

Proposal for a Regulation of the European Parliament and of the Council on aid for poverty diseases (HIV/AIDS, malaria and tuberculosis) in developing countries

(2002/C 151 E/10)

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(Submitted by the Commission on 4 March 2002)

THE EUROPEAN PARLIAMENT AND THE COUNCIL
OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 179 thereof,

Having regard to the proposal from the Commission,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) The right to good health is a fundamental human right recognised by Article 25 of the Universal Declaration of Human Rights. This right is being denied to over a fifth of the world's population.
- (2) Article 35 of the Charter of Fundamental Rights of the European Union calls for a high level of human health protection in the definition and implementation of all Union policies and activities.
- (3) HIV/AIDS, malaria and tuberculosis cause the deaths of more than five and a half million people each year, their greatest impact being on morbidity and life expectancy in developing countries.
- (4) The failure to reduce the burden of these diseases and the evidence of their increasing impact has brought them to the centre of the development debate and has led to calls for urgent action and a series of national, regional and international initiatives, all meant to achieve the Millennium Development Goals which include clear targets to fight HIV/AIDS, malaria and tuberculosis, and to which the European Community and its Member States committed themselves.
- (5) The international community, represented by United Nations Secretary General Kofi Annan, calls for an additional minimal investment of USD 7-10 billion per year for HIV/AIDS, malaria and tuberculosis.
- (6) HIV/AIDS, malaria and tuberculosis require an appropriate structural response, which is both comprehensive and coherent and which is beyond the financial and human resources of most developing countries.
- (7) The effectiveness of programmes to support national strategies to combat HIV/AIDS, malaria and tuberculosis partly depends on the improved coordination of aid at both the European and the international level, including partnerships with the private sector, and on the use of procedures tailored to the specific nature of the strategies and partners concerned.
- (8) For the partner countries and populations in question, the type of assistance provided for by this Regulation is a pre-requisite for development and thus contributes significantly to the Community's development co-operation policy.
- (9) In its Communications to the Council and the European Parliament of 20 September 2000 and 21 February 2001 on Action related to Communicable Diseases in the Context of Poverty Reduction, the Commission outlined the policy principles and strategic priorities needed to enhance the effectiveness of action by the Community and the Member States in this field.
- (10) In its Resolutions of 10 November 2000 and 14 May 2001, the Council emphasised the gravity of the HIV/AIDS, malaria and tuberculosis epidemics and the need to step up efforts to give more support at national, regional and global levels.
- (11) The European Parliament has adopted several Resolutions and reports on this subject, including the Khanbhai report adopted on 4 October 2001 on the Commission's Communications on accelerated action targeted at major communicable diseases within the context of poverty reduction.
- (12) In its Resolutions of September 1998 and October 2000, the ACP-EU Joint Parliamentary Assembly underlined the threat posed by HIV/AIDS to all development efforts and the need for rapid action.
- (13) The present Regulation renders obsolete Council Regulation (EC) No 550/97 of 24 March 1997 on HIV/AIDS-related operations in developing countries, which should therefore be repealed ⁽¹⁾.

⁽¹⁾ OJ L 85, 27.3.1997, p. 1.

(14) The present Regulation lays down, for the entire duration of the programme it establishes, a financial framework constituting the prime reference, within the meaning of point 33 of the Interinstitutional Agreement between the European Parliament, the Council and the Commission of 6 May 1999 on budgetary discipline and improvement of the budgetary procedure⁽¹⁾, for the budgetary authority during the annual budgetary procedure.

(15) Since the measures necessary for the implementation of this Regulation are management measures within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽²⁾, they should be adopted by use of the management procedure provided for in Article 4 of that Decision.

(16) In accordance with the principles of subsidiarity and proportionality set out in Article 5 of the Treaty, the objective of the proposed action, namely to combat the three major communicable diseases within the context of poverty reduction, with particular reference to developing countries, cannot be attained by the Member States acting alone and, by reason of the scale and effects of the proposed action, can therefore only be achieved by the Community. This Regulation confines itself to the minimum required to achieve that objective and does not go beyond what is necessary for that purpose,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

PURPOSE AND SCOPE

Article 1

1. The Community shall implement the European Community Programme for Action targeting the three major communicable diseases, namely HIV/AIDS, malaria and tuberculosis, in developing countries.

2. Under that Programme the Community shall provide financial assistance and appropriate expertise with a view to promoting investments in health, poverty reduction and equitable economic growth in developing countries.

