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**\*\*\*I**

## **REPORT**

on the proposal for a European Parliament and Council regulation on aid for poverty diseases (HIV/AIDS, malaria and tuberculosis) in developing countries (COM(2002) 109 – C5-0100/2002 – 2002/0051(COD))

Committee on Development and Cooperation

Rapporteur: Anders Wijkman

### ***Symbols for procedures***

- \* Consultation procedure  
*majority of the votes cast*
- \*\*I Cooperation procedure (first reading)  
*majority of the votes cast*
- \*\*II Cooperation procedure (second reading)  
*majority of the votes cast, to approve the common position  
majority of Parliament's component Members, to reject or amend  
the common position*
- \*\*\* Assent procedure  
*majority of Parliament's component Members except in cases  
covered by Articles 105, 107, 161 and 300 of the EC Treaty and  
Article 7 of the EU Treaty*
- \*\*\*I Codecision procedure (first reading)  
*majority of the votes cast*
- \*\*\*II Codecision procedure (second reading)  
*majority of the votes cast, to approve the common position  
majority of Parliament's component Members, to reject or amend  
the common position*
- \*\*\*III Codecision procedure (third reading)  
*majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

### ***Amendments to a legislative text***

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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## PROCEDURAL PAGE

By letter of 4 March 2002 the Commission submitted to Parliament, pursuant to Article 251(2) and Article 179 (1) of the EC Treaty, the proposal for a European Parliament and Council regulation on aid for poverty diseases (HIV/AIDS, malaria and tuberculosis) in developing countries (COM(2002) 109 - 2002/0051 (COD)).

At the sitting of 11 March 2002 the President of Parliament announced that he had referred this proposal to the Committee on Development and Cooperation as the committee responsible and the Committee on Budgets, the Committee on Budgetary Control and the Committee on the Environment, Public Health and Consumer Policy for their opinions (C5-0100/2002).

The Committee on Development and Cooperation appointed Anders Wijkman rapporteur at its meeting of 18 April 2002.

It considered the Commission proposal and draft report at its meetings of 28 Mai and 2 October 2002.

At its meeting of 11 November 2002 it adopted the draft legislative resolution unanimously.

The following were present for the vote: Joaquim Miranda, chairman; Margrietus J. van den Berg, vice-chairman, Marieke Sanders-ten Holte, vice-person, Anders Wijkman, vice-chairman and rapporteur; Niall Andrews (for Isabelle Caullery), Richard A. Balfe (for Nirj Deva), Jean-Pierre Bebear, Yasmine Boudjenah, John Bowis, Marie-Arlette Carlotti, Maria Carrilho, Vitaliano Gemelli, Richard Howitt, Glenys Kinnock, Karsten Knolle, Paul A.A.J.G. Lannoye, Nelly Maes (for Didier Rod), Miguel Angel Martínez Martínez, Hans Modrow, Luisa Morgantini, Ulla Margrethe Sandbæk, Francisca Sauquillo Pérez del Arco, Maj Britt Theorin and Elena Valenciano Martínez-Orozco (for Karin Junker).

The opinions of the Committee on Budgets and the Committee on the Environment, Public Health and Consumer Policy are attached; the Committee on Budgetary Control decided on 16 April 2002 not to deliver an opinion.

The report was tabled on 13 November 2002.

## DRAFT LEGISLATIVE RESOLUTION

**European Parliament legislative resolution on the proposal for a European Parliament and Council regulation on aid for poverty diseases (HIV/AIDS, malaria and tuberculosis) in developing countries (COM(2002) 109 – C5-0100/2002 – 2002/0051(COD))**

**(Codecision procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to the European Parliament and the Council (COM(2002) 109<sup>1</sup>),
  - having regard to Article 251(2) and Article 179(1) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0100/2002),
  - having regard to Rule 67 of its Rules of Procedure,
  - having regard to the report of the Committee on Development and Cooperation and the opinions of the Committee on Budgets and the Committee on Environment, Public Health and Consumer Policy (A5-0394/2002),
1. Approves the Commission proposal as amended;
  2. Asks to be consulted again should the Commission intend to amend the proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission

Amendments by Parliament

### Amendment 1 Recital 1

(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,

(1) The right to **enjoy the highest attainable standard of physical and mental 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,

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<sup>1</sup> OJ C 151 E 25.6.2002, p. 202.

### *Justification*

*Article 25 of the Universal Declaration on Human Rights and Article 12 of the Covenant on Economic, Social and Cultural Rights recognizes the right of everyone “to the enjoyment of the highest attainable standard of physical and mental health.” These provisions also note that to achieve the full realisation of this right, interventions shall include prevention, treatment and control of the epidemic, endemic, occupational and other diseases.*

### Amendment 2 Recital 3

(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,

(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;  
***moreover, these diseases wipe out years of development efforts and achievements and constitute a serious concern in the long run due to their destabilizing effects on society,***

### *Justification*

*Alongside the negative impact on mortality, morbidity and life expectancy, the adverse effects on social and economic development are both devastating and far-reaching.*

### Amendment 3 Recital 3 a (new)

***(3 a) It is now widely accepted that prevention, care and treatment are mutually dependent and synergistic,***

*Justification*

*Prevention and treatment/care must go hand-in-hand and be seen as complementary measures in the important fight against the poverty [diseases](#).*

Amendment 4

Recital 4

(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,

(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 - ***as evidenced by the Declaration of Commitment of the Special Session of the UN General Assembly of June 2001, which recognizes that HIV/AIDS has evolved to become a developmental emergency, and by the WHO's World Health Assembly's declaration of TB and Malaria as global emergencies*** - 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,

*Justification*

*Self-explanatory.*

Amendment 5

Recital 5

***(5) The international community, represented by United Nations Secretary General Kofi Annan, calls for an***

***(5) The Declaration of Commitment on HIV/AIDS of the Special Session of the UN General Assembly of June 2001***

*additional minimal investment of 7 - 10 billion USD per year for HIV/AIDS, malaria and tuberculosis.*

*agreed, for HIV/AIDS alone, by 2005, through a series of incremental steps, to reach an overall target of annual expenditure on the epidemic of between 7 and 10 billion United States dollars in low and middle-income countries and those countries experiencing or at risk of experiencing rapid expansion for prevention, care, treatment, support and mitigation of the impact of HIV/AIDS, and 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,*

#### *Justification*

*The original text of the Commission for this recital seems to be unprecise; 7-10 billion USD is necessary for HIV/AIDS alone.*

#### Amendment 6 Recital 6

(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,

(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; *because of their magnitude and cross-boundary nature, the poverty diseases constitute examples of problems that require a systematic, coordinate response by the international community, and where interventions are in everyone's interest and therefore should not be viewed as a question of development aid alone,*



### *Justification*

*The poverty diseases are extremely serious problems and the international community's response must be commensurate. In the light of the developments in different parts of the world, notably Central Asia, Eastern Europe and countries like India and China, it is important to ensure community support also for those regions, through other Community measures.*

### Amendment 7 Recital 6 a (new)

***(6 a) The Doha declaration on TRIPS and Public Health affirmed "that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health", 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".***

### *Justification*

*The costs involved in treatment, notably anti-retrovirals, have been barriers to access to treatment. The Doha Declaration must be seen as a huge step forward in that WTO members emphasized the rights for countries to use the TRIPS safeguards to protect public health.*

### Amendment 8 Recital 7

(7) The effectiveness of programmes to support national strategies to combat HIV/AIDS, malaria and tuberculosis partly depends on the improved co-ordination 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

(7) The effectiveness of programmes to support national strategies to combat HIV/AIDS, malaria and tuberculosis partly depends on the improved co-ordination of aid at both the European and the international level, ***notably with UN agencies, funds and programmes***, including partnerships ***between the private***,

the strategies and partners concerned,

**public and voluntary sectors**, and on the use of procedures tailored to the specific nature of the strategies and partners concerned,

*Justification*

*Self-explanatory.*

Amendment 9

Recital 7a (new)

***(7 a) 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 concerns diseases that are responsible for 90% of disease in the world. The dynamics of neglect are different for the 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,***

