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►B REGULATION (EC) NO 1568/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 July 2003

on aid to fight poverty diseases (HIV/AIDS, tuberculosis and malaria) in developing countries

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on aid to fight poverty diseases (HIV/AIDS, tuberculosis and malaria) in developing countries

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 ([1]),

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([2]),

Whereas:

(1) The right to enjoy the highest attainable standard of physical and mental health is a fundamental human right which is in line with the provisions of 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, tuberculosis and malaria 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. Moreover, these diseases wipe out years of development efforts and achievements and constitute a serious concern in the long run because of their destabilising effects on society.

(4) It is now widely accepted that prevention, care and treatment are mutually dependent and synergistic.

(5) The failure to reduce the burden of these diseases and the evidence of their increasing impact have brought them to the centre of the development debate — as evidenced by the Declaration of Commitment of the Special Session of the UN General Assembly of June 2001, which recognises that HIV/AIDS has evolved to become a developmental emergency, and by the WHO World Health Assembly's declaration of tuberculosis and malaria as global emergencies — and have 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, tuberculosis and malaria, and to which the European Community and its Member States committed themselves.

(6) The abovementioned UN Declaration of Commitment agreed, for HIV/AIDS alone, to reach by 2005 through a series of incremental steps an overall target of annual expenditure on the epidemic of between USD 7 and 10 thousand million in low and middle-income countries and countries experiencing or at risk of experiencing a rapid spread of the disease, for prevention, care, treatment, support and mitigation of the impact of HIV/AIDS, and to take measures to ensure that the resources needed are made available, particularly from donor countries and also from national budgets, bearing in mind that resources of the most affected countries are seriously limited.

([1]) OJ C 151 E, 25.6.2002, p. 202.

([2]) Opinion of the European Parliament of 30 January 2003 (not yet published in the Official Journal) and Decision of the Council of 16 June 2003.

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(7) HIV/AIDS, tuberculosis and malaria require an appropriate structural response, which is both comprehensive and coherent and which is beyond the financial and human resources of most developing countries. Because of their magnitude and cross-boundary nature, the poverty diseases are among the problems that require a systematic, coordinated response by the international community. Interventions in this area are in everyone's interest and therefore should not be viewed as a question of development aid alone.

(8) The Doha Declaration on the Agreement on trade-related aspects of intellectual property rights (TRIPs) and Public Health affirmed that 'the TRIPs Agreement does not and should not prevent members from taking measures to protect public health' and that it 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all' and reaffirmed 'the right of WTO members to use, to the full, the provisions in the TRIPs Agreement which provide flexibility for this purpose'.

(9) The effectiveness of programmes to support national strategies to combat HIV/AIDS, tuberculosis and malaria partly depends on the improved coordination of aid at both the European and the international level, notably with UN agencies, funds and programmes, including partnerships between the private, public and voluntary sectors, and on the use of procedures tailored to the specific nature of the strategies and partners concerned.

(10) Public health is a public responsibility. Inadequate public policy has compounded the failure of the market to generate research and development for neglected diseases. In 2000, only 10 % of all research and development concerned diseases that are responsible for 90 % of disease in the world. The dynamics of neglect are different for different diseases, and distinct strategies to correct this imbalance are needed. Comprehensive action needs to be taken to compensate for the market failure in drug development, through increased public funding, including supporting the research and development of specific global public goods and effective methods of prevention and treatment to confront these diseases in developing countries and the introduction of appropriate incentives for the private sector to invest accordingly.

(11) Actions specifically targeted at the poverty diseases must be appropriately situated within the larger context of generally improved, more effective systems of health care and health services in developing countries. Considerable improvement of these systems is vital if HIV/AIDS, tuberculosis and malaria are to be combated effectively. Special efforts must be made to integrate interventions targeting the poverty diseases with actions targeting sexual and reproductive health and rights.

(12) The improvement of health is a precondition for and a key element of sustainable development. For the partner countries and populations in question, the type of assistance provided for by this Regulation therefore plays a direct and tangible part in development and thus contributes significantly to the Community's development cooperation policy.

(13) In the interests of coherence, all Community policies should take account of the objective of improving health and reducing poverty.

(14) 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.

(15) In its Resolutions of 10 November 2000 and 14 May 2001, the Council emphasised the gravity of the HIV/AIDS, tuberculosis

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and malaria epidemics and the need to step up efforts to give more support at national, regional and global levels.