3. In the allocation of such funding and expertise, priority shall be given to:

(a) the poorest and least developed countries and the most disadvantaged sections of the population within developing countries;

⁽¹⁾ OJ C 172, 18.6.1999, p. 1.

⁽²⁾ OJ L 184, 17.7.1999, p. 23.

(b) action that complements and reinforces both the policies and capacities of developing countries and the assistance provided through other instruments of development cooperation.

Article 2

The purpose of activities carried out under this Regulation shall be to:

(a) optimise the impact of existing interventions, services and commodities targeted at the major communicable diseases affecting the poorest populations;

(b) increase the affordability of key pharmaceuticals;

(c) increase research and development, including vaccines, microbicides and innovative treatments.

Article 3

Community financial support shall be given to specific projects designed to further the objectives described in Article 2(1) and, in particular, to those which aim to:

(a) provide the necessary technical, scientific and normative input in order to prioritise health interventions within the total development cooperation budget and improve health outcomes related to the three major communicable diseases, keeping a balanced approach between prevention, treatment and care, with a primary focus on prevention;

(b) improve the performance of health interventions targeted at the three major communicable diseases within the context of a comprehensive health system;

(c) improve pharmaceutical policies and practice, and help developing countries, at regional or national level, to develop high-quality local production of off-patent and/or licensed key pharmaceuticals;

(d) promote global tiered pricing for key pharmaceuticals for developing countries;

(e) analyse the effects of factors, such as the level of net import price, tariffs, taxes, and importation, distribution and local registration fees, on consumer prices of medical goods in developing countries;

- (f) provide, where appropriate, technical assistance to developing countries to help them address public health issues in accordance with the provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) as clarified in the Doha Declaration on the TRIPs Agreement and Public Health;
- (g) develop an incentive package to encourage more private investment by the Research and Development based industries in new products, particularly vaccines and microbicides, designed to fight the major communicable diseases in developing countries;
- (h) support collaborative clinical, epidemiological, operational and social studies, so as to enable health-related research to be conducted on a sounder basis;
- (i) encourage capacity building in developing countries, to enable them to coordinate, host and conduct large-scale population trials;
- (j) support global initiatives targeting the major communicable diseases in the context of poverty reduction, including the Global Fund to fight HIV/AIDS, tuberculosis and malaria which came into operation on 29 January 2002.

Article 4

1. In the context of the operations referred to in Article 3, Community support may take the form of:

- (a) financial assistance;
- (b) technical assistance, training or other services;
- (c) supplies, such as medical supplies and commodities, and works;
- (d) audits and evaluation and monitoring missions.

Priority shall be given to enhancing national capacity with a view to long-term viability.

2. Community financing may cover both investment expenditure, excluding the purchase of real estate, and, in exceptional and duly substantiated cases, taking into account the fact that the operation must, as far as possible, aim at medium-term viability, recurring expenditure as well (including administrative expenditure, maintenance and running costs), the operation of which temporarily represents a burden for the partner, so that the maximum use is made of the support referred to in paragraph 1.

CHAPTER II

PROCEDURES FOR THE IMPLEMENTATION OF AID

Article 5

1. Community financing under this Regulation shall take the form of grants.
2. A financial contribution from the partners defined in Article 6 shall be sought for each cooperation operation. In specifying the amount of the contribution requested, regard shall be had to the capacity of the partners concerned and the nature of the operation in question. In certain circumstances, the contribution may be made in kind if the partner is either a non-governmental organisation (NGO) or a community-based organisation.
3. The provision of financial assistance under this Regulation may entail co-financing with other donors, in particular with Member States, the United Nations, and international or regional development banks or financial institutions.
4. In the context of the operations referred to in Article 3(1)(g)-(i), financial assistance shall be granted in coordination with the new instruments for product research and development on poverty-related communicable diseases implemented under the Community Framework Programme of Research and Development 2002-2006.

Article 6

1. The partners eligible for financial assistance under this Regulation include:
 - (a) administrative authorities and agencies at national, regional and local government level;
 - (b) local authorities and other decentralised bodies;
 - (c) local communities, NGOs, community-based organisations and other not-for-profit natural and legal persons from the private sector;
 - (d) regional organisations;
 - (e) international organisations, such as the United Nations and its agencies, as well as development banks, financial institutions, global initiatives, international public/private partnerships;
 - (f) research institutes and universities.