*Justification*

*Between 1975 and 1997 out of 1,223 new drugs developed only 13 (1%) were aimed at the treatment of tropical diseases. Only four of these were the result of R&D activities of the pharmaceutical industry. This imbalance shows the ridiculously low attention being paid by the R&D community to health problems in developing countries.*

*It is important that research be targeted both on prevention and on methods of treatment, including the development of medicines and vaccines.*

Amendment 10  
Recital 7 b (new)

***(7 b) 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 improvements of these systems are vital in order to allow for the effective fight against HIV/Aids, malaria and tuberculosis; special efforts must be made to integrate interventions targeting the poverty diseases with actions targeting sexual and reproductive health and rights,***

*Justification*

*In order to ensure efficient delivery of care and prevention, well-functioning basic health care infrastructure and, well-educated caretakers are crucial. Moreover, actions targeting the poverty diseases must be coordinated with interventions in the area of sexual and reproductive health, given the many linkages and synergies that exist.*

Amendment 11  
Recital 8

(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,

(8) ***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 co-operation policy,

*Justification*

*Clarification of the text.*

Amendment 12  
Recital 8a (new)

***(8a) In the interests of coherence, all Community policies should take account of the objective of improving health and reducing poverty,***

*Justification*

*Prevention should not be confined to immunisation programmes. Upstream, all the policies contributing to development and improving living conditions, including Community policies that have an impact on the populations of developing countries, help to prevent communicable diseases. A reference should therefore be made to the importance of the coherence of Community policies.*

Amendment 13  
Recital 11

(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,

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

*Justification*

*In order to effectively implement the objectives and realize the goals set, adequate human and financial resources are crucial.*

Amendment 14  
Recital 11 a (new)

***(11 a) The Joint Declaration of 31 May 2001 by the Council and the Commission, the European Parliament resolution of 4 October 2001 on communicable diseases and poverty, 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,***

*Justification*

*The regulation covers also the contribution of the EC to the Global Fund. Given the shortage of funds in Category 4, the principle of additionality is vital, so that the Community's GF contribution is not funded at the expense of other development cooperation commitments and priorities.*

Amendment 15  
Recital 11 b (new)

***(11 b) The Declaration of Commitment of the Special Session of the UN General Assembly of June 2001, and in particular the Monterrey Conference, stipulate that increased 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, malaria and tuberculosis,***

*Justification*

*Given the immense needs, new and innovative sources of financing for development must be explored.*

Amendment 16

Recital 12

(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,

(12) 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,

*Justification*

*The ACP-EU Joint Parliamentary Assembly, meeting in Cape Town in South Africa from 18 to 21 March 2002, adopted a resolution on health issues, young people, the elderly and people living with disabilities, containing a number of paragraphs on communicable diseases.*

Amendment 17

Article 1, paragraph 2

(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.***

(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.***

*Justification*

*Clarification of the text: the aim is not to increase investment in health (this is a means), but to fight communicable diseases in order to help improve health in the developing countries and reduce poverty.*

Amendment 18  
Article 2, point (a)

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

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

*Justification*

*Self-evident.*

Amendment 19  
Article 2, point (b)

(b) increase the affordability of key pharmaceuticals;

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

*Justification*

*Self-explanatory.*

Amendment 20  
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:

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

*Justification*

*Correction.*

Amendment 21  
Article 3, point (a)

(a) provide the necessary technical,

(a) provide the necessary technical,

scientific and normative input in order to prioritise health interventions within the total development co-operation 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;

scientific and normative input in order to prioritise health interventions within the total development co-operation budget and improve health outcomes related 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 multi-sectoral approach, including targeting behavioural patterns as well as factors such as clean water and sanitation, land-use planning, nutrition, gender mainstreaming, etc.,*

#### *Justification*

*Prevention should not be limited to immunisation programmes but should cover all public policies and health conditions that have an impact on health.*

#### Amendment 22 Article 3, point (b)

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

(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,*

#### *Justification*

*In some countries health services and systems are inadequate or practically non-existent. They should therefore be strengthened in order to enhance the effectiveness of action targeted at communicable diseases.*



Amendment 23  
Article 3, point (b) a (new)

***(b a) improve the understanding of the poverty diseases' effects on social and economic development, as well as the impact of strategies aimed at mitigating the negative socio-economic effects connected with the diseases;***

*Justification*

*It seems important to enhance specifically our understanding of the wider socio-economic effects of the epidemics.*

Amendment 24  
Article 3, point (c)

(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;

(c) improve pharmaceutical policies and practice, and help developing countries, at regional or national level, to develop quality local production of key **preventive and therapeutic** pharmaceuticals **consistent with the Doha declaration on TRIPS and Public Health**;

*Justification*

*-The WHO which is the only reference regarding quality of medicines has officially changed its reference from "high quality" to "quality" aiming at ending the confusion that could otherwise arise.*

*-According to the Doha declaration on TRIPs and Public Health, patents should not necessarily be seen as a barrier to local production.*

Amendment 25  
Article 3, point (d)

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

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

*Justification*

*A tiered pricing mechanism is one of the strategies, along with the use of the TRIPs safeguards and promoting generic competition, that aims at achieving prices that will be affordable for the developing countries. Progress on this issue is vital.*

Amendment 26  
Article 3, point (f)

(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;

(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, **so as to enable the developing countries to protect public health and promote access to medicines for all**;

*Justification*

*Self-explanatory.*

Amendment 27  
Article 3, point (g)

(g) develop an incentive package to encourage more private investment **by the** Research and Development **based**

(g) **encourage public investment and** develop an incentive package to encourage more private investment **in** Research and

**industries in new products**, particularly vaccines and microbicides, designed to fight the major communicable diseases in developing countries;

Development (**R&D**) for new treatments, particularly vaccines and microbicides, **diagnostics, and fixed-dosed combinations** designed to fight the major communicable diseases in developing countries;

*Justification*

*The WHO has formally recognised the urgent need for development of fixed dose combinations to treat the three diseases.*

Amendment 28  
Article 3, point (h)

(h) support **collaborative** clinical, epidemiological, operational and social studies, so as to enable health-related research to be conducted on a sounder basis;

(h) 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 are encouraged also to include personnel from the developing countries as a way of contributing to the training of such personnel;**

*Justification*

*The training of specialist medical and paramedical personnel is an essential component.*

Amendment 29  
Article 3, point (i)

(i) encourage capacity building in developing countries, to enable them to co-ordinate, host and conduct large-scale population trials;

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

*Justification*

*Conducting clinical drugs trials in the developing countries must not be used as a means of lowering the ethical standards and good practice that are compulsory in the European Union.*

*Over and above basic research on new molecules, what is often lacking, and should therefore*

*be increased, is the development of new treatments (development of the drugs, clinical trials and marketing arrangements).*

Amendment 30  
Article 3, point (ja) (new)

***(ja) support initiatives which enable the quality of pharmaceutical products to be supervised and monitored.***

*Justification*

*Checks are rarely carried out in poor countries and little action is taken to prevent the operation of a market in counterfeit medicinal products. Approximately 10% of the pharmaceutical products available in Africa are counterfeit, and in certain countries this figure rises to 50 or 60%. Checks need to be carried out, particularly on safety grounds.*

Amendment 31  
Article 4, paragraph 1, point (b)

(b) technical assistance, training or other services;

(b) technical assistance, training, ***including of doctors and paramedics*** or other services;

*Justification*

*Training for specialist doctors and paramedics must be provided within the Member States' hospitals.*

Amendment 32  
Article 4, paragraph 1, point (da) (new)

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

*Justification*

*One essential way of ensuring that the poorest countries have access to pharmaceuticals and treatments is to draw up legislation which not only enables tiered prices to be charged but also allows the transfer of technology and know-how.*

Amendment 33  
Article 5, paragraph (2)

(2) A financial contribution from the partners defined in Article 6 shall be sought for each co-operation 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.

(2) A financial contribution from the partners defined in Article 6 shall be sought for each co-operation operation. In specifying the amount of the contribution requested, regard shall be **given** 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.

