinated EU and international responses to health emergencies; develop risk communication and consultation procedures on counter-measures.

1.1.4. Promote the cooperation and improvement of existing response capacity and assets, including protective equipment, isolation facilities and mobile laboratories to deploy rapidly in emergencies.

1.1.5. Develop strategies and procedures for drawing up, improving surge capacity of, conducting exercises and tests of, evaluating and revising general contingency and specific health emergency plans and their inter-operability between Member States.

1.2. Improve citizens' safety.

1.2.1. Support and enhance scientific advice and risk assessment by promoting the early identification of risks; analyse their potential impact; exchange information on hazards and exposure; foster integrated and harmonised approaches.

1.2.2. Help to enhance the safety and quality of organs and substances of human origin, blood, and blood derivatives; promote their availability, traceability and accessibility for medical use while respecting Member States' responsibilities as set out in Article 152(5) of the Treaty.

1.2.3. Promote measures to improve patient safety through high-quality and safe healthcare, including in relation to antibiotic resistance and nosocomial infections.

2. Promote health.

2.1. Foster healthier ways of life and the reduction of health inequalities.

2.1.1. Promote initiatives to increase healthy life years and promote healthy ageing; support measures to promote and explore the impact of health on productivity and labour participation as a contribution to meeting the Lisbon goals; support measures to study the impact on health of other policies.

2.1.2. Support initiatives to identify the causes of, address and reduce health inequalities within and between Member States, including those related to gender differences, in order to contribute to prosperity and cohesion; promote investment in health in cooperation with other Community policies and funds; improve solidarity between national health systems by supporting cooperation on issues of cross-border care and patient and health professional mobility.

2.2. Promote healthier ways of life and reduce major diseases and injuries by tackling health determinants.

2.2.1. Address health determinants to promote and improve physical and mental health, creating supportive environments for healthy lifestyles and preventing disease; take action on key factors such as nutrition and physical activity and sexual health, and on addiction-related determinants such as tobacco, alcohol, illegal drugs and pharmaceuticals used improperly, focusing on key settings such as education and the workplace, and across the life cycle.

2.2.2. Promote action on the prevention of major diseases of particular significance in view of the overall burden of diseases in the Community, and on rare diseases, where Community action by tackling their determinants can provide significant added value to national efforts.

2.2.3. Address the health effects of wider environmental determinants, including indoor air quality, exposure to toxic chemicals where not addressed by other Community initiatives, and socio-economic determinants.

2.2.4. Promote actions to help reduce accidents and injuries.

3. Generate and disseminate health information and knowledge.

3.1. Exchange knowledge and best practice.

3.1.1. Exchange knowledge and best practice on health issues within the scope of the Programme.

3.1.2. Support cooperation to enhance the application of best practice within Member States, including, where appropriate, supporting European reference networks.

3.2. Collect, analyse and disseminate health information.

3.2.1. Develop further a sustainable health monitoring system with mechanisms for collection of comparable data and information, with appropriate indicators; ensure appropriate coordination of and follow-up to Community initiatives regarding registries on cancer, based, *inter alia*, on the data collected when implementing the Council Recommendation of 2 December 2003 on cancer screening [1]; collect data on health status and policies; develop, with the Community Statistical Programme, the statistical element of this system.

3.2.2. Develop mechanisms for analysis and dissemination, including Community health reports, the Health Portal and conferences; provide information to citizens, stakeholders and policy makers, develop consultation mechanisms and participatory processes; establish regular reports on health status in the European Union based on all data and indicators and including a qualitative and quantitative analysis.

3.2.3. Provide analysis and technical assistance in support of the development or implementation of policies or legislation related to the scope of the Programme.

---

[1] OJ L 327, 16.12.2003, p. 34.

TRILATERAL DECLARATION REGARDING THE SECOND COMMUNITY HEALTH PROGRAMME 2008-13

The European Parliament, the Council and the Commission:

— share the view that the second programme of Community action in the field of health (2008-13) must be provided with financial means that allow fully for its implementation;

— recall Article 37 of the Interinstitutional Agreement on budgetary discipline and sound financial management [1] stating that the budgetary authority and the Commission undertake not to depart by more than 5 % from the budget unless new, objective, long-term circumstances arise for which specific reasons are given. Any increase resulting from such variation must remain within the existing ceiling of the heading concerned;

— assure their willingness to evaluate in a sound manner the specific needs and circumstances of the health programme in the annual budget procedure.'

[1] OJ C 139, 14.6.2006, p. 1.

COMMISSION DECLARATION

1. On 24 May 2006, the Commission issued an amended proposal for a second programme of Community action in the field of health (2007-13) [1]. In Article 7, the reference amount of the programme was proposed to be set at EUR 365,6 million for the period starting in 2007 and ending in 2013.

2. Because of delays in the legislative procedure, on 23 March 2007 the Commission informed the Budget Authority that the start of the new public health programme will have to be postponed to budget year 2008 [2]. As a consequence, the envelope of the new public health programme 2008-13 would need to be adjusted to the level of EUR 321,5 million.

3. An amount of EUR 44,1 million will be used in the 2007 budget year under the present public health programme [3] in order to ensure maximum continuity concerning public health actions. Therefore, the total envelope for public health actions financed from the programmes over the period 2007-13 sums up to EUR 365,6 million.

[1] COM(2006) 234.
[2] COM(2007) 150.
[3] Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-08) (OJ L 271, 9.10.2002, p. 1).