2. Without prejudice to paragraph 1(e), Community financial assistance shall be available to partners whose head office is located in a Member State or in a third country that is a beneficiary or potential beneficiary of Community assistance under this Regulation, provided that this office is the actual centre directing business operations. In exceptional cases, this office may be located in another third country.

Article 7

1. Where operations are the subject of financing agreements between the Community and countries which benefit from operations financed under this Regulation, the agreements shall stipulate that the payment of taxes, duties and charges shall not be financed by the Community.

2. Any financing agreement or contract concluded under this Regulation shall stipulate that it is subject to the supervision and financial control of the Commission which may carry out spot-checks and inspections, and to audits by the Court of Auditors, in accordance with the usual arrangements laid down by the Commission under the provisions in force, particularly those in the Financial Regulation applicable to the general budget of the European Communities.

3. The necessary measures shall be taken to emphasise the Community character of aid provided under this Regulation.

Article 8

1. Participation in invitations to tender for the award of contracts shall be open on equal terms to all natural and legal persons in the Member States and in all developing countries. It may be extended, in exceptional cases, to other third countries.

2. Supplies shall originate in the beneficiary country, other developing countries or the Member States. In exceptional cases, supplies may originate from other third countries.

Article 9

1. In order to secure the objectives of consistency and complementarity referred to in the Treaty and to ensure maximum effectiveness of these operations as a whole, the Commission may take all necessary coordination measures, including:

- (a) establishing a system for the systematic exchange and analysis of information on the operations financed and those which the Community and the Member States propose to finance;
- (b) on-the-spot coordination of the implementation of operations through regular meetings and exchanges of information between the representatives of the Commission and the Member States in the recipient country.

2. The Commission, in liaison with the Member States, may take any initiative necessary for ensuring proper coordination with the other donors concerned, in particular those forming part of the United Nations system.

CHAPTER III

DECISION-MAKING PROCEDURES*Article 10*

1. The financial framework for the implementation of this Regulation for the period from 2003 to 2006 is hereby set at ... million euro [to be decided APS 2003].

2. The annual appropriation shall be authorised by the budgetary authority within the limits of the financial perspective.

Article 11

1. The Commission shall be responsible for drafting strategic programming guidelines, defining the Community's co-operation in terms of measurable objectives, priorities, deadlines for specific areas of action, assumptions and expected outcomes. Programming is annual and indicative.

2. An exchange of views with the Member States shall take place on the basis of a presentation by the representative of the Commission of the strategic programming guidelines for the operations to be carried out, within the Committee referred to in Article 13 paragraph 1.

Article 12

1. The Commission shall be responsible for appraising, deciding and administering the operations covered by this Regulation in accordance with the budgetary and other procedures in force, in particular those laid down in the Financial Regulation applicable to the general budget of the European Communities.

2. Decisions concerning operations for which financing under this Regulation exceeds 5 million euro and any changes to these operations that entail a cost overrun of more than 20 % of the amount initially fixed for the operation concerned, shall be adopted in accordance with the procedure referred to in Article 13, paragraph 2.

3. For decisions and changes to these operations amounting to 5 million euro or less, the Commission will inform the Member States.

Article 13

1. The Commission shall be assisted by the geographically determined committee competent for development.

2. Where reference is made to this paragraph, the management procedure laid down in Article 4 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. The period provided for in Article 4, paragraph 3, of Decision 1999/468/EC shall be set at 45 days.

CHAPTER IV

REPORTING AND FINANCIAL PROVISIONS*Article 14*

1. After each budget year, the Commission shall submit in its annual report on EC development policy to the European Parliament and to the Council, information on the operations financed in the course of that year and the Commission's conclusions on the implementation of this Regulation over the previous budget year. The summary shall in particular provide information about the strengths and weaknesses of operations, those with whom contracts have been concluded as well as the results of any independent evaluations of specific operations.

2. One year before the expiry of this Regulation, the Commission shall submit an independent appraisal report on the implementation of this Regulation to the European Parliament and the Council with a view to establishing whether its objectives have been achieved and providing guidelines for improving the effectiveness of future operations.

On the basis of this appraisal report the Commission may make proposals for the future of this Regulation and, if necessary, proposals for its amendment.

Article 15

Council Regulation (EC) No 550/97 is hereby repealed. Operations that have been decided under Regulation (EC) No 550/97 shall continue to be implemented under that Regulation.

Article 16

1. This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Communities*.

2. It shall apply until 31 December 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.