*Justification*

*Linguistic correction.*

Amendment 34  
Article 5, paragraph (4) a (new)

***(4 a) The contribution to the Global Fund will be made by means of a financing agreement to be concluded between the Commission and the Trustee on the Global Fund. The contribution will be administered following the rules and procedures established for the Global Fund, agreed with the Commission and to be annexed to the financing agreement.***

*Justification*

*Reference to the 2001 Decision concerning the Community contribution to the Global Fund.*

Amendment 35  
Article 5, point (4) b (new)

***(4 b) In the context of the operations referred to in Article 3 (g)-(i), efforts shall be made to capture the synergies with policies and programming in the area of sexual and reproductive health, namely***

*for HIV/Aids interventions.*

*Justification*

*Many linkages exist between actions in the field of poverty diseases and sexual and reproductive health interventions. Such linkages and synergies need to be recognized and used to the maximum.*

Amendment 36  
Article 6, paragraph 1, point (e)

(e) international organisations, such as the United Nations and its agencies, as well as development banks, financial institutions, global initiatives, international public/private partnerships;

(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;

*Justification*

*In line with am. 8 (Recital 7)*

Amendment 37  
Article 9, paragraph 2

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

(2) The Commission, in liaison with the Member States, may take any initiative necessary for ensuring proper co-ordination with the other donors concerned, in particular those forming part of the United Nations system; ***such co-ordination should aim at systematic exchange and analysis of information on operations planned and implemented in order to ensure coherence and complementarity.***

*Justification*

*The effectiveness of programmes to combat HIV/AIDS, malaria and tuberculosis partly*

*depends on the improved co-ordination of aid at the international level, not the least with the UN family.*

Amendment 38  
Article 11, paragraph 2

(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.

(2) An **annual** 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. ***The Committee shall give an opinion on these matters according to the management procedure referred to in Article 13(2) and (3).***

*Justification*

*Comitology in line with the Council.*

Amendment 39  
Article 14, paragraph 1

(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.

(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 guidelines for its annual indicative strategic programme***, the operations financed in the course of that year, ***including the operations of the Global Fund*** 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 ***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 about 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.*

#### *Justification*

*-The operations of the Global Fund must also be included in the annual report. In line with the general objective of moving towards a more results-oriented development cooperation policy, the importance of evaluating the results of interventions must be emphasized in the context of this regulation.*

*-It is more transparent to also specify the amounts of the signed contracts.*

*Parliament must be able to compare the measures carried out with the priorities established in the annual programme, and evaluate their effectiveness on the basis of their impact on the fight against the communicable diseases and poverty reduction, which are the objectives of this programme.*

#### *Amendment 40* *Article 14, paragraph (2)*

(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.

(2) ***At the latest*** 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.

#### *Justification*

*Under co-decision, sufficient time is needed to prolong or modify the Regulation.*



## EXPLANATORY STATEMENT

### INTRODUCTION

HIV/AIDS, tuberculosis (TB) and malaria constitute the three most serious communicable diseases affecting the world today. Though the diseases are different and consequently require diverse responses, they also share many features. They all affect the poor disproportionately, and tend to impoverish them further.

Currently, approximately 40 m people are estimated to be infected with HIV worldwide (Annex 1). Some 12.000-14.000 persons contract the infection every day, half of the cases occurring among young persons aged 15-24 – a group where ignorance about the disease is also widespread. Although it is a global problem, it is affecting developing countries disproportionately – more than 90 % of all persons infected with HIV/AIDS live in the developing world, and around 70 % in Sub-Saharan Africa. The Caribbean is the second-worst affected region. However, the steepest rate of increase is seen in Central Asia and in Eastern Europe. Some populous countries, such as China and India, also merit considerable attention.

New TB cases are increasing, mainly due to the spread of HIV in Africa and the economic crisis in the newly independent states of Central/Eastern Europe and Central Asia. According to current trends, between 2000 and 2020, nearly 1 bn people will be newly infected worldwide.

Ever since the 1970's, malaria has been on the rebound and is reappearing in some of the countries where it had been eradicated. At a minimum, 1 m people die from malaria annually, most of them (at least 70 %) being young children in Sub-Saharan Africa. Around 40 % of the world's population are currently at risk of contracting the disease.

Together, HIV/AIDS, malaria and TB account for a total of 5 m deaths per year, or 9 % of all deaths in the world. Since the beginning of the HIV/AIDS epidemic alone, it is estimated that more than 20 m people have died. Life expectancy in the worst affected countries in Sub-Saharan Africa has been estimated to have declined to 47 yrs – without AIDS, it would have been closer to 60 yrs.

Alongside the negative impact on mortality, morbidity and life expectancy, the adverse effects on social and economic development are devastating and far-reaching. Development gains and achievements of the last decades are rapidly erased in the wake of the communicable diseases, and the long-term negative effects on development and the social fabric are enormous (Annex 2).

Of the 20 countries with the highest HIV/AIDS prevalence, all are Sub-Saharan African, and the correlation between poverty and AIDS prevalence at country level has been found to be strong. At the individual level, people are pushed further into poverty as households lose their breadwinners, livelihoods are compromised, productive assets sold, and savings consumed by the cost of health care and funerals. Approximately 14 m children are estimated have lost one or both parents due to AIDS – 80 % of them live in Sub-Saharan Africa.

Yet another aspect to consider is the security dimension of the poverty diseases. Due to their profound negative impact on society, not the least HIV/AIDS, these pandemics risk destabilizing whole communities and societies. Such developments are in the interest of no one.

## GENERAL COMMENTS

- **Context**

For more than a decade, the poverty diseases did not hold any special place in EU development policy. The Commission initiative "Program for Action: Accelerated Action on HIV/AIDS, malaria and TB in the context of poverty reduction"(Action Program)<sup>1</sup>, was thus very welcome. The program sets the framework for EC action until 2006. The proposal for a regulation at hand is one important instrument to allow for effective implementation of the Action Program, as well as to cover the contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF).<sup>2</sup>

The regulation aims to: "optimize the impact of existing interventions, services and commodities targeted at the major communicable diseases affecting the poorest populations; increase the affordability of key pharmaceuticals; increase the research and development of vaccines, microbicides and innovative treatments".

In order to give a clear signal of the importance that the EU attaches to the poverty diseases your rapporteur recommends that considerable efforts be made to try to come to agreement already in the 1st reading.

- **Budget**

The financial framework proposed for the regulation is set at a total of € 300 m, or approximately € 75 m for each of the four years of the regulation's duration. This allocation is intended to consist of the EC's contribution to the GF, amounting to approximately € 35 m, as well as funding for the implementation of the Action Program, € 40 m. Given the immense needs and centrality of the problem (Annex 3), however, it is proposed to increase the final framework considerably. As the EU has played a leading role in the creation of the GF, it has an obligation to ensure that adequate funding is provided to enable it to carry out its tasks in a successful manner. Contributions to the GF should be additional to existing funding for development cooperation.<sup>3</sup> Due to their cross-boundary nature and magnitude, the poverty diseases constitute examples of problems that require a systematic response by the international community. (Here we refer to the on-going debate on so-called global public goods). Interventions are in everyone's interest and should not be viewed as a responsibility for development aid alone.

- **Geographical Scope**

The proposal targets developing countries (DAC List of Aid Recipients, Part 1), with particular emphasis to be given to the least developed countries and the most disadvantaged

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<sup>1</sup> COM (2001) 96

<sup>2</sup> The proposal replaces regulation (EC) no 550/97.

<sup>3</sup> The Joint Declaration of 31 May 2001 by the Council and the Commission, the European Parliament resolution of 4 October 2001 on communicable diseases and poverty, and the ACP-EU Joint Parliamentary Assembly resolution of 1 November 2001.

sections of the population in developing countries. These, no doubt, are crucial target groups. However, in light of the rampant developments in other parts of the world, notably in Central Asia, Eastern Europe, and countries like India and China, it is important to ensure EC support also for these regions, through other measures.

- ***The Prevention - Treatment/Care Continuum***

There is often the notion that efforts should be focused on either prevention or treatment/care. The reality, however, is that prevention efforts need to go hand in hand with interventions focusing on treatment and care. Both are of utmost importance.