(16) The Council, in its resolution of 14 May 2001, and the European Parliament, in its resolution of 4 October 2001 ([1]), endorsed the Community Programme for Action: accelerated action on HIV/AIDS, tuberculosis and malaria in the context of poverty reduction, and stressed the need to ensure that adequate and appropriate human and financial resources were in place to enable effective implementation.

(17) The Joint Declaration of 31 May 2001 by the Council and the Commission, the abovementioned European Parliament resolution of 4 October 2001 and the ACP-EU Joint Parliamentary Assembly resolution of 1 November 2001 welcomed the proposal of the UN Secretary-General to establish a Global Fund to fight HIV/AIDS, tuberculosis and malaria, which came into operation on 29 January 2002, and stressed that contributions to this Fund should be additional to existing resources.

(18) The abovementioned UN Declaration of Commitment, and in particular the Monterrey Conference, stipulates that increased Official Development Assistance (ODA) and debt relief schemes should be used for the benefit of better health and education outcomes. The Community and its Member States have an important role to play in exploring how increased ODA, including debt relief mechanisms, could be used more effectively as tools for combating HIV/AIDS, tuberculosis and malaria.

(19) In its Resolutions of September 1998, October 2000 and March 2002, the ACP-EU Joint Parliamentary Assembly underlined the threat posed by HIV/AIDS to all development efforts and the need for rapid action.

(20) This Regulation renders obsolete Council Regulation (EC) No 550/97 of 24 March 1997 on HIV/AIDS-related operations in developing countries ([2]), which should therefore be repealed.

(21) This Regulation lays down, for the entire duration of the programme, a financial framework constituting the prime reference, within the meaning of point 33 of the Interinstitutional Agreement of 6 May 1999 between the European Parliament, the Council and the Commission on budgetary discipline and improvement of the budgetary procedure ([3]), for the budgetary authority during the annual budgetary procedure.

(22) The measures necessary for the implementation of this Regulation should be adopted 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 ([4]).

(23) 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 sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of the proposed action, be better achieved at a Community level, in accordance with the principles of subsidiarity set out in Article 5 of the Treaty. In accordance with the principle of proportionality also set out in that Article, this Regulation does not go beyond what is necessary, in order to achieve that objective,

([1]) OJ C 87 E, 11.4.2002, p. 244.
([2]) OJ L 85, 27.3.1997, p. 1.
([3]) OJ C 172, 18.6.1999, p. 1.
([4]) OJ L 184, 17.7.1999, p. 23.

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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, tuberculosis and malaria, in developing countries.

2. Under that Programme the Community shall provide financial assistance and appropriate expertise to actors in development in order to improve access to health for all and to promote equitable economic growth, within the overall objective of reducing poverty with a view to its eventual eradication.

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;

(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 the activities carried out under this Regulation shall be to:

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

(b) increase the affordability of key pharmaceuticals and diagnostics for the three diseases;

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

Article 3

Community financial support shall be given to specific projects designed to achieve the purposes described in Article 2 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 relating to the three major communicable diseases, keeping a balanced approach between prevention, treatment and care, with prevention as a key priority, acknowledging that its effectiveness is increased when linked with treatment and care; recognition has to be given to the fact that important measures have to be looked for through a multisectoral approach, including targeting behavioural patterns as well as factors such as clean water and sanitation, land-use planning, nutrition and gender mainstreaming;

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

(c) improve understanding of effects of the poverty diseases on social and economic development, as well as the impact of strategies aimed at mitigating the negative socioeconomic effects connected with the diseases;

(d) improve pharmaceutical policies and practice, and help developing countries, at regional or national level, to develop high-quality local production of key preventive and therapeutic pharmaceuticals

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consistent with the Doha Declaration on the Agreement on trade-related aspects of intellectual property (TRIPs) and Public Health;

(e) promote a tiered pricing mechanism for key pharmaceuticals for developing countries that will guarantee the lowest possible prices;

(f) 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;

(g) provide, where appropriate, technical assistance to developing countries to help them address public health issues in accordance with the provisions of the TRIPs Agreement as clarified in the Doha Declaration on the TRIPs Agreement and Public Health, so as to enable the developing countries to protect public health and promote access to medicines for all;

(h) encourage public investment and develop an incentive package to encourage more private investment in Research and Development for new treatments, particularly vaccines and microbicides, diagnostics, and fixed-dose combinations designed to fight the major communicable diseases in developing countries;

(i) support team-based clinical, epidemiological, operational and social studies, so as to enable health-related research to be conducted on a sounder basis; where appropriate, teams shall be encouraged also to include personnel from the developing countries as a way of contributing to the training of such personnel;

(j) encourage capacity building in developing countries, to enable them to coordinate, host and conduct large-scale population trials and to complete all stages of the research and development process;

(k) 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;

(l) support initiatives which enable the quality of pharmaceuticals to be supervised and monitored.