2.2.4 欧州議会および欧州理事会決議 No1295/1999

(Decision No 1295/1999/EC of the European Parliament and of the Council of 23 October 2007)

I

(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,

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), 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;

(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;

(3) Whereas, as a guide, low prevalence can be understood as meaning prevalence which is generally recognised as less than 5 per 10 000 in the Community;

(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;

(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;

(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;

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

(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 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;

(1) OJ C 203, 3.7.1997, p. 6, and OJ C 160, 27.5.1998, p. 8.
(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 (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 [1], 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 [2]; 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;

[1] OJ C 32, 5.2.1996, p. 24.

[2] 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* [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;

(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 [2], 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.

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);

[1] OJ C 102, 4.4.1996, p. 1.
[2] OJ C 102, 4.4.1996, p. 4.

(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

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.

2.2.5 欧州委員会最終報告書:ヨーロッパのチャレンジ

(Commission Communication COM(2008)679 final: Europe's Challenge)

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.11.2008
COM(2008) 679 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

on Rare Diseases: Europe's challenges

{SEC(2008)2713}
{SEC(2008)2712}

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

on Rare Diseases: Europe's challenges

1. INTRODUCTION

Rare diseases are diseases with a particularly low prevalence; the European Union considers diseases to be rare when they affect not more than 5 per 10 000 persons in the European Union. This still nevertheless means than between 5 000 and 8 000 different rare diseases affect or will affect an estimated 29 million people in the European Union.

The specificities of rare diseases - limited number of patients and scarcity of relevant knowledge and expertise - single them out as a distinctive domain of very high European added-value. European cooperation can help to ensure that scarce knowledge can be shared and resources combined as efficiently as possible, in order to tackle rare diseases effectively across the EU as a whole.

The Commission has already taken specific steps in many areas to address the issues of rare diseases. Building on those achievements, this Communication on Europe's Challenges in the field of Rare Diseases aims to be an integrated approach document, giving clear direction to present and future Community activities in the field of rare diseases in order to further improve the access and equity to prevention, diagnosis and treatment for patients suffering from a rare disease throughout the European Union.

2. THE ISSUE

Most rare diseases are genetic diseases, the others being rare cancers, auto-immune diseases, congenital malformations, toxic and infectious diseases among other categories. Research on rare diseases has proved to be very useful to better understand the mechanism of common conditions such as obesity and diabetes, as they often represent a model of dysfunction of a single biological pathway. However, research on rare diseases is not only scarce, but also scattered in different laboratories throughout the EU.

The lack of specific health policies for rare diseases and the scarcity of the expertise, translate into delayed diagnosis and difficult access to care. This results in additional physical, psychological and intellectual impairments, inadequate or even harmful treatments and loss of confidence in the health care system, despite the fact that some rare diseases are compatible with a normal life if diagnosed on time and properly managed. Misdiagnosis and non-diagnosis are the main hurdles to improving life-quality for thousands of rare disease patients.

The national healthcare services for diagnosis, treatment and rehabilitation of people with rare diseases differ significantly depending on their availability and quality. Depending on the Member State and/or region where they live, EU citizens have unequal access to expert services and available care options. A few Member States have successfully addressed some of the issues raised by the rarity of the diseases, while others have not yet considered possible solutions.

Under the responsibility of the Commission and the EMEA (the European Medicines Agency) a policy is already implemented in the field of Orphan Drugs. These drugs are called "orphans" because the pharmaceutical industry has little interest, under normal market conditions, in developing and marketing products intended for only a small number of patients suffering from very rare conditions. The Orphan Medicinal Product Regulation (Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[1]) was proposed to set up the criteria for orphan designation in the EU and describes the incentives (e.g. 10-year market exclusivity, protocol assistance, access to the Centralised Procedure for Marketing Authorisation) to encourage the research, development and marketing of medicines to treat, prevent or diagnose rare diseases. The EU policy for orphan drugs is a success. However, Member States do not yet ensure full access to each authorised orphan drug approved.

3. OBJECTIVES

The Community's role in the area of health under Article 152 of the Treaty is to encourage cooperation between the Member States and if necessary to lend support to their action. The specificities of rare diseases - limited number of patients and scarcity of relevant knowledge and expertise - single them out as a unique domain of very high European added-value. The objective of this Communication is to set out an overall Community strategy for support to Member States in ensuring effective and efficient recognition, prevention, diagnosis, treatment, care, and research for rare diseases in Europe.

This will in turn contribute to the overarching goal - an improvement in health outcomes, and therefore a growth in Healthy Life Years, a key Lisbon Strategy indicator[2]. For this purpose this Communication will orient the operational actions in three main fields of work.

3.1. Improving Recognition and Visibility on Rare Diseases

The key to improving overall strategies for rare diseases is to ensure that they are recognised, so that all the other linked actions can follow appropriately. To improve diagnosis and care in the field of rare diseases, appropriate identification needs to be accompanied by accurate information, provided and disseminated in inventory and repertory formats adapted to the needs of professionals and of affected persons. This will contribute to tackling some of the main causes of neglecting the issue of rare diseases. The Commission therefore aims to put in place a thorough coding and classification system at European level, which will provide the framework for better sharing knowledge and understanding rare diseases as a scientific and public health issue across the EU.

3.2. Supporting Policies on Rare Diseases in the Member States

Efficient and effective action for rare diseases depends on a coherent overall strategy for rare diseases mobilising scarce and scattered resources in an integrated and well-recognised way, and integrated into a common European effort. That common European effort itself also depends on a common approach to work on rare diseases

---

1 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

2 See http://ec.europa.eu/health/ph_information/indicators/lifeyears_en.htm.