Assisting and supporting those infected so that they can maintain their health to the greatest extent possible is crucial for several reasons. There is the humanitarian aspect – to provide assistance to persons in need. Moreover, there is the link to prevention – the incentive to get tested is low if there is no help available, and clearly, unless a person is aware that he or she is ill, no change in behavior is likely, and thus the risk of the disease spreading is great. The availability of treatment and care is also important in that it can help decrease stigmatization of those infected. Furthermore, maintaining the health of persons infected is important in the sense that this helps mitigate the negative effects and pressures on the families affected, and may also allow those infected to continue to contribute productively to the household.

- ***Research & Development***

The issue of investment in research and development (R&D) for the poverty diseases must be addressed forcefully. Currently, a sharp imbalance remains between R&D in regards to diseases predominant in the industrialized world as opposed to the developing world. In fact, it has been estimated that 90 % of the world's disease burden attracts no more than 10 % of the USD 73.5 bn spent annually on health research (Annex 4). The focus on R&D for poverty diseases in the 6th Framework Program for Research is thus very welcome.

Increased funding for R&D is important. However, changes in the current system of patent legislation are also crucial. Reference is here made to on-going efforts at the international level, aimed at reaching agreement on how to ensure access to medicines for all, and the particular problems faced by developing countries.

- ***Strengthened Health Care Systems***

Actions specifically targeted at the poverty diseases must be appropriately situated within the larger context of a generally improved delivery of health care and health services. In order to ensure efficient delivery of care and prevention measures, basic health care infrastructure, well-educated caretakers and communities, and affordable prices of key pharmaceuticals, remain absolutely crucial. Consequently, for this regulation and other related efforts aimed at fighting the poverty diseases to be effective, considerable improvements in developing countries' health care systems must be undertaken, an issue that needs to be revisited in the context of the annual budget process as well as the recent communication "Health and Poverty Reduction in Developing Countries".<sup>1</sup>

- ***Links to Reproductive Health***

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<sup>1</sup> COM (2002) 129.

It is paramount that the measures covered by the regulation are coordinated with program planning and interventions in the area of sexual and reproductive health, given the many linkages and synergies that exist between these types of action.

- ***Complementarity***

Complementarity being one of the corner stones of EC development cooperation, interventions must be situated in the larger context, namely that of the Members States' activities in the area. This is important to consider not the least when determining the types of interventions to be undertaken by the EC (a primary focus on large or small projects? at the local, regional or national level? etc.).

- ***Human Resources***

In order to effectively implement the regulation the Commission must have the appropriate human resources. Understaffing has been a problem in the past, impacting negatively on its ability to ensure the maximum impact of its interventions. It is hoped that the budgetary decision of December 2001, where Parliament secured increased support for the administrative part of the budget, will have resulted in sufficient human resources. However, this issue must be followed closely in the future.

## Regional HIV/AIDS statistics and features, end of 2001

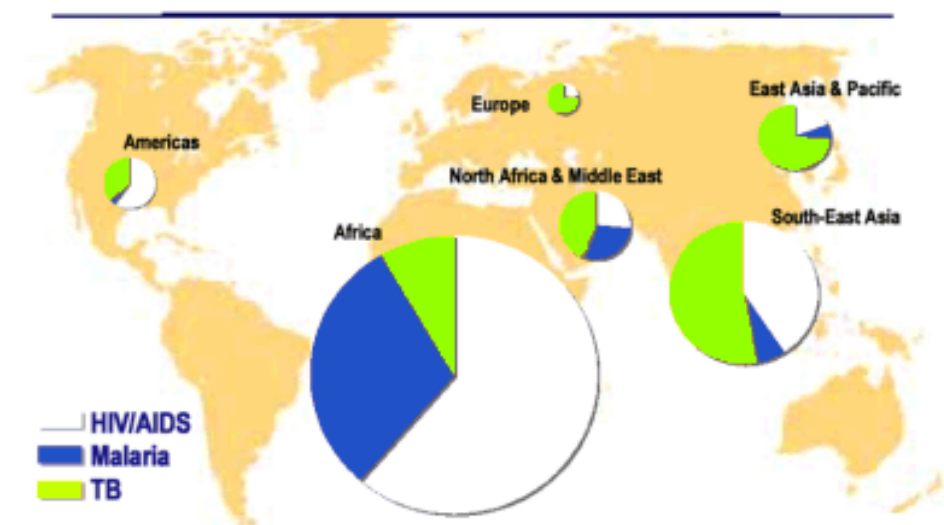
Region	Epidemic started	Adults and children living with HIV/AIDS	Adults and children newly infected with HIV	Adult prevalence rate (*)	% of HIV-positive adults who are women	Main mode(s) of transmission (#) for adults living with HIV/AIDS
<b>Sub-Saharan Africa</b>	late '70s early '80s	28.1 million	3.4 million	8.4%	55%	Hetero
<b>North Africa &amp; Middle East</b>	late '80s	440 000	80 000	0.2%	40%	Hetero, IDU
<b>South &amp; South-East Asia</b>	late '80s	6.1 million	800 000	0.6%	35%	Hetero, IDU
<b>East Asia &amp; Pacific</b>	late '80s	1 million	270 000	0.1%	20%	IDU, hetero, MSM
<b>Latin America</b>	late '70s early '80s	1.4 million	130 000	0.5%	30%	MSM, IDU, hetero
<b>Caribbean</b>	late '70s early '80s	420 000	60 000	2.2%	50%	Hetero, MSM
<b>Eastern Europe &amp; Central Asia</b>	early '90s	1 million	250 000	0.5%	20%	IDU
<b>Western Europe</b>	late '70s early '80s	560 000	30 000	0.3%	25%	MSM, IDU
<b>North America</b>	late '70s early '80s	940 000	45 000	0.6%	20%	MSM, IDU, hetero
<b>Australia &amp; New Zealand</b>	late '70s early '80s	15 000	500	0.1%	10%	MSM
<b>TOTAL</b>		<b>40 million</b>	<b>5 million</b>	<b>1.2%</b>	<b>48%</b>	

Source: *AIDS epidemic update: December*

2001. UNAIDS

\* The proportion of adults (15 to 49 years of age) living with HIV/AIDS in 2001, using 2001 population numbers.  
 # Hetero (heterosexual transmission), IDU (transmission through injecting drug use), MSM (sexual transmission among men who have sex with men).

### HIV/AIDS, TB and malaria -relative share of disease burden by region (Lost HL<sup>Y</sup>s), 2000



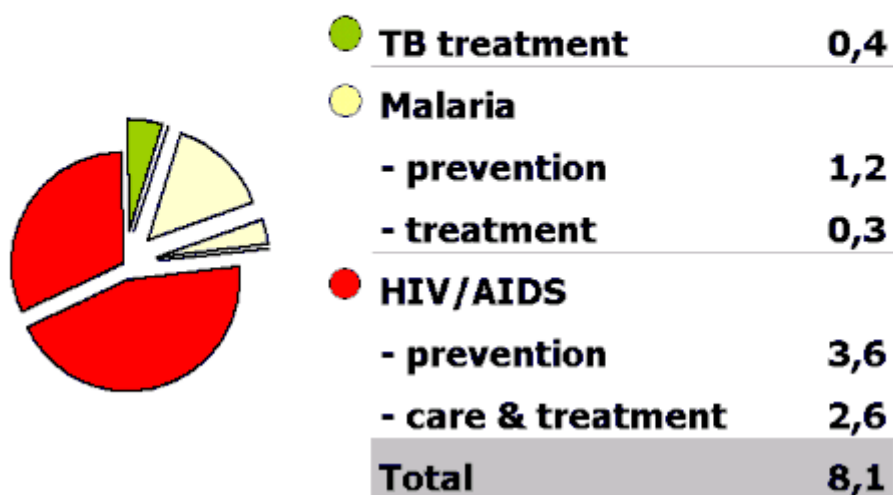
Source: *The World Health Report 2001 WHO*

\* HL<sup>Y</sup> = Years of healthy life lost.

According to health economists, the impact of death can be measured in terms of the years of healthy life lost. Seen this way, the losses incurred by the poverty diseases are enormous, not the least because young people tend to be so hard hit.