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, including of doctors and paramedics, or other services;

(c) supplies, such as medical supplies, commodities, and works;

(d) audits, evaluation and monitoring missions;

(e) transfer of technology and know-how, where possible, for the purpose of local pharmaceuticals production.

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), which temporarily represents a burden for the partner, so that maximum use is made of the support referred to in paragraph 1.

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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, account shall be taken of 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. ►M1 Participation in contractual procedures implemented through an international organisation or co-financed with a third country is defined in Regulation (EC) No 2110/2005 of the European Parliament and of the Council of 14 December 2005 on access to Community external assistance [1]. ◄

4. In the context of the operations referred to in Article 3(h), (i) and (j), 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.

5. The contribution to the Global Fund to fight HIV/AIDS, tuberculosis and malaria shall be made by means of a financing agreement to be concluded between the Commission and the Trustee of the Global Fund. The contribution shall be administered following the rules and procedures established for the Global Fund, agreed with the Commission and to be annexed to the financing agreement.

6. In the context of the operations referred to in Article 3(h), (i) and (j), efforts shall be made to exploit the synergies with policies and programming in the area of sexual and reproductive health, in particular for HIV/AIDS interventions.

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, funds and programmes, 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

[1] OJ L 344, 27.12.2005, p. 1.

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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 [1], hereinafter 'the Financial Regulation'.

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

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Article 8

1. Eligibility for participation in tendering procedures under this Regulation shall be determined in accordance with the rules of eligibility, and the derogations therefrom, set out in Regulation (EC) No 2110/2005.

2. The origin of supplies and materials purchased under this Regulation shall be determined in accordance with the rules of origin, and the derogations therefrom, set out in Regulation (EC) No 2110/2005.

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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) the establishment of 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. Such coordination shall aim at systematic exchange and analysis of information on operations planned and implemented in order to ensure coherence and complementarity.

Chapter III

Financial and 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 EUR 351 million. The annual allocation shall be subject to the agreement of the budgetary authority on the appropriate means of financing under the Financial

[1] OJ L 248, 16.9.2002, p. 1.

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Perspective or through the use of the instruments provided for by the Interinstitutional Agreement of 6 May 1999.

2. The annual appropriations 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 cooperation in terms of measurable objectives, priorities, deadlines for specific areas of action, assumptions and expected outcomes. Programming shall be annual and indicative.

2. An annual exchange of views with the Member States shall take place within the Committee referred to in Article 13(1), on the basis of a presentation by the representative of the Commission of the strategic programming guidelines for the operations to be carried out. The Committee shall give an opinion on these matters in accordance with the procedure referred to in Article 13(2).

Article 12

1. The Commission shall be responsible for appraising, deciding upon 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.

2. Decisions concerning operations for which financing under this Regulation exceeds EUR 5 million 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(2).

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

Article 13

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

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 45 days.

3. The Committee shall adopt its Rules of Procedure.

Chapter IV

Reporting and final provisions

Article 14

1. After each budget year, the Commission shall submit, in its annual report to the European Parliament and to the Council on Community development policy, information on the guidelines for its annual indicative strategic programme and on the operations financed in the course of that year, including the operations of the Global Fund to fight HIV/AIDS, tuberculosis and malaria, as well as 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 in terms of their impact on the fight against the three communicable diseases and poverty reduction, including concrete, qualified results achieved in relation to the objectives set. Moreover, information shall be provided on those with whom contracts have been concluded and the sums of those contracts, and the disbursements made as well as the results of any independent evaluations of specific operations.

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2. At the latest one year before the expiry of this Regulation, the Commission shall submit an independent appraisal report on its implementation 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

Regulation (EC) No 550/97 shall be repealed. However, operations that have been decided upon under that Regulation shall continue to be implemented under it.

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 Union*.

2. It shall apply until 31 December 2006.

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