### Additional annual resource needs to control the poverty diseases

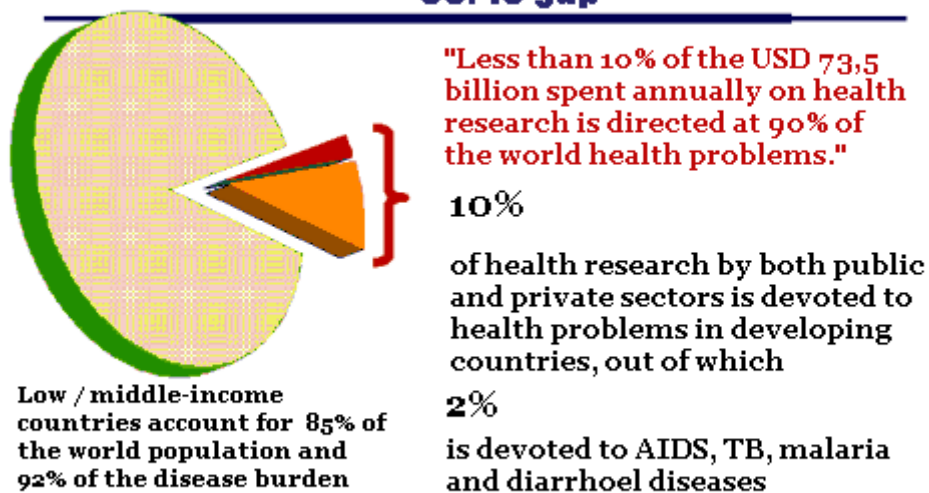
[in billion USD, minimum figures]



Source: *Commission on Macroeconomics and Health, 2001*

In 2001, the Commission on Macroeconomics and Health provided a "detailed conservative estimate of additional resource needs" (vs. 2001 levels of expenditure) to control the three poverty diseases: for TB treatment, an additional USD 400 million, for malaria control, USD 1.5 billion, and for Aids USD 6.2 million -- all figures minimums.

## Research & Development: 90/10 gap



Source: *Global Forum for Health Research*



19 July 2002

## **OPINION OF THE COMMITTEE ON BUDGETS**

for the Committee on Development and Cooperation

on the proposal for a European Parliament and Council regulation on aid for poverty diseases (HIV/AIDS, malaria and tuberculosis) in developing countries  
(COM(2002) 109 – C5-0100/2002 – 2002/0051(COD))

Draftsman: Neena Gill

## **PROCEDURE**

The Committee on Budgets appointed Neena Gill draftsman at its meeting of 19 March 2002.

It considered the draft opinion at its meeting of 17 July 2002.

At this meeting it adopted the following amendments unanimously.

The following were present for the vote: Terence Wynn chairman; Reimer Böge vice-chairman; Anne Elisabet Jensen, vice-chairman; Francesco Turchi vice-chairman Neena Gill draftsman; Ioannis Averoff, Manuel António dos Santos, Bárbara Dührkop Dührkop, Göran Färm, Markus Ferber, Jutta D. Haug, Christopher Heaton-Harris (for Den Dover), María Esther Herranz García, Juan de Dios Izquierdo Collado (for Joan Colom i Naval), Jan Mulder, Juan Andrés Naranjo Escobar, Seán Ó Neachtain, Giovanni Pittella, Guido Podestà, Giacomo Santini, Esko Olavi Seppänen (for Francis Wurtz), Per Stenmarck, Diemut R. Theato (for Salvador Garriga Polledo), Rijk van Dam (for Michel Raymond), Kyösti Tapio Virrankoski and Brigitte Wenzel-Perillo.

## SHORT JUSTIFICATION

### *Background*

The Commission has presented a proposal for a regulation on aid for poverty diseases (HIV/AIDS, malaria and tuberculosis) in developing countries. It would apply until 31 December 2006 and replace the 1997 Regulation (EC 550/97) on HIV/AIDS related operations in developing countries.

As is evident from the title, it would extend the scope of the Regulation to include actions on malaria and tuberculosis. It would also provide for possible contributions to the Global Fund to fight HIV/AIDS, tuberculosis and malaria.

The main aims of the proposal, consistent with the Community's overall health and poverty policy, and to be carried out in coordination and complementarity with other donors, are:

- maximise impact of existing interventions
- increase affordability of key medicines
- increase research and development of vaccines

A series of documents are relevant to outline the background of this proposal:

*A European Community Programme for accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction* was adopted by the General Affairs Council on 14 May 2001 and subsequently endorsed by European Parliament resolution of 4 October 2001. The general strategy of the Commission was welcomed and the Council and the EP called on the Commission to present more detailed plans on how to operationalise these goals, including what financial resources would be needed.

In a Joint Declaration of 31 May 2001, concerning the Global Fund, the Council (Development) and the Commission stated *"It is emphasised that contributions to the Fund should be additional to existing resources"*. Neither the Council nor the Commission have so far presented any proposals to find those additional resources.

On 19 December 2001, the EP and the Council adopted a Decision concerning the contribution to the Global Fund in 2001<sup>1</sup>. That Decision laid down that the Community should contribute € 60 million to the Fund from the 2001 budget. In order to finance this, the Budgets Committee approved two transfers, from the Fisheries budget line and from the ALA budget lines, of € 50 million and € 10 million respectively. In parallel, it was agreed that the same amount, € 60 million, would be contributed to the Fund from the EDF in 2002. A recital of the Decision states *"The Commission will propose a legal base for future contributions for the implementation of the Programme for Action on the three communicable diseases including any further contributions to the Global Fund."* There was no undertaking as to the level of future contributions, either for the programme of Action or for the Fund.

The present proposal would establish such a legal base.

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<sup>1</sup> OJ L 007, 11.1.2002.

### ***Budgetary aspects***

The Commission states that the proposed regulation reflects a substantial increase needed for the successful implementation of the EC Action Programme.. The proposal did not initially include an amount for a multi-annual financial envelope. Subsequently, by letter, the Commission has confirmed its proposed multi-annual financial envelope for 2003-2006, consistent with the 2003 PDB.

*€ million, proposed commitments, Budget heading B7-6311 and B7-6310A 2003-2006*

Budget 2002	PDB 2003	Diff. 2002-2003	2004	2005	2006	Total 2003-2006
26	75 *	+ 49* (+ 188 %)	75	75	75	300

*\* out of which € 35 million is estimated EC contribution to the Global Fund*

Contributions to the Global Fund should be evaluated after the first year and may subsequently change.

The draftsman stresses that this annual increase of € 49 million has mainly been financed through the reduction of other policies in the PDB. She notes that such a reorganising of priorities is for the specialised committee to decide, within the budget lines falling under its responsibility, but must insist that reductions of policies within the competence of other committees need to be consistent with identified priorities and have the consensus of the European Parliament as a whole. There is therefore a real question as to the compatibility of this proposal with the Financial Perspective in the context of the EP maintaining its strategy to defend existing policies. For the proposal to be compatible, it is possible that other budget lines will have to be cut, or that the ceiling would have to be revised. As a matter of realistic budgetary prudence, the draftsman cannot count on a revision of the existing ceiling and, in consequence, she is obliged to draw the conclusion that the Commission's proposal (as far as the financial increase is concerned) could be supported only on the understanding that the Budgetary Authority might have to decide on corresponding reductions under different lines under the same heading of the Financial Perspective.

She feels that it is vital to introduce an amendment to the legislative resolution making this clear.

She notes with real disappointment that the Council and the Commission have not put forward any proposals that could secure contributions to the Global Fund which would be *additional to existing resources*, as stated in their Joint Declaration. She recalls that the contributions to the Global Fund, at least from a budgetary point of view, is a new policy and that the EP principle is that new policies require 'new' money. This would imply either a revision of the financial ceiling or the use of the flexibility instrument, but not a reduction of policies in other areas.

In order to safeguard a substantial increase of this programme, which the draftsman fully supports, while at the same time ensuring that this increase is not done at the expense of other policies for the poorest countries, she proposes a financial framework for the programme establishing a minimum amount. This will constitute the prime reference for the Budgetary

Authority during the annual procedure in accordance with article 33 of the IIA. The minimum amount is in line with the Commission's proposal. The Budgetary Authority, taking into account the specific situation in any one year, and the existing ceiling, then has the possibility to adjust appropriations as circumstances allow.

### ***Rules of Procedure***

It should be noted that the Budgets Committee now has the right to raise the question of financial compatibility of proposals in accordance with the provisions contained in the EP's revised Rules of Procedure. If and how this might apply will of course depend on the final report adopted by the lead committee.

### ***Comitology***

The draftsman follows COBU's traditional approach that the advisory procedure should apply. She welcomes the Commission's proposal that the comitology procedure would only be necessary for decisions exceeding € 5 million.

## AMENDMENTS

The Committee on Budgets calls on the Committee on Development and Cooperation, as the committee responsible, to incorporate the following amendments in its report:

### AMENDMENT TO THE LEGISLATIVE RESOLUTION

*[The European Parliament]*

***Considers that the financial statement of the Commission proposal is compatible with the ceiling of heading 4 of the Financial Perspective if the Budgetary Authority decides to reduce other policies or through recourse to the provisions of the Interinstitutional Agreement of 6 May 1999.***

#### *Justification:*

*The financial statement of this programme entails additional expenditure under the ceiling of heading 4 of the FP. According to the common declaration of 20 July 2000, the budgetary authority is entitled to evaluate the compatibility of new proposals with the expenditure ceilings in place.*

Text proposed by the Commission<sup>1</sup>

Amendments by Parliament

#### Amendment 1 Recital 11 a (new)

The Council and the Commission, in their Joint Declaration of 31 May 2001, stated that contributions to the Global Fund should be additional to existing resources;

#### *Justification*

*The presented proposal contains provisions for contributions to the Global Fund and it is therefore necessary to emphasise what the Council and Commission have stated on this point.*

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<sup>1</sup>

Amendment 2  
Recital 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<sup>1</sup>, they should be adopted by use of the **management** procedure provided for in **Article 4** of that Decision,

Since the measures necessary for the implementation of this Regulation are **(deletion)** measures within the meaning of **Article 2(c)** of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>2</sup>, they should be adopted by use of the **advisory** procedure provided for in **Article 3** of that Decision,

*Justification*

*The traditional approach of the Budgets Committee in matters of comitology is that the advisory procedure should apply.*

Amendment 3  
Article 10 (1-2)

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]**.

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

The financial framework of this Regulation for the period from 2003 to 2006 is hereby set at **a minimum of 300 million Euro. The budgetary authority, during the annual procedure, can increase this amount if appropriations are available within the ceiling of the financial perspective. The annual appropriations shall be authorised by the budgetary authority.**

*Justification*

*This amendment seeks to provide a financial framework for this programme which addresses the urgent need to fight poverty diseases. At the same time, it must respect existing financial constraints and provide the necessary flexibility to adapt future appropriations as circumstances allow.*

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<sup>1</sup> OJ L 184, 17.7.1999, p. 23.

<sup>2</sup> OJ L 184, 17.7.1999, p. 23.

Amendment 4  
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.***

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

(2) Where reference is made to this paragraph, the **advisory** procedure laid down in **Article 3** of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

***Deleted***

*Justification*

*The traditional approach of the Budgets Committee in matters of comitology is that the advisory procedure should apply. Paragraph 3 is deleted because it does not apply in this case.*

Amendment 5  
Article 14 (1)

(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

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, ***including operations of the Global Fund***, 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 ***and the sums of those contracts***, as well as the results of any independent evaluations of specific operations.

specific operations.

*Justification*

*For the sake of transparency the sums of contracts concluded should be made available. Since the Global Fund may be financed through this Regulation, information on its operations should naturally be provided.*

Amendment 6  
Article 14 (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.

**18 months** 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.

*Justification*

*Under co-decision, at least 18 months would be necessary to prolong or modify the Regulation.*



17 July 2002

## **OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND CONSUMER POLICY**

for the Committee on Development and Cooperation

on the proposal for a European Parliament and Council regulation on aid for poverty diseases (HIV/AIDS, malaria and tuberculosis) in developing countries  
(COM(2002) 109 – C5-0100/2002 – 2002/0051(COD))

Draftsman: Didier Rod

### **PROCEDURE**

The Committee on the Environment, Public Health and Consumer Policy appointed Didier Rod draftsman at its meeting of 27 March 2002.

It considered the draft opinion at its meetings of 17 June and 10 July 2002.

At the latter meeting it adopted the following amendments unanimously.

The following were present for the vote: Caroline F. Jackson, chairman; Mauro Nobilia, Alexander de Roo and Anneli Hulthén, vice-chairmen; Didier Rod, draftsman; Per-Arne Arvidsson, María del Pilar Ayuso González, Hans Blokland, Dorette Corbey, Chris Davies, Avril Doyle, Anne Ferreira, Karl-Heinz Florenz, Cristina García-Orcoyen Tormo, Robert Goodwill, Françoise Grossetête, Heidi Anneli Hautala (for Hiltrud Breyer), Marie Anne Isler Béguin, Christa Klauf, Eija-Riitta Anneli Korhola, Bernd Lange, Peter Liese, Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Jorge Moreira da Silva, Ria G.H.C. Oomen-Ruijten, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Giacomo Santini, Inger Schörling, Jonas Sjöstedt, Renate Sommer (for Horst Schnellhardt), María Sornosa Martínez, Catherine Stihler, Antonios Trakatellis, Kathleen Van Brempt and Phillip Whitehead.

## SHORT JUSTIFICATION

<AmJust> This regulation is the legal instrument required to implement the action programme: 'Accelerated action targeting HIV/AIDS, malaria and tuberculosis in the context of poverty reduction' and to create the necessary legal basis for the European Community's contribution to the 'Global Fund to fight HIV/AIDS, tuberculosis and malaria'.

The effectiveness of this action programme will depend on the coherent combination of preventive measures (education/awareness campaigns and promoting better living conditions), treatment (improving health services and access to medicines), and research and development (R&D) (throughout the process). The example of Brazil, which began free treatment of all AIDS victims in 1996, speaks volumes. The putting in place of a comprehensive system (involving the creation of a vast health network - centres for diagnosis, follow-up, and treatment - training of specialists, manufacture of drugs, awareness and education campaigns for the population and through the media, support from the church and political parties, adoption of laws and budgets, etc.) has brought the AIDS-related death rate down by between 40 and 70% and has resulted in savings of almost US\$ 700 million in hospital spending (despite the cost of the programme).

Preventive measures generally mean information and awareness campaigns targeted at the most vulnerable population groups, in particular young people and women, in cooperation with local communities and associations as well as political and religious leaders in the region in order to ensure maximum effectiveness. More generally, prevention should include all measures with an impact on health (promotion of better nutrition, water quality, sanitation programmes, etc.).

Access to treatment involves improving health structures and the training and employment of medical staff, in a fair and balanced manner throughout the territory, in order to meet the needs of all population groups. Priority should also be given to the improvement of health systems in order to provide quality health care services free of charge, in particular to the poorest populations.

In this context, access to medicines and diagnostic products is of crucial importance and bringing down the cost of such treatments should be one of the programme's priorities. In the immediate future it is crucial to establish a system differentiated pricing for medicines (which should guarantee the sale of medicines at cost price to the poorest countries) but this is not sufficient in the longer term. Through its technical assistance, the EU should help national governments to take advantage of the safeguard clauses in the TRIPS agreements (which were confirmed by the Doha declaration) in order to manufacture or import generic drugs which are less expensive than patented medicines. The EU should also propose to the WTO that it revise Article 30 and/or 31 of the TRIPS agreement (without making their use subject to other conditions relating to production or export) in order to give developing countries with no production capacity the same access as other countries to essential drugs.

Bringing down the cost of drugs should enable the national authorities responsible to abandon treatments that have become ineffective because of increasing resistance and take advantage of new treatments based on drug combinations which are too costly at present.

Finally, forgotten diseases (including malaria and tuberculosis) have suffered from a lack of

investment in R&D. R&D, which is left mainly up to private pharmaceutical laboratories which have concentrated on profitable diseases with medicines that bring them a substantial return on their investment, must once again become a public health priority. Going beyond basic research, is important to encourage public and private actors to carry out the development, trials and marketing of new treatments. In this context, the European Commission's new programme of clinical trials - EDCTP (European Developing Countries Trials Programme) is an encouraging first step, provided that it complies with the ethical standards and practices observed in the EU.

The budget of EUR 300 million over four years is low in relation to the challenges faced. It is worth noting that in its resolution of October 2001 The European Parliament called for 10% of the Community development cooperation budget to be devoted to health. Furthermore, the annual contribution of EUR 30 million to the Global Fund is very much below the amounts pledged by the EU and the efforts made in 2001 and 2002 (EUR 60 million a year). Given that the EU cannot cut its contribution to the Global Fund (EUR 60 million a year) for the period 2003-2006, and that the budget for the action programme cannot be less than this contribution (EUR 60 million a year too), the total financial allocation for this regulation should be EUR 120 million a year, or EUR 480 million over four years. Furthermore, the resources allocated to the Global Fund should be in addition, i.e. they should not be drawn from Category 4 of the budget (External actions). Research measures, for their part, should be funded through the sixth Framework Programme for Research and Development.

## AMENDMENTS

The Committee on the Environment, Public Health and Consumer Policy calls on the Committee on Development and Cooperation, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission <sup>1</sup>	Amendments by Parliament
Amendment 1 Recital 2	
(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,	(2) Article 35 of the Charter of Fundamental Rights of the European Union <b><i>and Article 152 of the Treaty on European Union</i></b> call for a high level of human health protection in the definition and implementation of all Union policies and activities,

<sup>1</sup> OJ C not yet published.

*Justification*

*Self-explanatory.*

Amendment 2  
Recital 3

(Does not affect the English version)

Amendment 3  
Recital 4

(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,

(4) ***HIV/AIDS, tuberculosis and malaria, which mainly affect the poorest populations, are still spreading at a rapid rate in the developing countries.*** The failure to reduce the burden of these diseases, ***due in particular to the lack of resources deployed,*** and the evidence of their increasing impact has brought them to the centre of the development debate and ***call for urgent action and large-scale action over the long term combining local,*** 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. ***To ensure that it is effective, this action should involve a considerable increase in the financial resources earmarked for combating communicable diseases, implementing preventive programmes and improving health systems in general in the developing countries.***

### *Justification*

*It should be made clear that urgent action does not mean action in the short-term. On the contrary, the fight against communicable diseases is a long-term measure which should involve initiatives at all levels of public intervention, including local level.*

*The second part of the amendment reproduces a paragraph from Parliament's resolution of 4 October 2001 on the Action programme targeted at communicable diseases in the context of poverty reduction.*

### Amendment 4 Recital 5

(5) The international community, represented by United Nations Secretary General Kofi Annan, calls for an additional minimal investment of 7 - 10 billion USD per year for HIV/AIDS, malaria and tuberculosis,

(5) The international community, represented by United Nations Secretary General Kofi Annan, calls for an additional minimal investment of 7 - 10 billion USD per year for HIV/AIDS, malaria and tuberculosis. ***The European Union has donated EUR 120 million for 2001-2002 and the contributions so far pledged to the Global Fund amount to US \$1.9 billion over three years.***

### *Justification*

*The commitments made by the international community, including the European Union, to combat communicable diseases are still far from sufficient to cover real and established needs.*

### Amendment 5 Recital 6

(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,

(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, ***in some cases owing to military spending or corruption and also because of restrictions on their social services***

***budgets, imposed by macro-economic structural adjustment programmes and debt repayment.***

### *Justification*

*For 20 years, the developing countries have been forced reduce their public spending on health in particular as part of their 'cooperation' with international fund providers and the international financial institutions in order to put their macro-economic environment on a healthy footing and repay their debts.*

### Amendment 6 Recital 6a (new)

***(6a) As prevention and treatment are mutually dependent and create synergies, the action programme should simultaneously combine prevention, treatment and research and development (R&D):***

- prevention must take the form of education and information campaigns (directed especially at young people and women), the promotion of better living conditions and vaccination campaigns,***
- interventions to address conditions or factors relating to disease (for example, the malaria mosquito),***
- timely diagnosis and treatment, especially among groups with high-risk behaviour or living conditions,***
- treatment and prevention require access to pharmaceuticals and the availability of healthcare structures, services and systems,***
- investment in R&D should focus primarily on the whole process of developing more effective preventive and curative treatments that are adapted to the needs and conditions of the developing countries.***

### *Justification*

*This action programme should not, as was the case with earlier measures to combat HIV/AIDS, concentrate exclusively on prevention, which is a long-term process which does not, however, make it possible to help the millions of people who already have the disease.*

*Access to pharmaceuticals is often only mentioned in connection with treatment, but it is at least as essential in relation to prevention.*

*There must be a comprehensive approach to each disease, including vaccination campaigns where practicable.*

### *Amendment 7* *Recital 6b (new)*

***(6b) Only 10% of all research and development concerns diseases that are responsible for 90% of disease in the world. In order to reverse this trend, it is necessary in particular to promote research (carried out in particular by the public sector) into diseases which have been neglected, especially with regard to the development of suitable and effective methods of prevention and treatment for communicable diseases.***

### *Justification*

*Obviously, diseases which mainly affect people in developing countries are not profitable for the pharmaceuticals industry, which has therefore not invested in research and development relating to such diseases. It is therefore necessary to reactivate public-sector research and focus it on poverty-related diseases.*

*It is important that research be targeted both on prevention and on methods of treatment, including the development of medicines and vaccines.*

Amendment 8  
Recital 7

(7) The effectiveness of programmes to support national strategies to combat HIV/AIDS, malaria and tuberculosis partly depends on the improved co-ordination 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,

(7) The effectiveness of programmes to support national strategies to combat HIV/AIDS, malaria and tuberculosis partly depends on the improved co-ordination of aid at both the European and the international level, 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,

*Justification*

*Self-explanatory.*

Amendment 9  
Recital 7a (new)

***(7a) The Doha Declaration on the TRIPS agreement and public health affirms that public health takes priority over intellectual property and that countries have the 'right to protect public health and, in particular, to promote access to medicines and preventive medical technology for all'. It is necessary to support and encourage the developing countries in the use of the safeguard clauses in the TRIPS agreements, such as compulsory licences and parallel imports, and to facilitate their access to generic products in order to help them break down certain barriers to access to essential drugs.***

*Justification*

*This amendment inserts a reference to the Doha declaration which clarifies the interpretation of the TRIPS agreements by recognising that public health take precedence over patents. Any measures that will improve access to quality medicines at the lowest possible prices, in particular use of the safeguard clauses in the TRIPS agreements, should be encouraged.*



*Preventive medical technology can also make a substantial contribution to protecting public health.*

Amendment 10  
Recital 8

(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,

(8) ***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 co-operation policy,

*Justification*

*Clarification of the text.*

Amendment 11  
Recital 8a (new)

***(8a) promoting better living conditions (hygiene, nutrition, access to drinking water, etc) is an integral part of the strategy to combat these three diseases. In the interests of coherence, all Community policies, including the common agricultural policy, the fisheries policy and trade policy, should take account of the objective of improving health and reducing poverty.***

*Justification*

*Prevention should not be confined to immunisation programmes. Upstream, all the policies contributing to development and improving living conditions, including Community policies that have an impact on the populations of developing countries, help to prevent communicable diseases. A reference should therefore be made to the importance of the coherence of Community policies.*

Amendment 12  
Recital 12

(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,

(12) 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,

*Justification*

*The ACP-EU Joint Parliamentary Assembly, meeting in Cape Town in South Africa from 18 to 21 March 2002, adopted a resolution on health issues, young people, the elderly and people living with disabilities, containing a number of paragraphs on communicable diseases.*

Amendment 13  
CHAPTER I  
Article 1, point (2)

(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.***

(2) Under that Programme the Community shall provide financial assistance and appropriate expertise ***to actors in the developing countries in order to improve access to health for all, raise the standard of health of populations and reduce poverty.***

*Justification*

*Clarification of the text: the aim is not to increase investment in health (this is a means), but to fight communicable diseases in order to help improve health in the developing countries and reduce poverty.*

Amendment 14  
CHAPTER I  
Article 2, point (a)

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

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

*Justification*

*Self-evident.*

Amendment 15  
CHAPTER I  
Article 2, point (b)

(b) ***increase the affordability of key*** pharmaceuticals

(b) ***make pharmaceuticals, new treatments, vaccines and diagnoses (and also the distribution thereof and healthcare service and system facilities for these three diseases) available at the lowest possible prices;***

*Justification*

*If action intended to help combat poverty diseases in developing countries is to be effective, it must not be restricted to making certain pharmaceuticals more affordable. Rather, it must form part of a comprehensive policy which is designed to make all structures, health care services, pharmaceuticals and new treatments available and which addresses the problem of distributing such items and services with the aim of bringing them to the sick by means of appropriate local-government policies and lower prices.*

Amendment 16  
CHAPTER I  
Article 2, point (c)

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

(c) increase ***the training of specialist medical personnel and upgrade***, research and development, ***at all stages of the design, development and marketing process, with a view to introducing appropriate and effective preventive*** (including vaccines, microbicides and innovative treatments) ***and curative treatments***.

#### *Justification*

*Over and above basic research on new molecules, what is often lacking, and should therefore be increased, is the development of new treatments (development of the drugs, clinical trials and marketing arrangements). The concept of access to pharmaceuticals in the poorest regions of the world also includes, the training of specialist medical personnel.*

#### Amendment 17 CHAPTER I Article 2, point (ca) (new)

***(ca) promote better living conditions***

#### *Justification*

*All policies which help to improve the living conditions of people in developing countries also help to prevent transmissible diseases.*

#### Amendment 18 CHAPTER I Article 3, point (aa) (new)

***(aa) Prevention should include, in particular, measures concerning behaviour and policies upstream in the area of vaccination, public health, water and sanitation, land-use planning, nutrition, etc.***

*Justification*

*Prevention should not be limited to immunisation programmes but should cover all public policies and health conditions that have an impact on health.*

Amendment 19  
CHAPTER I  
Article 3, point (c)

(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;

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

*Justification*

*The WHO refers to the 'production of quality', not the 'production of high quality'. The introduction of new terminology should be avoided as it could result in differences in treatment depending on the level of quality. The specific reference to off-patent and/or licensed pharmaceuticals is no longer relevant after the Doha Declaration.*

Amendment 20  
CHAPTER I  
Article 3, point (d)

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

(d) **guarantee a system of differentiated pricing** for key pharmaceuticals for developing countries **by encouraging the sale of pharmaceuticals at the lowest possible price which developing countries can afford**;

### *Justification*

*The introduction of tiered pricing must guarantee that essential drugs are sold to the developing countries at the lowest possible price (cost price).*

#### Amendment 21 CHAPTER I Article 3, point (g)

(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;

(g) develop an incentive package to encourage **public-sector and private investment in research into and development of new treatments, new preventive medical technologies and diagnoses, including combined treatments**, designed to fight the major communicable diseases in developing countries;

### *Justification*

*There has not been an awful lot of R&D concerning these diseases, which in particular affect people in developing countries, as they are not particularly profitable for the pharmaceuticals industry. The public-sector and private research community should therefore be encouraged to focus on these neglected diseases. Research into and development of new preventive medical technologies are also an important part of the measures to be taken.*

#### Amendment 22 CHAPTER I Article 3, point (h)

(h) support **collaborative** clinical, epidemiological, operational and social studies, so as to enable health-related research to be conducted on a sounder basis;

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

*Justification*

*The training of specialist medical and paramedical personnel is an essential component.*

Amendment 23  
CHAPTER I  
Article 3, point (i)

(i) encourage capacity building in developing countries, to enable them to co-ordinate, host and conduct large-scale population trials;

(i) encourage capacity building in developing countries, to enable them to co-ordinate, host and conduct large-scale population trials ***(in compliance with the ethical standards and good clinical practice applied within the European Union), and to enable them to complete all stages of the research and development process;***

*Justification*

*Conducting clinical drugs trials in the developing countries must not be used as a means of lowering the ethical standards and good practice that are compulsory in the European Union.*

*Over and above basic research on new molecules, what is often lacking, and should therefore be increased, is the development of new treatments (development of the drugs, clinical trials and marketing arrangements).*

Amendment 24  
CHAPTER I  
Article 3, point (ja) (new)

***(ja) support initiatives (such as the WHO prequalification process) which enable the quality of pharmaceutical products to be supervised and monitored and which are designed to impede the market in counterfeit medical products;***

*Justification*

*Checks are rarely carried out in poor countries and little action is taken to prevent the operation of a market in counterfeit medicinal products. Approximately 10% of the pharmaceutical products available in Africa are counterfeit, and in certain countries this figure rises to 50 or 60%. Checks need to be carried out, particularly on safety grounds.*

Amendment 25

CHAPTER I

Article 4, paragraph 1, point (b)

(b) technical assistance, training or other services;

(b) technical assistance, training ***of doctors and paramedics*** or other services;

*Justification*

*Training for specialist doctors and paramedics must be provided within the Member States' hospitals.*

Amendment 26

CHAPTER I

Article 4, paragraph (1), point (c)

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

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

*Justification*

*The purchase of pharmaceuticals at the lowest possible price is of crucial importance.*

Amendment 27

CHAPTER I

Article 4, paragraph 1, point (da) (new)

***(da) transfer of technology, of know-how and (for the purpose of pharmaceuticals production and where the public interest is at stake) of patents with a view to***



***encouraging - where possible - local production in the interests of sustainable development.***

*Justification*

*One essential way of ensuring that the poorest countries have access to pharmaceuticals and treatments is to draw up legislation which not only enables tiered prices to be charged but also allows the transfer of technology and know-how and, in the event of health emergencies or other extremely urgent circumstances, of patents, as provided for in the Trips agreement.*

Amendment 28

CHAPTER I

Article 4, paragraph 1, point (dd) (new)

***(dd) technical and financial assistance to allow parallel imports of pharmaceuticals from countries which offer more favourable financial terms;***

*Justification*

*In view of the fact that not all developing countries are able, once the required licence has been obtained, to produce the pharmaceutical products in question one essential way of ensuring that the poorest countries have access to pharmaceutical products and to treatment is to allow a country to import a pharmaceutical product (even if only for a limited period) from the country which offers it the most favourable financial terms without having to ask for the patent holder's consent, as provided for in Article 6 of the Trips agreement.*

Amendment 29

CHAPTER II

Article 5, paragraph (4)

(4) In the context of the operations referred to in Article 3 (1) (g)-(i), financial assistance shall be granted in co-ordination with the new instruments for product research and development on poverty-related communicable diseases implemented under the Community

(4) In the context of the operations referred to in Article 3 (1) (g)-(i), financial assistance shall be granted in co-ordination with the new instruments for product research and development on poverty-related communicable diseases ***financed and*** implemented under the Community

*Justification*

*As the funds available for this regulation are very limited, it is logical that the cost of R&D activities, in particular the new programme of clinical trials in the developing countries (EDCTP) should be borne by the Sixth Framework Programme for Research and Development, which includes a budget line for this purpose.*

Amendment 30  
CHAPTER II  
Article 8, point 2

(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.

(2) Supplies shall originate, ***in order of priority***, in the beneficiary country, other developing countries or the Member States. In exceptional cases, supplies may originate from other third countries.

*Justification*

*Sustainable development in the developing countries should be based on local and regional production and supply.*

Amendment 31  
CHAPTER II  
Article 9, paragraph 1, point (ba) (new)

***(ba) the evaluation of actions based on the objectives set out in Article 2.***

*Justification*

*This is a means of controlling the effectiveness of the regulation.*

Amendment 32  
CHAPTER IV  
Article 14, point (1)

(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.

(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 guidelines for its annual indicative strategic programme***, 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 ***in terms of their impact on the fight against the three communicable diseases and poverty reduction***, those with whom contracts have been concluded as well as the results of any independent evaluations of specific operations.

*Justification*

*Parliament must be able to compare the measures carried out with the priorities established in the annual programme, and evaluate their effectiveness on the basis of their impact on the fight against the communicable diseases and poverty reduction, which are the objectives of this programme.*